



**California Department of Public Health**

Center for Infectious Diseases

Division of Communicable Disease Control

Immunization Branch

California Immunization Registry (CAIR) 2.0 Strategy Project

Project Number 4265-21

**Feasibility Study Report**

July 14, 2011 (Version 3.0)

**Information Technology Project Request  
Feasibility Study Report  
Executive Approval Transmittal**



<b>Department Name</b>		
California Department of Public Health		
<b>Project Title (maximum of 75 characters)</b>		
California Immunization Registry 2.0 Strategy		
<b>Project Acronym</b>	<b>Department Priority</b>	<b>Agency Priority</b>
CAIR 2.0	1	N/A

I am submitting the attached Feasibility Study Report (FSR) in support of our request for the California Technology Agency's approval to undertake this project.

I certify that the FSR was prepared in accordance with State Administrative Manual Sections 4920-4930.1 and that the proposed project is consistent with our information technology strategy as expressed in our current Agency Information Management Strategy (AIMS).

I have reviewed and agree with the information in the attached Feasibility Study Report.

I also certify that the acquisition of the applicable information technology (IT) product(s) or service(s) required by my department that are subject to Government Code 11135 applying Section 508 of the Rehabilitation Act of 1973 as amended meets the requirements or qualifies for one or more exceptions (see following page).

<b>APPROVAL SIGNATURES</b>	
<b>Deputy Director, Chief Information Officer</b>	
<b>Date Signed</b>	
<b>Printed name:</b>	Nabil Fares
<b>Budget Officer</b>	
<b>Date Signed</b>	
<b>Printed name:</b>	Patty Lee
<b>Department Director</b>	
<b>Date Signed</b>	
<b>Printed name:</b>	Ron Chapman, MD, MPH
<b>Agency Information Officer</b>	
<b>Date Signed</b>	
<b>Printed name:</b>	Gretchen Hernandez
<b>Agency Secretary</b>	
<b>Date Signed</b>	
<b>Printed name:</b>	Diana S. Dooley

**Information Technology Project Request  
Feasibility Study Report  
Executive Approval Transmittal**

#1030



**Department Name**

California Department of Public Health

**Project Title (maximum of 75 characters)**

California Immunization Registry 2.0 Strategy

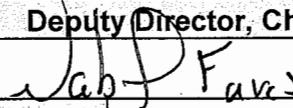
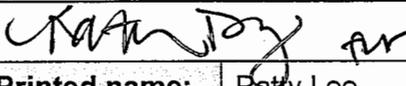
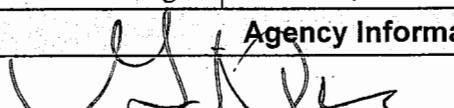
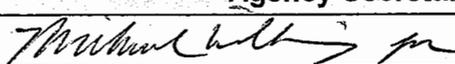
Project Acronym	Department Priority	Agency Priority
CAIR 2.0	1	N/A

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I also certify that the acquisition of the applicable information technology (IT) product(s) or service(s) required by my department that are subject to Government Code 11135 applying Section 508 of the Rehabilitation Act of 1973 as amended meets the requirements or qualifies for one or more exceptions (see following page).

APPROVAL SIGNATURES		
<b>Deputy Director, Chief Information Officer</b>		<b>Date Signed</b>
		7/25/2011
<b>Printed name:</b>	Nabil Fares	
<b>Budget Officer</b>		<b>Date Signed</b>
		8/12/2011
<b>Printed name:</b>	Patty Lee	
<b>Department Director</b>		<b>Date Signed</b>
		8/21/11
<b>Printed name:</b>	Ron Chapman, MD, MPH	
<b>Agency Information Officer</b>		<b>Date Signed</b>
		2.6.12
<b>Printed name:</b>	Gretchen Hernandez	
<b>Agency Secretary</b>		<b>Date Signed</b>
		2/3/12
<b>Printed name:</b>	Diana S. Dooley	

## Feasibility Study Report - Executive Approval Transmittal

### IT Accessibility Certification

#### Yes or No

<b>Yes</b>	<b>The Proposed Project Meets Government Code 11135 / Section 508 Requirements and no exceptions apply.</b>
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#### Exceptions Not Requiring Alternative Means of Access

<b>Yes or No</b>	<b>Accessibility Exception Justification</b>
N/A	The IT project meets the definition of a national security system.
N/A	The IT project will be located in spaces frequented only by service personnel for maintenance, repair, or occasional monitoring of equipment (i.e., "Back Office Exception").
N/A	The IT acquisition is acquired by a contractor incidental to a contract.

#### Exceptions Requiring Alternative Means of Access for Persons with Disabilities

<b>Yes or No</b>	<b>Accessibility Exception Justification</b>
N/A	Meeting the accessibility requirements would constitute an "undue burden" (i.e., a significant difficulty or expense considering all agency resources). Explain: Describe the alternative means of access to be provided to allow individuals with disabilities to obtain the information or access the technology.
N/A	No commercial solution is available to meet the requirements for the IT project that provides for accessibility. Explain: Describe the alternative means of access to be provided to allow individuals with disabilities to obtain the information or access the technology.
N/A	No solution is available to meet the requirements for the IT project that does not require a fundamental alteration in the nature of the product or its components. Explain: Describe the alternative means of access to be provided to allow individuals with disabilities to obtain the information or access the technology.

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**Appendix A: Abbreviations and Acronyms**

**Appendix B: Questionnaire for Information Security and Privacy Components**

**Appendix C: Complexity Assessment**

**Appendix D: CAIR Software Application version 3.30 Entity Relationship Diagram**

**Appendix E: CAIR Software Application Import Entity Relationship Diagram**

**Appendix F: Procurement Phase High Level Schedule**

## 2.0 Project Summary Package

### 2.1 Section A: Executive Summary

1	Submittal Date	July 18, 2011
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		FSR	SPR	PSP Only	Other:
2	Type of Document	X			
	Project Number	4265-21			

			Estimated Project Dates	
3	Project Title	California Immunization Registry 2.0 Strategy	Start	End
	Project Acronym	CAIR 2.0	December 2012	November 2015

4	Submitting Department	California Department of Public Health
5	Reporting Agency	California Health and Human Services Agency

6	Project Objectives
	<ol style="list-style-type: none"> <li>1. Provide CAIR 2.0 software users access to statewide immunization information by May 2016.</li> <li>2. Reduce the time required to provide the U.S. Centers for Disease Control (CDC) annual Immunization Information System Activity Report (IISAR) report from 1 week to 1 hour by May 2016.</li> <li>3. Increase the number of California birth records being added to the CAIR 2.0 database from 45,000 records every 6 months to 250,000 records every 6 months by May 2016.</li> <li>4. CAIR 2.0 can directly consume patient and vaccine doses-containing Health level 7 (HL7) messages by May 2016.</li> <li>5. Reduce the time to compile a statewide Tdap/Pertussis booster doses administered Report from 1 week to 1 hr. by May 2016.</li> <li>6. Reduce the time to produce a cross-regional or statewide HEDIS patient match report from 1 week to 1 hour by May 2016.</li> <li>7. Increase the number of health information exchanges (HIEs) exchanging data with the IIS from 1 to 5 by May 2016.</li> </ol>

8	Major Milestones	Est Complete Date
	Project Start	December 2012
	Solicitation Document Preparation	May 2013
	Conduct Solicitation	September 2013
	Evaluate Responses	December 2013
	Vendor On-Board	April 2014
	Requirements Complete	July 2014
	Design Complete	October 2014
	System Build Complete	April 2015
	System Testing Complete	June 2015
	User Acceptance Testing Complete	September 2015
	Training Complete	November 2015
	System Go Live	November 2015
	Product Acceptance	November 2015
	Project Complete	November 2015
	PIER	November 2016

7	Proposed Solution
<p>The CDPH proposes the initiation of a procurement seeking a technical solution from vendors to implement a partial consolidation of CAIR, California's SIIS, by consolidating the CAIR Software Regions. Partial consolidation allows for the independent registries to migrate to the consolidated system, though it is not required or mandated. The existing software used by the CAIR Software Regions would be replaced with new software (i.e., internally developed, commercial-off-the shelf (COTS) software, public domain software, or another registry's software), with the addition of a patient indexing function and HL7 messaging capability.</p>	

Key Deliverables	Est Complete Date
Solicitation Document	May 2013
Vendor Final Proposals	November 2013
Notification of Intent to Award	December 2013
Approved Contract	March 2014
Requirements Specifications	July 2014
Design Documents	October 2014
System Build	April 2015
System Testing Results	June 2015
User Acceptance Testing Sign-off	September 2015
Training Material / User Manuals	November 2015
Go / No-Go Document Approved	November 2015
Formal Product Acceptance	November 2015
Project Completion Checklist	November 2015
PIER	November 2016

## 2.2 Section B: Project Contacts

Project #	4265-21
Doc. Type	FSR

Executive Contacts						
	First Name	Last Name	Area Code	Phone #	Ext.	Electronic mail
Agency Secretary	Diana	Dooley	916	654-3454		DDooley@chhs.ca.gov
Dept. Director	Ron	Chapman, MD, MPH	916	558-1700		Ron.Chapman@cdph.ca.gov
Budget Officer	Patty	Lee	916	445-8682		Patty.Lee@cdph.ca.gov
Deputy Director, CIO	Nabil	Fares	916	445-8052		Nabil.Fares@cdph.ca.gov
Project Sponsor	Gilberto F.	Chávez, MD, MPH	916	445-0062		Gil.Chavez@cdph.ca.gov

Direct Contacts						
	First Name	Last Name	Area Code	Phone #	Ext.	Electronic Mail
Doc. prepared by	Chris	Kim	510	978-4819		ckim@caleconnect.org
Primary contact	Steve	Nickell, PhD	510	620-3780		Steve.Nickell@cdph.ca.gov
Project Manager	Deb	Wong	916	324-9442		Deb.Wong@cdph.ca.gov

## 2.3 Section C: Project Relevance to State and/or Departmental Plans

1	What is the date of your current Disaster Recovery Plan (DRP)?	Date	April 2011
2	What is the date of your current Agency Information Management Strategy (AIMS)?	Date	Oct 2010
3	For the proposed project, provide the page reference in your current AIMS and/or strategic business plan.	Doc.	ITCP
		Priority	1

Project #	4265-21
Doc. Type	FSR

		Yes	No
4	Is the project reportable to control agencies?	X	
	If YES, CHECK all that apply:		
	<input type="checkbox"/> The project involves a budget action.		
	<input type="checkbox"/> A new system development or acquisition that is specifically required by legislative mandate or is subject to special legislative review as specified in budget control language or other legislation.		
	<input checked="" type="checkbox"/> The estimated total development and acquisition cost exceeds the departmental cost threshold and the project does not meet the criteria of a desktop and mobile computing commodity expenditure (see SAM 4989 – 4989.3).		
	<input type="checkbox"/> The project meets a condition previously imposed by Finance.		

## 2.4 Section D: Budget Information

Project #	4265-21
Doc. Type	FSR

Budget Augmentation Required?		No	X								
		Yes		If YES, indicate fiscal year(s) and associated amount:							
		FY	12/13	FY	13/14	FY	14/15	FY	15/16	FY	
			0		0		0		0		\$

### PROJECT COSTS

1	Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017	TOTAL
2	One-Time Cost	\$260,499	\$906,064	\$2,466,169	\$1,016,662	0	\$4,649,394
3	Continuing Costs	0	0	\$77,295	\$877,001	\$1,393,009	\$2,347,305
4	<b>TOTAL PROJECT BUDGET</b>	\$260,499	\$906,064	\$2,543,464	\$1,893,663	\$1,393,009	\$6,996,699

### SOURCES OF FUNDING

5	General Fund	0	0	0	0	0	\$0
6	Redirection	0	0	0	0	0	\$0
7	Reimbursements	\$164,114	\$570,821	\$1,553,686	\$640,497	0	\$2,929,118
8	Federal Funds	\$78,150	\$271,819	\$817,146	\$1,182,000	\$1,393,009	\$3,742,124
9	Special Funds	\$18,235	\$63,424	\$172,632	\$71,166	0	\$325,457
10	Grant Funds	0	0	0	0	0	\$0
11	Other Funds	0	0	0	0	0	\$0
12	<b>PROJECT BUDGET</b>	\$260,499	\$906,064	\$2,543,464	\$1,893,663	\$1,393,009	\$6,996,699

### PROJECT FINANCIAL BENEFITS

13	Cost Savings/Avoidances	\$(111,749)	\$(640,044)	\$(1,933,694)	\$(817,227)	\$16,761	\$(3,485,952)
14	Revenue Increase	\$	\$	\$	\$	\$	\$

Note: The totals in Item 4 and Item 12 must have the same cost estimate.

## 2.5 Section E: Vendor Project Budget

<b>Vendor Cost for FSR Development (if applicable)</b>	\$143,000
<b>Vendor Name</b>	Cal eConnect

Project #	4265-21
Doc. Type	FSR

### VENDOR PROJECT BUDGET

1	Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017	TOTAL
2	Primary Vendor Budget		\$360,000	\$1,440,000	\$600,000		\$2,400,000
3	Independent Oversight Budget						
4	IV&V Budget		\$17,500	\$70,000	\$29,167		\$116,667
5	Other Budget	\$148,750	\$256,250	\$600,000	\$250,000		\$1,255,000
6	<b>TOTAL VENDOR BUDGET</b>	\$148,750	\$633,750	\$2,110,000	\$879,167		\$3,771,667

## 2.6 Section F: Risk Assessment Information

Project #	4265-21
Doc. Type	FSR

### RISK ASSESSMENT

	Yes	No
Has a Risk Management Plan been developed for this project?	X	

<b>General Comment(s)</b>
Please see Risk Management Plan in section 7 of this FSR.

## 3.0 Business Case

### 3.1 Business Program Background

This section provides background on the California Immunization Registry (CAIR), the existing Statewide Immunization Information System (SIIS) in California, the business problems, business opportunities, business objectives and functionality needed to improve CAIR for its many stakeholders, including the California Department of Public Health (CDPH).

**Note:** Throughout this Feasibility Study Report (FSR):

- The use of the term “**CAIR**” will refer to the SIIS of California including **all** regions regardless of whether the immunization information systems (IIS) in those regions use the CAIR Software Application or not.
- The use of the term “**CAIR Software Regions**” will refer to the seven regions currently using the CAIR software.
  - The use of the term “**CAIR Software Application**” will refer to the software application used by the CAIR Software Regions.
- The remaining regions not using the CAIR Software Application will be referred to as the “**independent registries**” or **specifically by their region name** (i.e., San Diego, San Joaquin, or Imperial).

#### 3.1.1 Business Program Supported by Proposal

The CDPH Center for Infectious Diseases (CID), Division of Communicable Disease Control (DCDC), and Immunization Branch’s mission is to provide leadership and support to public and private sector efforts to protect the population against vaccine-preventable diseases. The CDPH Immunization Branch tracks and monitors immunizations and diseases throughout the state; works in partnership with health officials, health care providers, and the public to administer state and national immunization efforts; and provides epidemiological assessments and analyses. CDPH utilizes immunization data for epidemiological assessments and mandatory reporting.<sup>1</sup>

#### **Benefits of Immunizations (Vaccines)**<sup>2</sup>

Immunizations stimulate the immune system to protect individuals from infections, some life-threatening, and are among the greatest achievements of medicine and public health. At the beginning of the 20<sup>th</sup> century, infectious diseases exacted an enormous toll in the United States (U.S.). Fortunately, vaccines against life-threatening diseases have been developed, leading to dramatic declines in illness and death as well as large economic savings. As examples:

- ***Polio***. Before polio vaccine was licensed in the U.S. in 1955, an average of 16,316 paralytic polio cases and 1879 deaths from polio were reported each year. As of 1991, polio has been eliminated from the Western Hemisphere. In 1994, every dollar spent to

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<sup>1</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>2</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

administer oral poliovirus vaccine saved \$3.40 in direct medical costs and \$2.74 in indirect societal costs.

- Measles. Before measles vaccine was licensed in the U.S. in 1963, an average of 503,282 measles cases and 432 measles-associated deaths were reported each year. A nationwide measles resurgence of 1989 to 1991 resulted in more than 55,000 cases, 11,000 hospitalizations, 120 deaths, and \$100 million in direct medical care costs. California had the most cases in this outbreak. Measles now occurs in the U.S. at historically low levels, fewer than 200 cases per year. In 1994, every dollar spent to purchase measles-containing vaccine saved \$10.30 in direct medical costs and \$3.20 in indirect societal costs.
- Severe Haemophilus influenzae type b (Hib) infection. Before the first Hib vaccine was licensed, an estimated 20,000 cases of Hib invasive disease occurred each year, and Hib was the leading cause of childhood bacterial meningitis and postnatal mental retardation. In less than a decade, the use of the Hib conjugate vaccines nearly eliminated Hib invasive disease among children. Every dollar spent to purchase Hib vaccine saved two dollars in direct medical costs.
- Pertussis (whooping cough). The first pertussis vaccine was developed in the 1930s and was in widespread use by the mid-1940s, when pertussis vaccine was combined with diphtheria and tetanus toxoids to make the combination DTP vaccine. A series of 4 doses of whole-cell DTP vaccine was quite (70–90%) effective in preventing serious pertussis disease; however, up to half of the children who received the vaccine developed local reactions such as redness, swelling, and pain at the injection site. In 1991, concerns about safety led to the development of more purified (acellular) pertussis vaccines with fewer associated side effects. These acellular pertussis vaccines have replaced the whole cell DTP vaccines in the U.S.<sup>3</sup>

Within the last year, California has experienced a whooping cough epidemic. As of April 13, 2011, California had recorded 9,273 cases of pertussis in 2010, the most cases in 63 years since there were 9,394 cases reported in 1947. Ten infants, all three months of age or younger, have died from the disease and over 700 more have been hospitalized in 2010. In addition, over 700 cases were reported in the first four months of 2011. Pertussis is cyclical. Cases tend to peak every two to five years. In 2005, California recorded 3,182 cases and eight deaths.<sup>4</sup> In response to the high levels of disease and death from pertussis in California during 2010, CDPH is recommending that all Californians make sure that they are immunized against pertussis, especially if they are in contact with infants. CDPH has issued new recommendations for health care providers to help with this effort.<sup>5</sup> The diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP) vaccine saves about \$24 in direct medical costs for every dollar spent on immunization.

<sup>3</sup> Immunization Action Coalition. *Vaccine Information for the Public and Health Professionals – Pertussis Vaccine*. 25 April 2011 <<http://www.vaccineinformation.org/pertuss/qandavax.asp>>.

<sup>4</sup> California Department of Public Health. *Whooping Cough Epidemic May be Worst in 50 Years*. 25 April 2011 <<http://www.cdph.ca.gov/Pages/NR10-041.aspx>>.

<sup>5</sup> California Department of Public Health. *Pertussis (Whooping Cough)*. 25 April 2011 <<http://www.cdph.ca.gov/healthinfo/discond/pages/pertussis.aspx>>.

Other vaccines also provide significant cost benefits. When indirect savings, such as avoidance of work loss by parents of ill children and prevention of death and disability, are factored in, the economic benefits are even higher.

The more people who are immunized in the community, the less likely that a single case of disease, perhaps introduced from a traveler, will cause an outbreak. Those who are immunized also help to protect vulnerable contacts who:

- are too young to be vaccinated (children less than a year old cannot receive the measles vaccine but can be infected by the measles virus)
- cannot be vaccinated for medical reasons (e.g., severe allergies, cancer)
- have not responded to vaccination (e.g., weakened immune system, or vaccine inadvertently weakened through improper storage.)

### **Challenges and Remaining Needs**<sup>6</sup>

Despite remarkable progress, several challenges face the U.S. vaccine-delivery system. Many under-immunized children remain, leaving the potential for outbreaks of disease. Each year in the U.S. at least 300 children under age six are hospitalized or die from complications of vaccine preventable diseases.

The infrastructure of the immunization system must be capable of successfully implementing an increasingly complex vaccination schedule, maintaining high coverage of prior immunizations against disease which have not been eradicated, and incorporating new vaccinations into the schedule every few years. 11,000 children are born each day in the U.S., each requiring over 20 doses of vaccine by age 18 months to be protected against over a dozen childhood diseases. These challenges frequently lead to missed opportunities to provide one or more recommended vaccines during medical appointments.

Many children visit clinics sporadically and do not have a stable primary physician. When these children are first seen by a new health care provider, immunization records may be absent or incomplete, increasing the chance that children are either under-vaccinated or over-vaccinated.

In addition, the vaccine-delivery system must be extended to adolescents and adults to optimally prevent disease, disability, and death. Each year, thousands of cases of potentially-preventable cases of influenza, pneumococcal disease, and hepatitis B occur in these populations. Many vaccines, such as the shingles and meningococcal vaccines are targeted at these older age groups. Immunization data help state and local health departments develop programs to decrease missed opportunities and improve vaccination coverage at all ages in both the public and private sectors.

Monitoring of immunization records assist in the vital effort to maintain and improve vaccine safety. Knowing the safety profile of vaccines is essential to accurately assess the risks and benefits of vaccination, to formulate appropriate vaccine recommendations, and to address public concerns.

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<sup>6</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

The federal Centers for Disease Control and Prevention (CDC) and Advisory Committee of Immunization Practices (ACIP) have identified effective use of information technology in the support of timely vaccinations as a key step to achieve the full potential of vaccines.

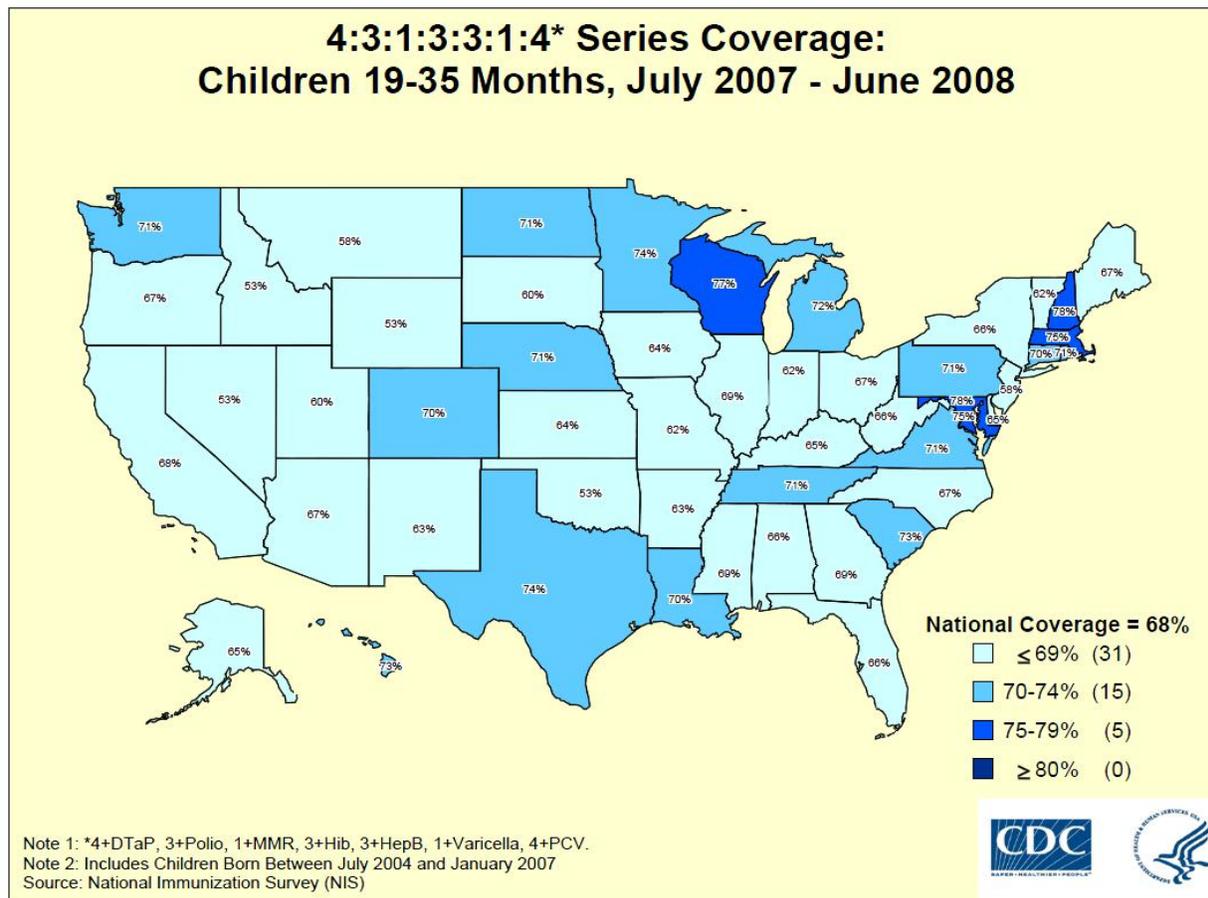
### **Status of Immunizations in California**<sup>7</sup>

While immunization protects children and adults alike, a majority of immunizations are given to young children, and many of these are required by law for the child to enter kindergarten or licensed child care facilities. Between July 2007 and June 2008, 31% of children between the ages of 19-35 months in California were not fully up-to-date with their immunizations. These children and their under-immunized or unimmunized contacts of any age are at risk of hospitalization and possible death from whooping cough, influenza, measles and other vaccine-preventable diseases. Immunization rates in California are aligned with the national immunization coverage rates (see Figure 3-1); however, there is room for improvement in decreasing the percentage of under-immunized and unimmunized children in California.

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<sup>7</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

Figure 3-1: 4:3:1:3:3:1:4 Series Coverage<sup>8</sup>



The complexity of the evolving immunization schedule, the migration of children among health care providers through childhood, and the constraints of traditional medical record systems make tracking children’s immunizations difficult. These factors contribute to both the lack of immunizations and to over-immunization, which occurs when records cannot be found to verify prior vaccinations. Many of these issues are especially difficult in California given its size and diversity.

An effective tool in helping the Immunization Branch achieve its mission is immunization registries, also known as immunization information systems or IIS. IIS are confidential, population-based, computerized information systems used to capture, store, track, and consolidate vaccination data from multiple sources and serve as an important tool in preventing and controlling vaccine preventable diseases and in increasing and sustaining vaccination coverage rates. The Immunization Branch includes the Registry and Assessment Section which is responsible for, and provides oversight for CAIR, California’s SIIS.

Benefits of immunization registries include the following<sup>9</sup>:

<sup>8</sup> 4:3:1:3:3:1:4 Series Coverage: Children 19-35 Months, July 2007 - June 2008. 03 May 2011  
<<http://www.cdc.gov/vaccines/stats-surv/nis/figures/downloads/0708-4313314.pdf>>.

#### FOR PARENTS:

- Consolidate in one record all immunizations a child has received.
- Provide an accurate, official copy of a child's immunization history for personal, day care, school, or camp entry requirements.
- Help ensure that a child's immunizations are up to date.
- Provide reminders when an immunization is due.
- Provide reminder calls (recalls) when an immunization has been missed.
- Help ensure timely immunization for children whose families move or switch healthcare providers.
- Prevent unnecessary (duplicative) immunizations.

#### FOR PROVIDERS, PLANS AND PURCHASERS:

- Consolidate immunizations from all providers into one record for each child.
- Provide a reliable immunization history for any child, whether a new or continuing patient.
- Provide definitive information on immunizations due or overdue.
- Provide current recommendations and information on new vaccines.
- Produce reminders and recalls for immunizations due or overdue.
- Complete required school, camp, and day care immunization records.
- Reduction of paperwork.
- Facilitate introduction of new vaccines or changes in the vaccine schedule.
- Help manage vaccine inventories.
- Generate coverage reports for managed care (e.g., Healthcare Effectiveness Data and Information Set [HEDIS®]) and other organizations.
- Reinforce the concept of the medical home (single source for medical information).

#### FOR COMMUNITIES:

- Help control vaccine-preventable diseases.
- Help identify high-risk populations and under-immunized populations.
- Help prevent disease outbreaks.
- Provide information on community and state coverage rates.
- Streamline vaccine management.

#### FOR PUBLIC HEALTH OFFICIALS:

- Provide information to identify pockets of need, target interventions and resources, and evaluate programs.
- Promote reminder and recall of children who need immunizations.
- Ensure providers follow the most up-to-date recommendations for immunization practice.
- Facilitate introduction of new vaccines or changes in the vaccine schedule.
- Integrate immunization services with other public health functions.
- Help to monitor adverse events.

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<sup>9</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

- Improve California's eligibility for Federal funding that may be contingent upon a specific level of IIS completeness.

### **3.1.1.1 Relevant Features of the Program**

The relevant features of CAIR, California's SIIS, either experiencing problems or opportunities, are described in this section.

#### **Regionalized IIS Strategy**

Historically, California's IIS strategy has been a de-centralized regionalized approach where the State provides funding to the regional registries which function autonomously. Until quite recently, each regional registry was independently managed and operated at the regional or local level, had a separate governance mechanism for decision making with respect to operations, maintenance, staff and provider support, and was responsible for registry support and provider recruitment, training, and retention. Within the past two years, the regional registries have moved toward standardization of materials, policies and procedures, and centralized operations and server consolidation, but not data consolidation. See section 3.1.1.3 for the current business process impacted and section 3.1.1.5 for the customers and users of the business program and process.

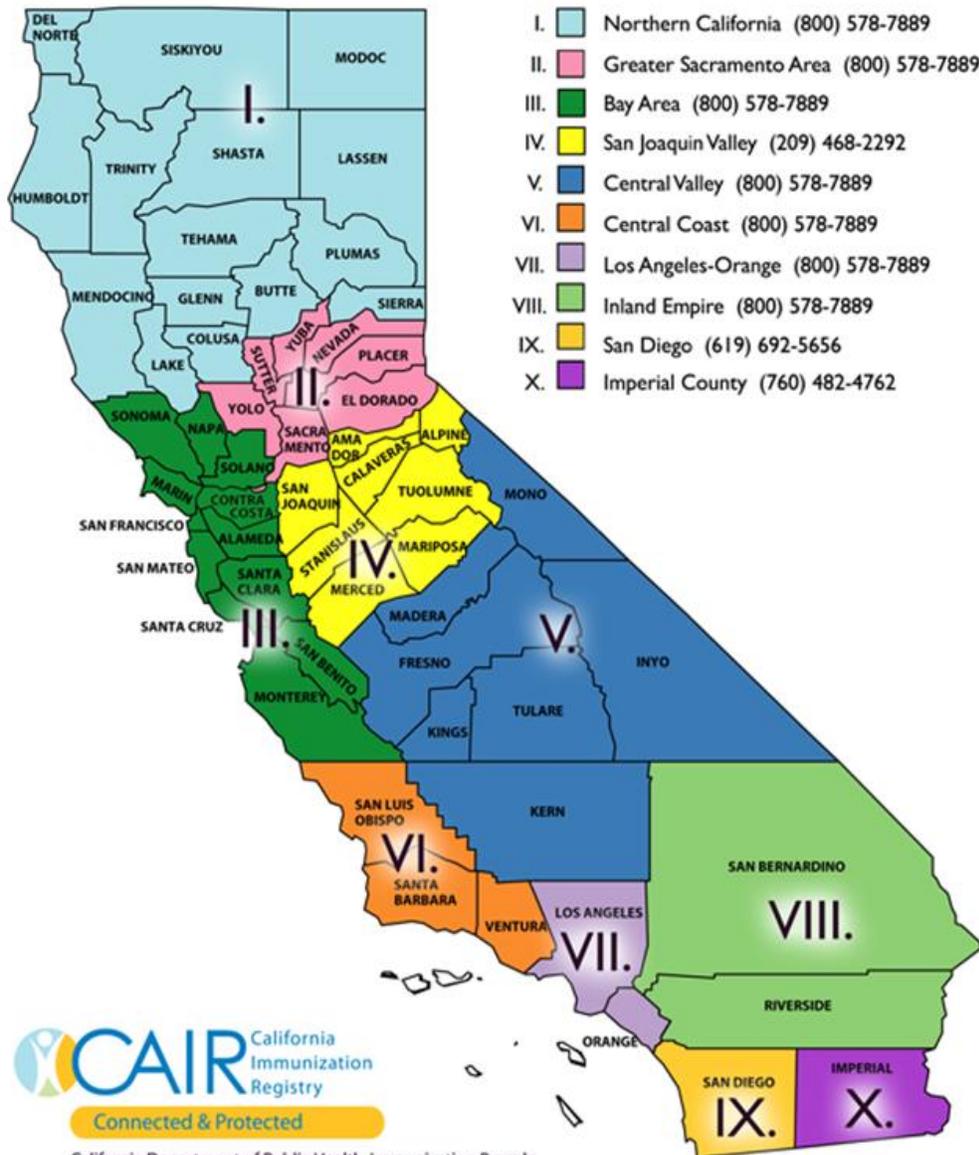
CAIR's vision is for any authorized user anywhere in the state of California to be able to immediately obtain comprehensive immunization information on any California child to ensure the secure, electronic exchange of immunization records to support the elimination of vaccine preventable diseases. CAIR is currently a collaboration of registries, not a network of registries, comprised of ten<sup>10</sup> regions (see Figure 3-2). The CAIR Software Regions are using a standardized single instance of the CAIR Software Application. The remaining independent registries are each using their own software products (see Figure 3-3).

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<sup>10</sup> The Imperial County region does not utilize State funds.

Figure 3-2: CAIR Regions

# California Immunization Registry (CAIR)

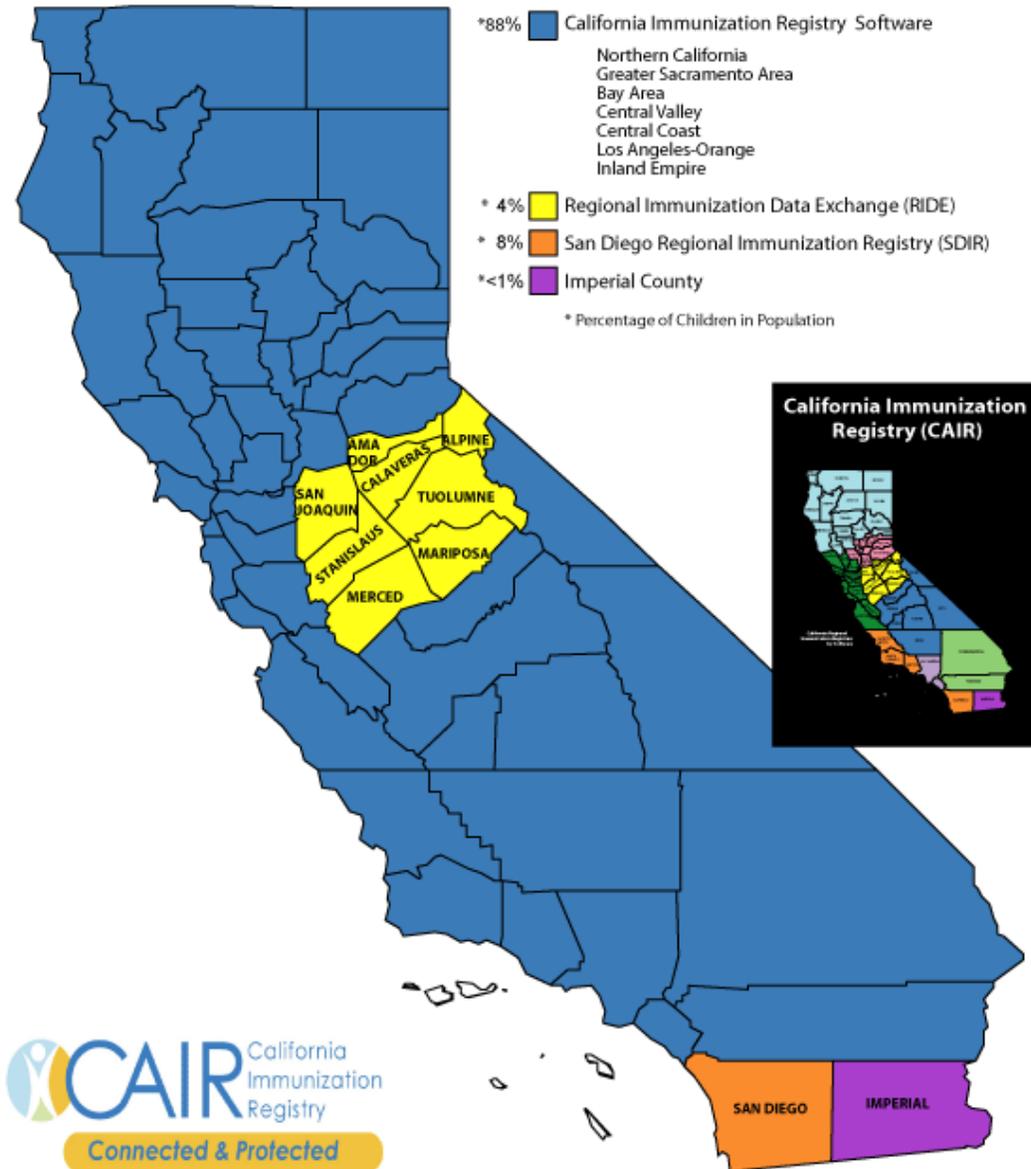


California Department of Public Health, Immunization Branch  
850 Marina Bay Parkway, Building P, 2nd Floor, Richmond, CA 94804  
www.CAIRWEB.org 1-800-578-7889

January 2011

Figure 3-3: CAIR by Software Application

## California Immunization Registry (CAIR) By Software Application



California Department of Public Health, Immunization Branch  
850 Marina Bay Parkway, Building P, 2nd Floor, Richmond, CA 94804  
www.cairweb.org 1-800-578-7889

January 2011

Participating providers and other authorized users can easily review immunizations on a new patient recorded in their regional registry. But, if previous providers are located in different regions or do not participate in a registry, then a child's complete immunization record will not be available electronically, leaving the registry user in the same quandary as the non-user (see section 4); whether to immunize, perhaps redundantly, to assure protection or risk leaving the child unprotected. Similarly, immunizations given outside the region are not readily available to local public health departments trying to control disease outbreaks or determine immunization rates of local residents. Aggregated immunization data would increase the completeness of individual records and assist registry users in protecting their clients.<sup>11</sup>

## **Participation Rates**

### *Individual Participation Rates*

CAIR, California's SIIS, is an all-ages registry. The CAIR Software Application is deployed in areas of the state covering 87% of California's children from age 0 to 5. CAIR, the SIIS, includes significant numbers of children from age 6-18 enrolled in the registry. In June 2010, 42% of California's children ages 6-18 had two or more immunizations recorded in CAIR.<sup>12</sup> In 2010, California had approximately 52.1% of children under six years of age with two or more immunizations in regional registries.<sup>13</sup> This is approximately half of the proportion of children (95%) who should be participating in an immunization registry according to the national Healthy People 2020 objectives.

Healthy People is a comprehensive national health promotion and disease prevention agenda issued by the U.S. Department of Health and Human Services (HHS) and provides an ambitious, achievable ten-year agenda for improving the Nation's health. One of the many topic areas of Healthy People 2020 is immunization and infectious diseases with one of its objectives to increase to 95% the proportion of children under six years of age whose immunization records are in fully operational, population-based IIS.<sup>14</sup> As of 2009, 77% of children under six years of age in the United States had two or more immunizations recorded in an IIS.<sup>15</sup> As depicted in Figure 3-4, with about 20 states reporting greater than 95% of children under six years of age participating in an IIS, California falls behind many other states in its rate of participation and can improve on its percentage of children participating in IIS. Many of these high enrollment states have benefited from state laws mandating immunization reporting; California, however, does not mandate immunization reporting<sup>16</sup> (see Legal Implication section

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<sup>11</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>12</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

<sup>13</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

<sup>14</sup> Healthy People 2020. 29 March 2011

<<http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=23>>.

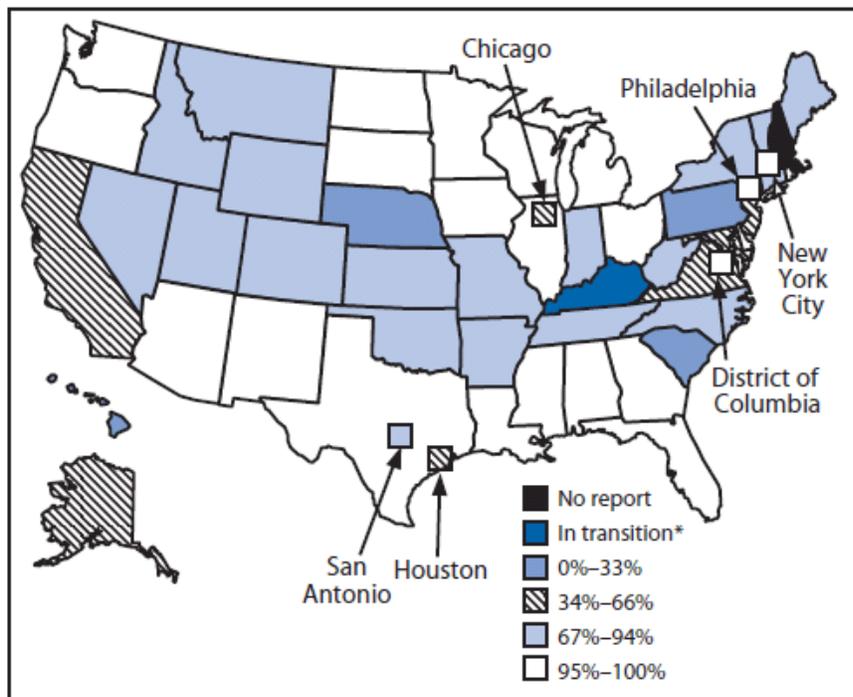
<sup>15</sup> "Progress in Immunization Information Systems --- United States, 2009." Morbidity and Mortality Weekly Report (MMWR) January 14, 2011: 60(01);10-12. 17 March 2011

<[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a3.htm?s\\_cid=mm6001a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a3.htm?s_cid=mm6001a3_w)>.

<sup>16</sup> Centers for Disease Control and Prevention National Center of Immunization and Respiratory Diseases (NCIRD). *Survey of State Immunization Information System Legislation*. 18 April 2011  
<<http://www.cdc.gov/vaccines/programs/iis/privacy/legsurr.htm>>.

below). Attainment of Healthy People goals was a key driver towards a new SIIS strategy as noted in discussions with other states in regard to their SIIS experience.

**Figure 3-4: Percentage of children aged <6 years participating in a grantee immunization information system --- 50 states, five cities, and District of Columbia, 2009**



\* Grantee is implementing a new IIS project.

The figure above is U.S. map showing the percentage of children aged <6 years participating in an immunization information system (IIS) in the 50 states, five cities, and District of Columbia in 2009. Of the 53 responding grantees, 23 (43%) reported that >95% of children aged <6 years in their geographic area were participating in an IIS. Ten (19%) of the 53 reported participation ranging from 80% to 94%. Overall in the United States, approximately 77% of children aged <6 years (18.4 million) participated in an IIS in 2009 (a small but statistically significant increase from 75% in 2008).<sup>17</sup>

### Provider Participation Rates<sup>18</sup>

In 2010, 54% of Vaccines for Children<sup>19</sup> (VFC) providers in California were enrolled in CAIR. Between April 2010 to June 2010, 43.6% of the clinical providers enrolled in CAIR did not add any doses to CAIR.

The percentage of public provider sites actively participating in a grantee IIS in the U.S., six cities, and eight Territories in 2009 is depicted in Figure 3-5. California had 79% of public provider sites actively participating in a grantee IIS in 2009.<sup>20</sup>

<sup>17</sup> "Progress in Immunization Information Systems --- United States, 2009". *Morbidity and Mortality Weekly Report (MMWR)* January 14, 2011; 60(01):10-12. 17 March 2011

<[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a3.htm?s\\_cid=mm6001a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a3.htm?s_cid=mm6001a3_w)>.

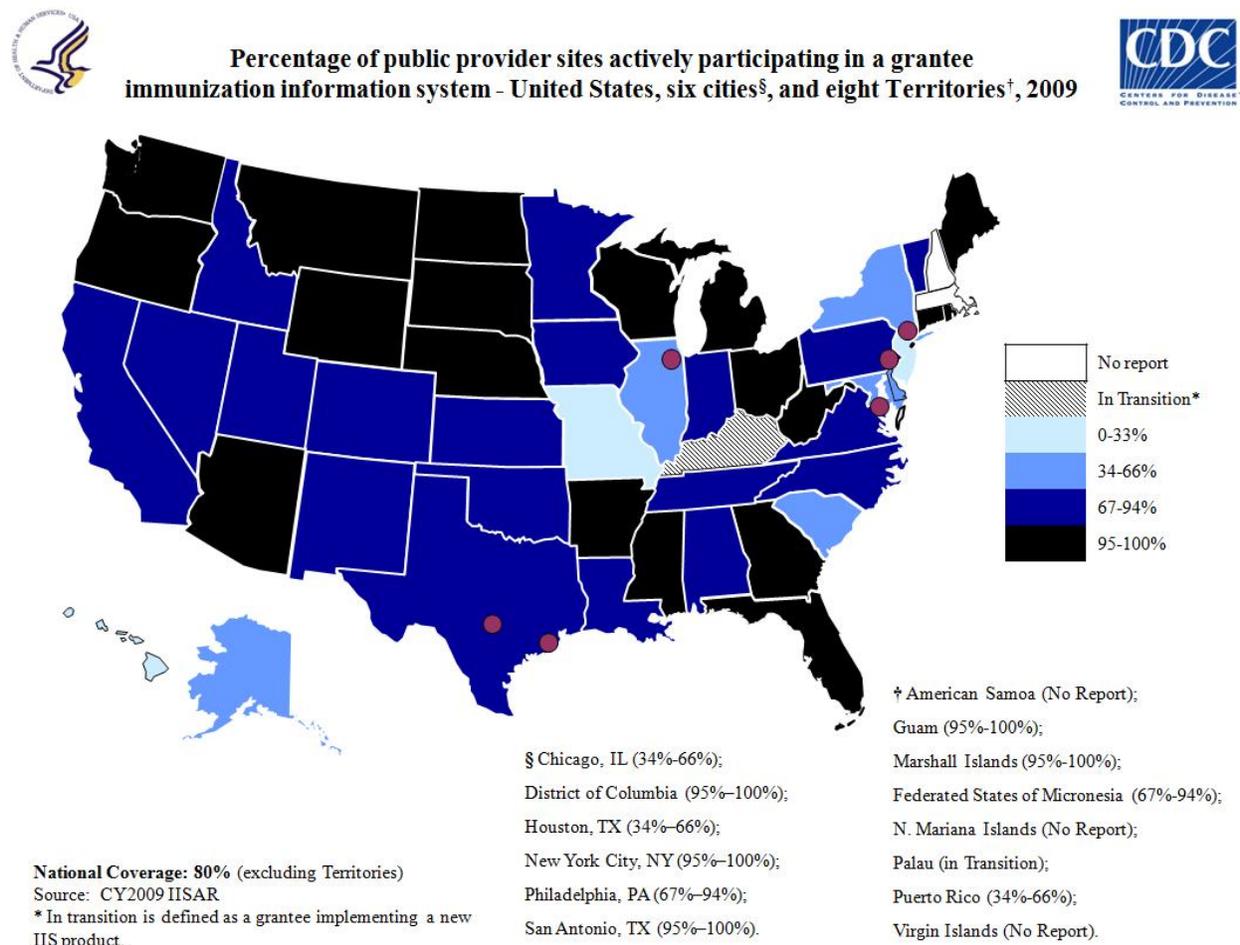
<sup>18</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

<sup>19</sup> The Vaccines for Children Program, established by an act of Congress in 1993, helps families by providing free vaccines to doctors who serve eligible children 0 through 18 years of age.

<sup>20</sup> Centers for Disease Control and Prevention. *2009 Public Provider Participation Table and Map*. 03 May 2011

The percentage of private provider sites actively participating in a grantee IIS in the U.S., six cities, and eight Territories in 2009 is depicted in Figure 3-6. California had 35% of private provider sites actively participating in a grantee IIS in 2009.<sup>21</sup>

**Figure 3-5: Percentage of public provider sites actively participating in a grantee IIS --- U.S., six cities, and eight Territories, 2009<sup>22</sup>**



<<http://www.cdc.gov/vaccines/programs/iis/rates/2009-participate-map.htm>>.

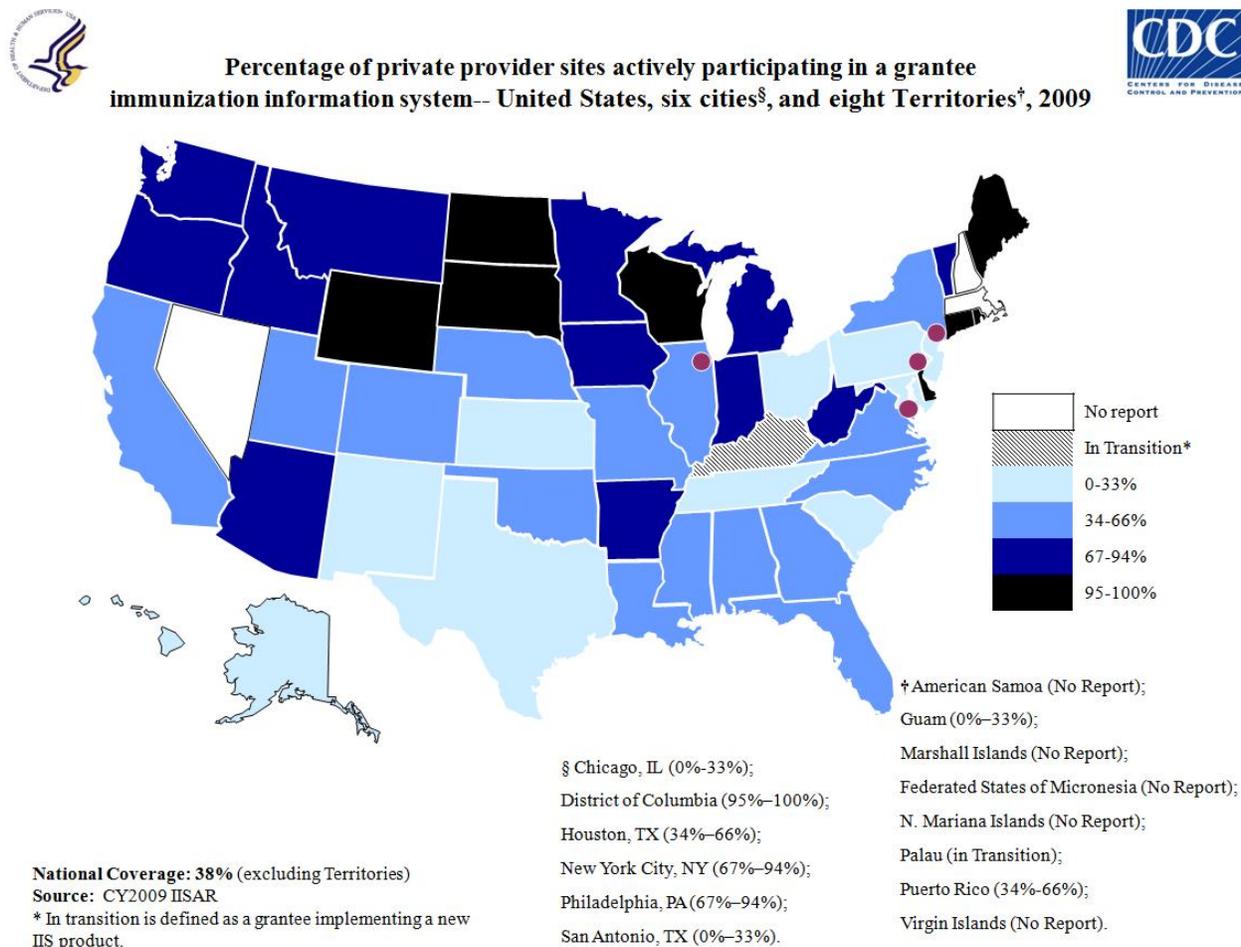
<sup>21</sup> Centers for Disease Control and Prevention. *2009 Private Provider Participation Table and Map*. 03 May 2011

<<http://www.cdc.gov/vaccines/programs/iis/rates/2009-private-map.htm>>.

<sup>22</sup> Centers for Disease Control and Prevention. *2009 Public Provider Participation Table and Map*. 03 May 2011

<<http://www.cdc.gov/vaccines/programs/iis/rates/2009-participate-map.htm>>.

**Figure 3-6: Percentage of private provider sites actively participating in a grantee IIS --- U.S., six cities, and eight Territories, 2009<sup>23</sup>**



### **Provider Recruitment, Training, Retention and Support<sup>24</sup>**

Until quite recently, each regional registry was responsible for registry support and provider recruitment, training, and retention. Regions have been directed to recruit high volume VFC providers first, then non-VFC immunization providers.<sup>25</sup>

The CAIR Software Regions are currently in the process of moving from a regionalized to statewide provider recruitment, training, retention, and support model whereby:

- The Immunization Branch would be responsible for the hiring and supervision of registry provider support field staff.

<sup>23</sup> Centers for Disease Control and Prevention. 2009 Private Provider Participation Table and Map. 03 May 2011 <<http://www.cdc.gov/vaccines/programs/iis/rates/2009-private-map.htm>>.

<sup>24</sup> State of California. Department of Public Health. *Immunization Registry Support and Provider Recruitment, Training, and Retention: Moving from a Regional to a Statewide Model*.

<sup>25</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

- Local supervisory responsibilities would be assumed by the five existing regional Senior VFC field staff who would oversee ten new Registry field staff.

### **Immunization Records**

With California's mobile populations, fragmentation in health care delivery, and lack of a consistent medical home, immunization records are incomplete which can lead to under immunization or unnecessary over-immunization and challenges in performing coverage assessments, quality assessments, and evaluating and targeting interventions to areas of need.

### **Data Exchange**

The regional registries currently do not have the capability to easily share information with one another. The CAIR Software Regions support bi-directional flat file data exchange, but are currently in the process of implementing standards-based Health-Level Seven<sup>26</sup> (HL7) data exchange; this capability is not yet fully implemented due to its dependence on a shared messaging infrastructure currently under development within the State. An independent interface to receive and upload HL7 messages from Indian Health Service (IHS) clinics through their electronic health record systems (EHR systems) has been implemented. The independent registries all currently support HL7 messaging, though on a limited scale.

### **Legal Implication**

California law permits, but does not require health care providers and people receiving vaccines to participate in the registry. All users must treat data in CAIR as confidential.<sup>27</sup> Patients who wish to decline sharing their immunization information can "opt out" of data sharing by informing their health care provider or submitting an affidavit to registry staff.<sup>28</sup>

Some counties in California currently receive birth data in their registries from their County Vital Records<sup>29</sup> Offices, with the Vital Records data inserted into the registry with the addresses removed. With establishment of a CDPH IIS, specific vital record data may be made available to the registry to support improved efficiencies.

### **Technical Infrastructure**

The CAIR Software Regions and independent registries are all utilizing web-based registry applications. The CAIR Software Regions are using a standardized single instance of the CAIR application; its production servers are all co-located at the University of California (U.C.) Berkeley Data Center with backup servers located in San Francisco. Reporting is run on the backup servers as to not affect the production servers' performance. The technology used by the CAIR Software Regions is based on aging Microsoft technology that is no longer supported.

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<sup>26</sup> Health Level Seven International (HL7) is the global authority on standards for interoperability of health information technology with members in over 55 countries.

<sup>27</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>28</sup> State of California. Department of Public Health Immunization Branch. *California Immunization Registry Final Draft Assessment Report*. August 31, 2010.

<sup>29</sup> Vital records include live birth, fetal death, marriage, and divorce records.

San Joaquin, San Diego, and Imperial regions are each using their own applications developed over time using varying technologies and are maintained and supported independently.

### **3.1.1.2 Conditions Creating the Problem/Opportunity**

California has reached a juncture with the opportunity to re-examine its strategy for CAIR, the SIIIS, and is proposing a new approach (see section 5) to better serve the needs of Californians. Key drivers in formulating the new strategy for CAIR include the following:

- Reduction in the fiscal year (FY) 2010-2011 state budget to the Immunization Branch.
- Inability of the regions to easily interoperate and exchange data.
- Challenges in performing statewide analysis, assessments, program evaluation, and quality improvement because of data fragmentation.
- Inefficiencies due to redundancy in staff and technology across regions.
- New requirements for standards-based data interoperability imposed by the American Recovery and Reinvestment Act (ARRA) of 2009, Health Information Technology for Economic and Clinical Health Act (HITECH) legislation (see section 3.2) – Enabling and achieving Stage 1 Meaningful Use to maximize eligible professional and hospital incentive payments.
- Aging software technology underpinning the CAIR software which makes it expensive to sustain and support, and uncertainty whether it will reliably scale to statewide use.

### **3.1.1.3 Current Business Process Impacted**

This section includes the current business processes impacted by the proposed solution (see section 5) described in this FSR. For more information on the current business process, see section 4.

#### **Submission/Retrieval of Immunization Information**

CAIR is populated by providers who directly enter data into the web-based registry applications or submit data via data exchange. The CAIR Software Regions support bi-directional flat file data exchange, but are currently in the process of implementing HL7 data exchange. The independent registries all support HL7 data exchange on a limited scale.

Immunization information could be retrieved by querying the web-based registry applications, however due to the fragmentation of data in California's disparate regional immunization registries, the retrieval of consolidated, up-to-date, accurate, complete immunization information on individuals is difficult to achieve. At best, an attempt to build a more consolidated record could be possible by querying the other regional immunization registries for data, but this functionality is not currently supported.

#### **Provider Recruitment, Training, Retention and Support**

See section 3.1.1.1.

## **Immunization Data for Authorized Parties Nationwide and Quality Improvement Programs**

CAIR is able to provide authorized parties nationwide with aggregated, statewide, and current immunization data from California to meet the mandates of the Comprehensive Child Immunization Act of 1993 (see section 3.2).

Health care plans, including those participating in MediCal Managed Care; obtain immunization data from CAIR or from time-consuming manual chart reviews for standard performance measures, such as HEDIS (see section 3.2).

Because of the data fragmentation in disparate registry databases, obtaining immunization data for both of these purposes may not be comprehensive and is inefficient and not very timely because data may need to be assembled and compiled from multiple regions and databases.

### **3.1.1.4 Impact of Proposal in Business Program and Process**

The proposed solution for a consolidation of data in the CAIR Software Regions with new registry software, leveraging a patient indexing function and HL7 messaging capability is described in section 5. The following describes the functional capabilities of the program or process to be impacted by the proposed solution.

#### **Further Consolidation of Immunization Records**

While a partial consolidation will not ensure a single unified record for all individuals, by consolidating the CAIR Software Regions which account for 87% of California's children from age 0 to 5, the State will come closer to producing a unified record for this key segment of the population. Records will no longer be captured in seven separate databases currently used by the CAIR Software Regions, but rather in one database. This will facilitate clinician access to complete immunization information for most patients at the point of care, as well as more timely and efficient access to immunization data for reporting purposes and quality improvement programs such as HEDIS (see section 3.2). If the independent regions decide to use the new solution instead of their existing products, the percentage of children participating in the unified database will increase.

#### **Submission/Retrieval of Immunization Information**

Consolidation of all immunization data in the CAIR Software Regions into a single database will facilitate the submission and retrieval of immunization information. Submission and retrieval of immunization information from and between the independent registries and the consolidated CAIR Software Regions will also be easier via standards-based data exchange (HL7 version 2.3.1 or higher messaging) and also the use of a patient indexing function.

#### **Provider Recruitment, Training, Retention and Support**

Because the proposed solution will include the upgrade of the existing CAIR software or implementation of new registry software, all users in the CAIR Software Region will need to be trained either on the upgraded or new software. Registry support needs will likely increase during the learning curve period and will need to be considered with respect to the new statewide provider recruitment, training, retention, and support model (see section 3.1.1.1).

The proposed solution may also be more attractive to providers, thus having a positive impact on provider recruitment and retention.

### **Standards-based Interoperability**

The proposed solution will have an impact on the standards-based interoperability efforts to implement HL7 data exchange currently underway in the CAIR Software Regions. Additionally, while the independent registries all support HL7 data exchange, they will need to scale-up their support of HL7 to support broader use, including query of their systems.

### **Vital Records Interfaces**

With a consolidation of CAIR Software Region data, counties receiving birth record data in their registries could exchange Vital Records data between themselves if the system was governed by CDPH. Otherwise, they would need to ensure the new application will not display, or return in a query or a report, any Vital Records data to a registry users from another county.

#### **3.1.1.5 Customers and Users of Business Program and Process**

CAIR's users include health care providers, public health departments, schools, child care facilities, family child care homes, Women Infants and Children (WIC) service providers, foster care agencies, welfare departments, juvenile justice facilities, and other programs either providing, tracking or promoting immunization.<sup>30</sup>

There are currently 83,195 users of CAIR, California's SIIS. This number does not include users in the San Joaquin or Imperial regions (see Table 3-1). The CAIR Software Application supports 300 concurrent users comfortably.<sup>31</sup>

**Table 3-1: CAIR Users**

Organization Type	Number of Provider IDs	Number of User IDs
Clinical Organizations/Sites	2,371	42,844*
Read-Only Organizations/Sites	3,345	40,351*
TOTAL	5,716	83,195

\*Does not include User ID information from San Joaquin or Imperial regions.

## **3.2 Business Problem or Opportunity**

The following identifies the problems or opportunities which will be addressed by a CAIR Software Region data consolidation with new registry software leveraging a patient indexing function and HL7 messaging capability.

- 1. California's multiple regional electronic immunization registries currently cannot easily share information with one another. As a result, immunization records are**

<sup>30</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>31</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

**incomplete for California's mobile populations, and health care providers may give too few or too many vaccines.<sup>32</sup>**

Medical records are often missing or incomplete for mobile populations (up to 15% of children change their address each year, including families of military personnel, migrant workers, children in foster care) who change health care providers. When information is lacking, health care providers either:

- give redundant immunizations, with associated public and private costs, or
- miss opportunities to immunize, leaving their patients and society vulnerable to life-threatening and costly diseases.

When information is not available, providers attempt, often unsuccessfully, to obtain immunization records on new patients by telephone or correspondence. Immediate access to more complete records will reduce the administrative cost to providers in acquiring, assembling, and recording this information.

California's recent pertussis outbreak illustrates the impact that poor vaccination levels have on the occurrence of disease. During 2010, there were over 10,000 confirmed cases of pertussis and 10 infant deaths, the most cases and deaths in over 65 years. Because the current pertussis vaccine is not life-long, adolescents and adults need to get booster doses to maintain their immunity. Poor vaccination levels in adults and adolescents led to this outbreak. Immunization registries facilitate improved vaccination coverage making it easier for healthcare providers to access patient immunization histories and vaccinations due.

There is an increased cost to health plans from redundant immunizations, including MediCal and Healthy Families for reimbursement (double charging). The cost of over-immunizations of children insured by Medi-Cal and other State safety net programs has been estimated to be \$1,114,000 annually. As more recently introduced vaccines are much more expensive, this cost may be significantly higher.

Additional savings from children receiving needed immunizations range from \$24 in direct medical costs for every dollar spent on DTaP to \$2 in direct medical costs for the Hib (*Haemophilus influenzae* type b) vaccine.

Also, large health care systems can span regional registry boundaries, resulting in the need to access two or more registry applications and work with two or more registry policies and operations in order to assemble a complete assessment of their system's performance in immunizations.

Electronic access to more complete immunization data will assist providers in protecting public health while reducing redundant services and costs.

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<sup>32</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

**2. Epidemiologists at CDPH are unable to *efficiently gather comprehensive and timely* statewide immunization information for analysis and assessment.<sup>33</sup>**

CDPH is charged with improving the health of all Californians. Epidemiologists assist in this effort by tracking and analyzing health trends throughout the state and the nation. This information is used by public health officials and health care providers to manage medical events such as outbreaks of infectious disease, movement of large segments of the population due to natural disasters, and the tracking of recalled or expired vaccines.

State and local health departments promptly investigate reports of suspected cases of vaccine-preventable diseases to institute appropriate measures to limit the spread of disease. Analysis of immunization records also provides important information on groups at highest risk for disease and pockets of need. Such data are important for allocating resources, targeting interventions, and making policies to maximize the effectiveness of immunization programs.

The current fragmented nature of the immunization registry system in CA, with 10 isolated independent registries, makes it difficult to assemble vaccination histories, particular during epidemics such as the recent pertussis epidemic. CA is the only current state with a fragmented system

Although epidemiologists at CDPH can compile immunization information by querying multiple regions and databases, they are unable to do this in a timely and efficient manner. In addition, only the data from regions using the CAIR Software Application is readily available to them – data from the independent regions can only be obtained on request.

- **It is difficult and time-consuming to determine the impact of a new vaccine or immunization outreach strategy.**

State and local health departments and their partners are currently unable to *comprehensively and efficiently* identify where, how and to whom vaccines have been administered. Without comprehensive and timely information, it is difficult to monitor the effectiveness of a new vaccine or the immunization strategy.

- **It is cost-prohibitive to identify children at risk during a vaccine-preventable disease outbreak in a community.**

When an outbreak occurs in multiple regions, often introduced by someone who has been traveling, it is cost-prohibitive to send public health staff into all area clinics and hospitals to review medical charts and to assemble immunization histories. This is needed not only to identify who is under-immunized and so at risk, but sometimes to identify who could receive added protection by receiving a booster dose earlier than normally given; for instance, providing measles boosters to four and five year olds during a measles outbreak rather than waiting until age six. A registry could readily identify these children and their last known

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<sup>33</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0.* July 23, 2008.

health care provider. The registry could help to preserve patient confidentiality while completely avoiding the need to have chart reviewers examining an entire medical record in order to assemble an immunization history.

Access to more aggregated immunization data will allow CDPH and local health departments to gather information in a more efficient and timely manner, guide vaccination policies and programs, and manage public health emergencies.

**3. California is unable to *efficiently* meet the Comprehensive Child Immunization Act of 1993 goal of developing a nationwide network of immunization tracking systems.**<sup>34</sup>

The federal Comprehensive Child Immunization Act of 1993 provided for a collaborative Federal and State effort to track the immunization status of the Nation's children. It authorized the Secretary to make grants to States to establish and operate State immunization registries containing specific information for each child in the State. Access to aggregated immunization data will further assist in the efficient and timely identification of children who need vaccinations and will help parents and providers ensure that children are appropriately immunized.

- **California cannot promptly provide other states with immunization data on children and families displaced by disaster.**

Children and families displaced by disaster require proof of immunization to begin school where they relocate. Children evacuated from Gulf Coast States after Hurricane Katrina in 2005 fortunately had their immunization records stored in comprehensive statewide systems that rapidly provided immunization records to California and other states receiving evacuees. California is currently able to provide comprehensive data to authorized parties; however, California is unable to do this efficiently because data must sometimes be compiled from multiple databases and regions.

Efficient access to aggregated immunization data will allow local health departments and health care providers outside of California, to gather information in a timely and effective manner and to use findings to manage public health emergencies.

**4. It is difficult for health care plans, including those participating in Medi-Cal Managed Care, to *efficiently* obtain *comprehensive* immunization data for standard performance measures, such as HEDIS.**<sup>35</sup>

HEDIS is a quality assurance tool developed by the non-profit National Committee for Quality Assurance. HEDIS is being used by more than 90% of America's health plans, including those participating in Medi-Cal Managed Care, to measure performance on important dimensions of medical care and service. HEDIS consists of 71 separate measures of care, including immunization rates of plan members.

<sup>34</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>35</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

HEDIS makes it possible to compare the performance of health plans. Employers, consultants, and consumers use HEDIS data to help them select the best health plan for their needs. HEDIS data also are the centerpiece of health plan “report cards” appearing in national magazines and local newspapers.

Health plans also use HEDIS results themselves to see where they need to focus their improvement efforts.

Without the use of immunization registries, health plans obtain quality assurance data on immunization through laborious manual chart review. Use of immunization registries for HEDIS saves substantial time and money. As many health plans cover multiple immunization registry regions in California, aggregated data would assist in obtaining HEDIS and related data for Medi-Cal beneficiaries. Accessing aggregated rather than distributed registry data for Med-Cal beneficiaries would increase efficiency and would likely contribute to increased quality and safety of health care for those patients.

**5. The technology used in the CAIR Software Regions is aging, difficult to support, and not compliant with current State standards and policies.**

The State has a set of IT standards related to various aspects of software development and implementation, including security, architecture, and products supported. The CAIR Software Application was implemented before many of these standards existed.

The CAIR Software Application is operated by CDPH employees but is not officially within the State’s IT infrastructure. The CAIR Software is based on aging technologies, i.e., Classic Active Server Pages (ASP), Visual Basic (VB6), complex middle tier structure, which are no longer supported by the State or by Microsoft technical support. All new systems must undergo a code review as a part of the State security standards. Currently, the State does not support the review of ASP code.

The CAIR Software Application also has limited Macintosh/Apple (MAC) support. Currently, there is difficulty in accessing the CAIR Software Application’s front end via MAC-based browsers.

The aging software is increasingly more costly to support, difficult to find qualified programmers to maintain or enhance, and is prohibited from being operated and managed within the State’s IT infrastructure. The State cannot support the old technology if they were to take on the responsibility of its operations and management.

Replacement of the legacy software with new software will provide a stable, supportable technical platform that conforms to current State security, software and hosting standards and policies.

**6. CAIR does not meet all of CDC's IIS: 2001 Minimum Functional Standards for Registries.**<sup>36</sup> (Also referred to herein as "CDC Minimum Functional Standards".)

CAIR meets most, but not all, of the CDC Minimum Functional Standards. CAIR is unable to fully meet the CDC Minimum Functional Standard #2 (*Establish a registry record within 6 weeks of birth for each newborn child born in the catchment area*) due to the restrictions on the sharing of Vital Records data (see section 4.2.5).

Additionally, while the CAIR Software Application used by the CAIR Software Regions is in the process of implementing HL7 data exchange, it has not met the CDC Minimum Functional Standard #7 (*Exchange immunization records using HL7 standards*) as described in section 3.1.1.1.

Implementing the proposed solution (see section 5) with an HL7 data exchange capability will help bring CAIR closer to meeting the CDC's Minimum Functional Standards.

**7. The reduction in the FY2010-2011 State budget to the Immunization Branch.**

The reduction in the FY2010-2011 state budget to the Immunization Branch has resulted in the elimination of roles at CDPH, the expansion of responsibilities in other roles, and a revision to the Provider Recruitment, Training, Retention and Support model from a regional to a statewide model.

Implementing the proposed solution (see section 5) will provide a more cost-effective and sustainable SIIS given the need for the efficient use of limited funds.

**8. ARRA HITECH Legislation provides the opportunity to enable and achieve Stage 1 Meaningful Use to maximize eligible providers and hospitals incentive payments.**

ARRA HITECH legislation has implications on the SIIS strategy. In 2010, the Centers for Medicare and Medicaid Services (CMS) established an incentive program to encourage eligible professionals and hospitals to implement health information technology. The primary focus of this program is the implementation of EHR systems and their "meaningful use" (MU). This multi-year program is rolling out in several phases, or "stages", i.e., MU Stage 1, MU Stage 2, MU Stage 3.

One of the MU Stage 1 measures specifically relevant to public health is immunization capture and submissions, which is one of three public health menu set items from which eligible professionals and hospitals may choose. The following is the objective and measure relative to IIS in MU Stage 1:

- **Eligible Professional/Eligible Hospital Objective:**<sup>37</sup> Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice.

<sup>36</sup> Centers for Disease Control and Prevention. *IIS: 2001 Minimum Functional Standards for Registries*. 19 April 2011  
<<http://www.cdc.gov/vaccines/programs/iis/stds/min-funct-std-2001.htm>>.

<sup>37</sup> "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule." *Federal Register* July 28, 2010: Vol. 75, No. 144. 29 March 2011

- **Eligible Professional/Eligible Hospital Measure:**<sup>38</sup> Performed at least one test of certified electronic health record (EHR) technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP, eligible hospital or Critical Access Hospital (CAH) submits such information have the capacity to receive the information electronically).

Currently, the CAIR Software Regions do have the capability to receive immunization information electronically in a standards-based format compliant with the legislation (2006 pilot with the San Diego region), but this capability is not yet implemented due to its dependence on a shared messaging infrastructure currently under development within the State. The independent registries are able to accept compliant electronic messages and have each begun to do so on a limited scale.

**9. Statewide Health Information Exchange (HIE) services are being implemented to facilitate interoperability. There is the opportunity for the SIIS to leverage these HIE services when available and appropriate.**

Regional entities are creating and servicing HIE's in California (see section 3.4.8). As these services become available, they can be leveraged to minimize duplication of efforts and align with national HIE efforts. These services would enable the new system to maintain minimal direct connections between information systems and process incoming data as efficiently as possible.

### 3.3 Business Objectives

Several objectives and anticipated benefits have been identified for a new SIIS strategy for the State of California. These are described in Table 3-2 and were informed from several sources including, but not limited to:

- SIIS Project Feasibility Study Report Version 1.0<sup>39</sup> (July 23, 2008)
- 2011 – 2012 CAIR System Business Plan<sup>40</sup> (August, 2010)
- California Immunization Registry Final Draft Assessment Report<sup>41</sup> (August 31, 2010)
- Centers for Medicare and Medicaid Services EHR Incentive Program Meaningful Use Objectives
- Cal eConnect Technical Implementation Plan
- Feedback from Stakeholders SIIS Strategy webinars (April 2011)

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<<http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>>.

<sup>38</sup> "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule." *Federal Register* July 28, 2010: Vol. 75, No. 144. 29 March 2011

<<http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>>.

<sup>39</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>40</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

<sup>41</sup> State of California. Department of Public Health Immunization Branch. *California Immunization Registry Final Draft Assessment Report*. August 31, 2010.

**Table 3-2: Business Objectives & Measures**

#	Business Objective	Recipient of Value	Metric	Baseline	Target	By Date	Methodology
1	Provide CAIR 2.0 software users access to statewide immunization information by May 2016.	Public, State, Local Health Departments (LHD)	Example test case: Can CAIR 2.0 Bay Area Region access records in other regions? PASS/FAIL	FAIL	PASS	May 2016; 6 months post-implementation	The requirements traceability process will ensure that one or more test cases address this requirement. After the user acceptance testing process, the CDPH Immunization Branch Chief signs off on the system acceptance form signifying that this key requirement has been met.
2	Reduce the time required to provide the U.S. Centers for Disease Control (CDC) annual Immunization Information System Activity Report (IISAR) report from 1 week to 1 hour by May 2016.	Public, State, CDC	Amount of time it takes to produce the CDC annual Immunization Information System Activity Report (IISAR)	1 week	1 hr.	May 2016; 6 months post-implementation	Create the IISAR report. (This report includes aggregated, statewide, and current immunization data from California to meet requirements of the Comprehensive Child Immunization Act of 1993. <sup>42</sup> )
3	Increase the number of California birth records being added to the CAIR 2.0 database from 45,000 records every 6 months to 250,000 records every 6 months by May 2016.	Public, State, CDC	Count the number of new birth records being added to the CAIR database	45,000 birth records/6 months	250,000 birth records/6 months	May 2016; 6 months post-implementation	Create a report that counts the number of new birth records in CAIR 2.0 six months post-implementation. Compare to previous 6 month total.

<sup>42</sup> "Progress in Immunization Information Systems --- United States, 2009." Morbidity and Mortality Weekly Report (MMWR) January 14, 2011: 60(01);10-12. 17 March 2011 <[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a3.htm?s\\_cid=mm6001a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a3.htm?s_cid=mm6001a3_w)>.

#	Business Objective	Recipient of Value	Metric	Baseline	Target	By Date	Methodology
4	CAIR 2.0 can directly consume patient and vaccine doses-containing Health level 7 (HL7) messages by May 2016.	Public, State, LHDs, CDC	Ability of CAIR 2.0 to directly consume HL7 messages (without aid of add-on translator)	FAIL	PASS	May 2016; 6 months post-implementation	The requirements traceability process will ensure that one or more test cases address this requirement. After the user acceptance testing process, the CDPH Immunization Branch Chief signs off on the system acceptance form signifying that this key requirement has been met.
5	Reduce the time to compile a statewide Tdap/Pertussis booster doses administered Report from 1 week to 1 hr. by May 2016.	Public, State, LHDs, CDC	The amount of time it takes for CDPH to create the Tdap/Pertussis Report.	1 week	1 hr.	May 2016; 6 months post-implementation	Create a report for all Tdap/pertussis immunizations administered in 2010 for all of California.
6	Reduce the time to produce a cross-regional or statewide HEDIS patient match report from 1 week to 1 hour by May 2016.	Public, State	The amount of time to create the HEDIS report.	1 week	1 hr.	May 2016; 6 months post-implementation	Run a standard HEDIS patient match report before implementation, then after implementation
7	Increase the number of health information exchanges (HIEs) exchanging data with the IIS from 1 to 5 by May 2016.	Public, State, LHDs, CDC	Number of HIEs exchanging data with CAIR	1	5 (assumes >=5 HIEs exist)	May 2016; 6 months post-implementation	Query CAIR system for the number of HIEs exchanging data with CAIR.

### 3.4 Business Functional Requirements

The high-level requirements for the implementation of a new SIIS strategy described in this section are pertinent to meeting the objectives stated in this FSR and were informed and drawn upon from several sources including, but not limited to:

- SIIS Project Feasibility Study Report Version 1.0<sup>43</sup> (July 23, 2008)
- 2011 – 2012 CAIR System Business Plan<sup>44</sup> (August, 2010)
- California Immunization Registry Final Draft Assessment Report<sup>45</sup> (August 31, 2010)
- IIS: 2001 Minimum Functional Standards for Registries
- IIS: 2011 Minimum Functional Standards for Registries (Proposed)<sup>46</sup>
- Centers for Medicare and Medicaid Services EHR Incentive Program Meaningful Use Objectives
- Health Information Technology Planning-Advanced Planning Document<sup>47</sup> (Updated) (June 21, 2010)
- Healthcare Financing Administration (HCFA) Medicaid Action Transmittal<sup>48</sup> (July 6, 2000)
- Care Management Business Area Immunization Registry (RI) Checklist – MMIS Interfaced<sup>49</sup>
- Cal eConnect Technical Implementation Plan
- CDPH/DCDC/CID/Immunization Branch, Registry and Assessments Section
- CDPH/DCDC Information Technology Section
- Feedback from Stakeholders SIIS Strategy webinars (April 2011)

The high-level requirements are categorized into the following areas and described in the subsequent sections of this FSR.

- Statewide Consolidated Records
- Data Export and Analysis
- Continuous Operations
- Standards-based Data Exchange
- Security and Privacy of Data
- Support for Clinical Operations
- Store Required Data
- Support HIE Core Services
- Stable, Well-supported Technology

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<sup>43</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>44</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

<sup>45</sup> State of California. Department of Public Health Immunization Branch. *California Immunization Registry Final Draft Assessment Report*. August 31, 2010.

<sup>46</sup> New 2011 CDC Minimum Functional Standards are imminent.

<sup>47</sup> State of California. Health and Human Services Agency Department of Healthcare Services. *Health Information Technology Planning-Advanced Planning Document (Updated)*. June 21, 2010.

<sup>48</sup> U.S. Department of Health and Human Services. *Healthcare Financing Administration (HCFA) Medicaid Action Transmittal*. 6 July 2000. <<http://www.cms.gov/smdl/downloads/smdl070600.pdf>>.

<sup>49</sup> State of California. *Care Management Business Area Immunization Registry (RI) Checklist – MMIS Interfaced*. August 3, 2007.

Note: It is expected that the core functionality in the current CAIR Software Application will be produced in any new solution for the SIIIS.

### 3.4.1 Statewide Consolidated Records

Entering immunization information and accessing consolidated records for individuals residing anywhere in the state of California, as described in Table 3-3, are important requirements in a new SIIIS strategy.

**Table 3-3: Statewide Consolidated Records High-Level Requirements**

ID	Requirement	Priority
R-1	The system must provide users the ability to easily enter immunization information and access consolidated accurate, complete immunization records on individuals who reside anywhere in the State. All demographic and immunization information should be de-duplicated at the data level to ensure the accuracy of the immunization information.	High
R-2	The system must provide a patient indexing/matching function and have the capability to integrate with a HIE Master Patient Index (MPI) to facilitate querying and de-duplication of records.	High
R-3	The system must provide access to IIS records to patients or their legal guardians.	Low

### 3.4.2 Data Export, Analysis and Reporting

Providing data export and analysis capabilities in the IIS may support users in their quality assessment and improvement measures. Additionally, providing reporting capabilities in the IIS is beneficial for system users in generating the various types of reports to serve their needs. High-level reporting, export and analysis requirements are described in Table 3-4 below.

**Table 3-4: Data Export and Analysis High-Level Requirements**

ID	Requirement	Priority
R-4	<p>The system must provide the ability to generate reports including but not limited to:</p> <ul style="list-style-type: none"> <li>• Standard, Dynamic and Ad hoc quality reports.</li> <li>• By date and/or scheduled on a periodic basis.</li> <li>• Missed opportunities/missed immunizations reports.</li> <li>• Provider profiles.</li> <li>• Export data for importing into the Comprehensive Clinic Assessment Software Application (CoCASA).</li> <li>• Automatically produce immunization coverage reports by providers, age groups, geographic areas, population groups (Medicaid/non-Medicaid) e.g., to measure immunization coverage (%of children “age-appropriately” immunized) as of a given date for an individual provider’s practice, for the registry’s entire catchment area, and for subgroups within a practice of the catchment area.</li> <li>• School reports (e.g., school entrance, yearly reports for additional vaccine requirements).</li> <li>• Reports that show the aggregate number of records in the Vital Records dataset versus the subset aggregate that have an immunization record match. This will allow selected personnel the ability to see the proportion of the Vital Records dataset that have received immunizations. The system shall provide the ability to restrict the ability to see this aggregate data to appropriate users (e.g., Public Health epidemiologists).</li> </ul> <p>Report generation must not impose undue strain on production system performance.</p>	High
R-5	<p>The system must provide users the ability to access detailed data elements to perform analysis. Data must be available to authorized users to perform additional data analysis. Analyses include data elements that contain information on:</p> <ul style="list-style-type: none"> <li>• Demographics – analysis of immunization rates over time by various attributes (e.g., age, sex, and ethnicity/race).</li> <li>• Geographic – analysis of immunization rates by county and city and which geographic areas are protected or which need additional immunization services.</li> <li>• Trend – analysis of how immunization rates and services changing over time.</li> <li>• Statistical – analysis to support interventions or design of interventions.</li> <li>• Quality measures – analysis of immunization rates by practice, health plan (e.g., HEDIS) or institution, quality of data within the registry.</li> </ul>	Medium
R-6	<p>The system must provide users the ability to export data to perform analysis. Users must be able to export data to popular file formats such as Text (TXT), Comma Separated Values (CSV), Tab-separated text, HTML or XML.</p>	Medium
R-7	<p>The system must provide the capability for schools to upload student rosters into the system to facilitate producing missed immunization reports for state compliance as well as increased immunization data into the system.</p>	High

### 3.4.3 Continuous Operations

Immunization data that is accessible as close to 24 hours a day, 7 days a week as possible is important since many clinics operate evenings and weekends and emergency rooms operate all hours. Currently the CAIR Software Application operates at this level of availability. In order to continue following the current CAIR Software Application operating model, high-level continuous operations requirements are described in Table 3-5 below.

**Table 3-5: Continuous Operations High-Level Requirements**

ID	Requirement	Priority
<b>R-8</b>	<p>The system must provide continuous operations. i.e.,</p> <ul style="list-style-type: none"> <li>• Targeted system availability for 98.8% of the time with a standard maintenance window of 2 hours of downtime per week for patching/maintenance, etc.</li> <li>• Enable access to and retrieval of immunization information in the registry at the time of encounter to allow the possibility of a timely immunization being provided as well as minimize missed immunization opportunities.</li> </ul>	High

### 3.4.4 Standards-based Data Exchange

The ability to support standards-based interoperability between IIS and other information systems is key to meeting several of the objectives described in this FSR. High-level Standards-based Data Exchange requirements are described in Table 3-6 below.

**Table 3-6: Standards-based Data Exchange High-Level Requirements**

ID	Requirement	Priority
<b>R-9</b>	<p>The system must support interoperability between IIS and other information systems using appropriate standards such as HL7 messaging or clinical documents. This includes, but is not limited to:</p> <ul style="list-style-type: none"> <li>• Interoperability with provider systems (e.g., EHR systems).</li> <li>• Support for Meaningful Use requirements of the CMS EHR Incentive Program.</li> <li>• Support for real-time as well as batch data exchange.</li> <li>• Major regional health systems.</li> <li>• MMIS and its data warehouse. Data exchange with the MMIS must be on a weekly basis to fully populate the registry with Medicaid children in order to provide immunization rates. Ideally, the interface would represent real-time, on-line data exchange.</li> <li>• Health information exchanges.</li> <li>• Naval Hospital and Kaiser Permanente (through the Nationwide Health Information Network (NwHIN) backbone).</li> <li>• Other collaboration partners.</li> <li>• Other local, state and Federal public health systems such as: <ul style="list-style-type: none"> <li>○ Child Welfare (SACWIS)</li> <li>○ Women, Infants and Children (WIC)</li> <li>○ Early Periodic Screening, Diagnosis and Treatment (EPSDT) Program</li> <li>○ Vital Records systems under CDPH Health Information and Strategic Planning</li> <li>○ Children’s Health Insurance Program (S-CHIP)</li> <li>○ Public Health Clinics</li> <li>○ EHR Systems</li> <li>○ Vaccine Management System (VACMAN) and Vaccine Tracking System (VTrckS) (CDC)</li> <li>○ Other</li> </ul> </li> </ul>	High
<b>R-10</b>	<p>Interoperability must be bi-directional in capability, with the IIS able to receive demographic and clinical information from appropriate sources and able to send demographic and clinical information to appropriate destinations.</p>	High

### 3.4.5 Security and Privacy of Data

Ensuring the confidentiality and security of health care information in the IIS is of utmost importance in protecting the privacy and security of patient information, establishing confidence in any system, and in complying with privacy regulations and State law. High-level privacy and security requirements are described in Table 3-7 below.

**Table 3-7: Security and Privacy of Data High-Level Requirements**

ID	Requirement	Priority
R-11	<p>The system must protect the confidentiality of health care information and must ensure data security, i.e.,</p> <ul style="list-style-type: none"> <li>• Ensure privacy and security protections for confidential information through operating policies, procedures, and technologies and compliance with applicable law, e.g., the aggregated data must comply with existing state and federal law including California Health and Safety Code Section 120440, the system must be capable of documenting disclosure and data sharing status.</li> <li>• Ensure the privacy and security of immunization information in transit and at rest.</li> <li>• Compliance with Health Information Portability and Accountability Act (HIPAA) Privacy and Security Rules and state laws.</li> <li>• Compliance with fair data sharing practices set forth in the Nationwide Privacy and Security Framework.</li> <li>• Compliance with privacy and security guidelines set forth by California Office of Health Information Integrity (CalOHII).</li> <li>• Provide safeguards as described in the October 22, 1998 State Medicaid Director letter, Collaborations for Data Sharing between State Medicaid and Health Agencies.</li> <li>• Use summarized or de-identified data when reporting data for population health purposes, where appropriate, so that important information is available with minimal privacy risk.</li> <li>• Protect sensitive health information to minimize reluctance of patient to seek care because of privacy concerns.</li> <li>• Ensure individual Vital Records will not be directly accessible to users of the system. Instead, providers entering immunization information on a patient may enter identifying information that will match against the Vital Records dataset. If a match is found, the Vital Records dataset shall complete blank fields in the immunization record that are complete in the Vital Record. The system will require that providers verify all data that were transferred from the Vital Record, via check box or other electronic means.</li> </ul>	High
R-12	<p>The system must provide a system timeout capability to provide an automatic timeout, requiring re-authentication of the user session. The time to trigger this automatic timeout should not exceed 20 minutes of inactivity, and the time must be configurable through the administrator's user interface</p>	High
R-13	<p>The system must provide warning banners. All systems containing protected data must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only. User must be directed to log off the system if they do not agree with these requirements.</p>	High

ID	Requirement	Priority
R-14	The system must provide system logging capabilities to maintain an automated audit trail which can identify the user or system process which initiates a request for Protected Data, or which alters Protected Data. The audit trail must be date and time stamped, must log both successful and failed accesses, must be read only, must create log entry before and after any data change to the system, and must be restricted to authorized users. If Protected Data is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least three years after occurrence.	High
R-15	The system must use role based access controls for all user authentications, enforcing the principle of least privilege.	High
R-16	The system shall provide transmission encryption capabilities. All data transmissions of Protected Data outside the secure internal network must be encrypted using a Federal Information Processing Standard (FIPS) 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128 bit key or higher. Encryption can be end to end at the network level, or the data files containing Protected Data can be encrypted. This requirement pertains to any type of protected data in motion such as website access, file transfer, and E-Mail.	High
R-17	The system must provide intrusion detection capabilities. All systems involved in accessing, holding, transporting, and protecting Protected Data that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution. Host based intrusion detection system (IDS) cannot block, impact or interfere with the intrusion prevention system (IPS) within Office of Technology Services (OTech) Tenant Managed Services - Premium hosting environment.	High

### 3.4.6 Support for Clinical Operations

Clinical decision support features such as a forecasting algorithm are extremely valuable in an IIS, not only to allow providers to determine immunization status to ensure the correct vaccinations are administered at the point of care, but also to determine and generate reminder/recall notifications for individuals who are due or overdue for immunizations. The ability to maintain this forecasting algorithm as new vaccines are added or deleted from the recommended vaccine schedule is crucial in providing clinical decision support in an IIS. High-level clinical decision support requirements are described in Table 3-8 below.

**Table 3-8: Support for Clinical Operations High-Level Requirements**

ID	Requirement	Priority
R-18	The system must apply clinical decision support at the point of care, i.e., the system must have a vaccine forecasting algorithm to automatically determine the routine childhood immunization(s) needed, in compliance with current ACIP recommendations, when an individual presents for a scheduled immunization.	High
R-19	The system must provide the ability to add/delete vaccines as new vaccinations are added to the recommended schedule and others are removed.	High
R-20	The system must automatically identify individuals due/late for immunization(s) to enable the production of reminder/recall notifications and letters, including alerts for guardians of Medicaid children.	High

ID	Requirement	Priority
R-21	The system must provide the ability for automated vaccine inventory reporting, managing vaccine inventories, generating reports on management, and wastage, and a VFC vaccine ordering, management, and accountability function integrated with the CDC's VACMAN and VTrckS.	High

### 3.4.7 Store Required Data

Capturing the appropriate data elements to meet the needs of IIS users and to meet the CDC Minimum Functional Standards, or core functions, for an IIS are important requirements as described in Table 3-9 below.

**Table 3-9: Store Required Data High-Level Requirements**

ID	Requirement	Priority
R-22	The system must establish a registry record within six weeks of birth for each newborn child born in the catchment area.	High
R-23	The system must receive and process immunization information within one month of vaccine administration.	High
R-24	The system must electronically store data on all National Vaccine Advisory Committee (NVAC)-approved core data elements.	High
R-25	The system must track individual active/inactive status at both the provider organization/site and geographic levels.	High
R-26	The system must produce official immunization records.	High
R-27	The system must have the capability to upload Vital Records datasets that are based off of the Birth Index dataset, at regular intervals, in a secure manner.	High
R-28	The system must have the ability to store the time periods of Medicaid eligibility.	Low
R-29	The system must have the ability to store the Primary Care Provider/Medical Home for a Medicaid child.	Low
R-30	The system must identify the following: <ul style="list-style-type: none"> <li>Adoptions: record information about adoptive services, including the adoptive parents' information within the parameter of State law.</li> <li>Deaths: record information about a Medicaid child's death before the age of 18.</li> </ul>	Medium
R-31	The system must store information on contraindications, disease history, waivers, and personal and/or philosophical exemptions.	Medium
R-32	The system must provide the ability to store vaccine adverse event data.	Low
R-33	The system must provide the capability for regional control for adding schools into the system, alleviating workload on the CDPH.	High
R-34	The system must provide functions to support integration with other public health programs, including childhood obesity prevention initiatives, by recording data including but limited to: <ul style="list-style-type: none"> <li>Height and weight and calculating Body Mass Index (BMI).</li> <li>Health and oral health exams for school.</li> <li>Lead screening.</li> <li>Tuberculosis (TB) screening and results.</li> </ul>	High

ID	Requirement	Priority
R-35	The system must provide the ability to support the data capture and storage requirements of emergency preparedness and bio-terrorism protection initiatives. Note: the capacity to store additional emergency medications is built into most of the available COTS registry software systems and would not significantly impact hardware or system architecture requirements.	Low
R-36	The system must use a geocoding service that returns geocoding match rates of above 95%.	Medium

### 3.4.8 Support HIE Core Services

Statewide HIE Core Services are being implemented to facilitate HIE. These HIE Core Services, as described in Table 3-10, can be leveraged by the state where appropriate and when available.

**Table 3-10: Support HIE Core Services High-Level Requirements**

ID	Requirement	Priority
R-37	The system must leverage, where appropriate and when available, HIE Core Services provided in the State: <ul style="list-style-type: none"> <li>• Trust Framework.</li> <li>• Entity Level Provider Directory (ELPD) – Provides a trusted registry of authorized entities to send and receive information. Entities are validated and authenticated based on standards adopted by the State.</li> <li>• Individual Level Provider Directory (ILPD) – Provides a trusted registry of authorized providers to send and receive information. Individual providers are validated and authenticated based on standards adopted by the State.</li> <li>• Services Registry – Provides information about where and how to send the transaction. Only approved/authorized entities may complete transactions.</li> <li>• Connectivity Services – Provides services to transform protocols and content to/from a State standard. Only approved/authorized entities may utilize these services as part of the Trust Framework.</li> </ul>	Medium

### 3.4.9 Stable, Well-supported Technology

Stable, well-supported technology and the capacity to support the state’s technical standards and total data capacity needs are important requirements for an IIS. Additionally, other systems could potentially leverage SIIS functionality provided as discreet functions via callable web services. These high-level requirements are described in Table 3-11 below.

**Table 3-11: Stable, Well-supported Technology High-Level Requirements**

ID	Requirement	Priority
<b>R-38</b>	The system must be implemented upon a stable, supportable, cost-effective technical platform compliant with State policies and standards.	High
<b>R-39</b>	The system must be capable of supporting the State's total data capacity needs. Currently, CAIR contains records on approximately 65% of California's children and a small percentage of adults as well. The system must support 100% of the data currently maintained by all CAIR registries combined and ultimately needs to scale over time, to accommodate the entire population of the state, child and adult. In the future, additional needs may require the storage of information to support emergency preparedness.	High
<b>R-40</b>	The system must provide IIS functions to other systems as callable web services where unique functionality may be required. IIS functions may include, but are not limited to: <ul style="list-style-type: none"> <li>• Forecasting algorithm and vaccine recommendations</li> <li>• Immunization reporting</li> <li>• Immunization history retrieval</li> <li>• Patient indexing</li> <li>• Reminder/Recall</li> <li>• Inventory management and vaccine ordering</li> </ul>	Low
<b>R-41</b>	The system must be hosted in a Tier III data center as designated by the California Technology Agency (Technology Agency).	High

The Requirements Traceability matrix in Table 3-12 will be leveraged as part of the project's Project Management methodology to develop a comprehensive and complete set of requirements to meet specified objectives and needs.

**Table 3-12: Matrix of Problems / Opportunities / Objectives / High-Level Requirements**

Problem / Opportunity	1. California's multiple regional electronic immunization registries currently cannot easily share information with one another.	2. Epidemiologists at CDPH are unable to <i>efficiently</i> gather <i>comprehensive and timely</i> statewide immunization information for analysis and assessment.	3. California is unable to <i>efficiently</i> meet the Comprehensive Child Immunization Act of 1993 goal of developing a nationwide network of immunization tracking	4. It is difficult for health care plans, including those participating in Medi-Cal Managed Care, to <i>efficiently</i> obtain <i>comprehensive</i> immunization data for standard performance measures, such as <i>HEPAC</i>	5. The technology used in the CAIR Software Regions is aging, difficult to support, and not compliant with current State standards and policies.	6. CAIR does not meet all of CDC's IIS: 2001 Minimum Functional Standards for Registries.	7. The reduction in the FY2010-2011 State budget to the Immunization Branch.	8. ARRA HITECH Legislation provides the opportunity to enable and achieve Stage 1 Meaningful Use to maximize eligible providers and hospitals incentive payments.	9. Statewide Health Information Exchange (HIE) services are being implemented to facilitate interoperability. There is the opportunity for the SIS to leverage these HIE services when available and appropriate.
Objective 1	✓	✓	✓	✓					
Objective 2			✓				✓		
Objective 3						✓			
Objective 4	✓	✓	✓	✓	✓	✓		✓	
Objective 5		✓					✓		
Objective 6				✓			✓		
Objective 7								✓	
R-1	✓	✓	✓	✓				✓	
R-2	✓	✓	✓	✓				✓	
R-3	✓	✓	✓	✓				✓	
R-4		✓		✓					
R-5	✓	✓	✓	✓					
R-6	✓	✓	✓	✓					
R-7	✓	✓	✓	✓					
R-8	✓	✓	✓	✓	✓				
R-9	✓	✓	✓	✓	✓	✓		✓	

Problem / Opportunity	1. California's multiple regional electronic immunization registries currently cannot easily share information with one another.	2. Epidemiologists at CDPH are unable to <i>efficiently</i> gather <i>comprehensive and timely</i> statewide immunization information for analysis and assessment.	3. California is unable to <i>efficiently</i> meet the Comprehensive Child Immunization Act of 1993 goal of developing a nationwide network of immunization tracking	4. It is difficult for health care plans, including those participating in Medi-Cal Managed Care, to <i>efficiently</i> obtain <i>comprehensive</i> immunization data for standard performance measures, such as <i>HEAC</i>	5. The technology used in the CAIR Software Regions is aging, difficult to support, and not compliant with current State standards and policies.	6. CAIR does not meet all of CDC's IIS: 2001 Minimum Functional Standards for Registries.	7. The reduction in the FY2010-2011 State budget to the Immunization Branch.	8. ARRA HITECH Legislation provides the opportunity to enable and achieve Stage 1 Meaningful Use to maximize eligible providers and hospitals incentive payments.	9. Statewide Health Information Exchange (HIE) services are being implemented to facilitate interoperability. There is the opportunity for the SIS to leverage these HIE services when available and appropriate.
R-10					✓	✓		✓	
R-11					✓	✓			
R-12					✓				
R-13					✓				
R-14					✓				
R-15					✓				
R-16					✓				
R-17					✓				
R-18						✓			
R-19						✓			
R-20						✓			
R-21						✓			
R-22						✓			
R-23						✓			
R-24						✓			
R-25						✓			
R-26						✓			

Problem / Opportunity	1. California's multiple regional electronic immunization registries currently cannot easily share information with one another.	2. Epidemiologists at CDPH are unable to <i>efficiently</i> gather <i>comprehensive and timely</i> statewide immunization information for analysis and assessment.	3. California is unable to <i>efficiently</i> meet the Comprehensive Child Immunization Act of 1993 goal of developing a nationwide network of immunization tracking	4. It is difficult for health care plans, including those participating in Medi-Cal Managed Care, to <i>efficiently</i> obtain <i>comprehensive</i> immunization data for standard performance measures, such as <b>HEPC</b>	5. The technology used in the CAIR Software Regions is aging, difficult to support, and not compliant with current State standards and policies.	6. CAIR does not meet all of CDC's IIS: 2001 Minimum Functional Standards for Registries.	7. The reduction in the FY2010-2011 State budget to the Immunization Branch.	8. ARRA HITECH Legislation provides the opportunity to enable and achieve Stage 1 Meaningful Use to maximize eligible providers and hospitals incentive payments.	9. Statewide Health Information Exchange (HIE) services are being implemented to facilitate interoperability. There is the opportunity for the SIRS to leverage these HIE services when available and appropriate.
R-27						✓			
R-28				✓					
R-29				✓					
R-30				✓					
R-31	✓	✓							
R-32	✓	✓							
R-33	✓	✓							
R-34	✓	✓	✓	✓					
R-35			✓						
R-36	✓	✓	✓	✓					
R-37									✓
R-38					✓				
R-39	✓	✓	✓	✓	✓				
R-40	✓	✓	✓	✓	✓				
R-41					✓				

## 4.0 Baseline Analysis

### 4.1 Current Method

Immunization information is recorded, tracked or analyzed in California by thousands of health care providers and other parties, including A) Providers not using a Registry B) Regional Registries and their users, and C) the State.<sup>50</sup>

#### A. Immunization Providers not using a Regional Registry<sup>51</sup>

Immunization information for individuals in the U.S. is stored by health care providers in medical charts, either as paper copies or in electronic health records. Providers fill out copies of histories for the personal use by patients and their families on paper forms such as the California Immunization Record (CIR) or “Yellow Card” (see Figure 4-1). The form typically includes name, birth date, and immunization history. A sample California Immunization Record is shown in Figure 4-1.<sup>52</sup>

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<sup>50</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>51</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>52</sup> State of California. Department of Public Health. *Sample California Immunization Record*. 19 April 2011  
<<http://www.cdph.ca.gov/programs/immunize/Documents/SampleRecord-0802.pdf>>.

Figure 4-1: Sample California Immunization

# Sample California Immunization Record

VACCINE	DATE GIVEN	DOCTOR OFFICE OR CLINIC	DATE NEXT DOSE DUE																								
1 <b>PNEUMOCOCCAL</b> (Prevnar®-70) (Prevnar®-13)		<input type="checkbox"/> Yes <input type="checkbox"/> No																									
	2	<input type="checkbox"/> Yes <input type="checkbox"/> No																									
	3	<input type="checkbox"/> Yes <input type="checkbox"/> No																									
	4	<input type="checkbox"/> Yes <input type="checkbox"/> No																									
<table border="1"> <thead> <tr> <th>To</th> <th>Type**</th> <th>Date given</th> <th>Given by</th> <th>Date read</th> <th>Read by</th> <th>Imm status</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td>TE, TSP</td> <td><input type="checkbox"/> PPD Mantoux <input type="checkbox"/> Tuberculin</td> <td>/ /</td> <td>/ /</td> <td>/ /</td> <td>/ /</td> <td></td> <td><input type="checkbox"/> Pos <input type="checkbox"/> Neg</td> </tr> <tr> <td>Fraxibac de la Tubercu- losis</td> <td><input type="checkbox"/> PPD Mantoux <input type="checkbox"/> Other</td> <td>/ /</td> <td>/ /</td> <td>/ /</td> <td>/ /</td> <td></td> <td><input type="checkbox"/> Pos <input type="checkbox"/> Neg</td> </tr> </tbody> </table> <p>** If dual entry may be indicated if dual test is positive. ** If response for tuberculin tests, must be recorded within exception granted by local health department.</p>				To	Type**	Date given	Given by	Date read	Read by	Imm status	Interpretation	TE, TSP	<input type="checkbox"/> PPD Mantoux <input type="checkbox"/> Tuberculin	/ /	/ /	/ /	/ /		<input type="checkbox"/> Pos <input type="checkbox"/> Neg	Fraxibac de la Tubercu- losis	<input type="checkbox"/> PPD Mantoux <input type="checkbox"/> Other	/ /	/ /	/ /	/ /		<input type="checkbox"/> Pos <input type="checkbox"/> Neg
To	Type**	Date given	Given by	Date read	Read by	Imm status	Interpretation																				
TE, TSP	<input type="checkbox"/> PPD Mantoux <input type="checkbox"/> Tuberculin	/ /	/ /	/ /	/ /		<input type="checkbox"/> Pos <input type="checkbox"/> Neg																				
Fraxibac de la Tubercu- losis	<input type="checkbox"/> PPD Mantoux <input type="checkbox"/> Other	/ /	/ /	/ /	/ /		<input type="checkbox"/> Pos <input type="checkbox"/> Neg																				
CHEST X-RAY (Indicated)		Film date: ____/____/____ Interpretation: <input type="checkbox"/> normal <input type="checkbox"/> abnormal Person in line of communicable tuberculosis: <input type="checkbox"/> Yes <input type="checkbox"/> No																									
<p><b>Parents:</b> Your child must meet California immunization requirements to be enrolled in school and child care. Keep this Record as proof of immunization. <b>Padres:</b> Su niño debe cumplir con los requisitos de vacunación para entrar a la escuela y a la guardería. Manténgalo en Compliance lo necesitará.</p>																											

**IMMUNIZATION RECORD**  
Comprobante de Inmunización



Name: \_\_\_\_\_  
Birthdate: \_\_\_\_\_  
Allergies: \_\_\_\_\_  
Vaccine reactions: \_\_\_\_\_

RETAIN THIS DOCUMENT — CONSERVE ESTE DOCUMENTO

VACCINE	DATE GIVEN	DOCTOR OFFICE OR CLINIC	DATE NEXT DOSE DUE
1 <b>FOLIO</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
	2	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	3	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	4	<input type="checkbox"/> Yes <input type="checkbox"/> No	
1 <b>DTaP</b> <b>DTP</b> <b>Td</b> <b>Td</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
	2	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	3	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	4	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	5	<input type="checkbox"/> Yes <input type="checkbox"/> No	
1 <b>HIB</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
	2	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	3	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	4	<input type="checkbox"/> Yes <input type="checkbox"/> No	
1 <b>MMR</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
	2	<input type="checkbox"/> Yes <input type="checkbox"/> No	
1 <b>HEPATITIS B</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
	2	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	3	<input type="checkbox"/> Yes <input type="checkbox"/> No	
1 <b>VARICELLA</b> (chickenpox)		<input type="checkbox"/> Yes <input type="checkbox"/> No	
	2	<input type="checkbox"/> Yes <input type="checkbox"/> No	

**PROVIDERS:** If using combination vaccines, remember to record dose in all appropriate spaces.

**DT** = diphtheria, tetanus (difteria, tétano)  
**DTaP** = diphtheria, tetanus, pertussis (whooping cough) (difteria, tétano y tos ferina)  
**FLU** = influenza  
**Hep A** = Hepatitis A, **Hep B** = Hepatitis B  
**Hib** = HiB meningitis (Haemophilus influenzae type B) (meningitis HiB)  
**IPV** = inactivated polio (poliovirus inactivado), **OPV** = oral polio (vacuna oral contra la polio)  
**MMR** = measles, mumps, rubella (sarampión, paperas y rubéola (sarampión alemán))  
**PCV** = pneumococcal conjugate vaccine (inmunización conjugada)  
**PPV** = pneumococcal polysaccharide vaccine (vacuna polivalente contra el neumococo)  
**Td** = tetanus, diphtheria (tétano, difteria)  
**VAR** = varicella (chickenpox) (varicela)

(H 111, 8/04) Rev. 2

Note: Not shown at actual size. The California Immunization Record (yellow card) can be folded to fit into the plastic holder.

When a child receives an immunization, typically the parent or guardian presents the child's paper record to the provider for amendment or replacement. However, the paper record is often lost or incomplete, especially if immunizations have been given by multiple providers throughout early childhood, as is common for California's highly mobile population.

A provider who does not use a regional immunization registry has few options to obtain missing immunization information on a new patient. The provider may attempt to contact previous providers by telephone or correspondence, but this is time-consuming, laborious, and often unsuccessful.

When information is absent, providers either give possibly redundant shots to assure protection or choose not to administer a vaccine, which may result in under-immunization. Under-immunization leaves the child and the population at risk for disease, while redundant immunizations incur unnecessary costs that are increasing, as newer vaccines tend to be much more expensive than their predecessors.

## **B. Regional Immunization Registries and their users**

See sections 3.1.1.1 and 3.1.1.5.

## **C. State of California<sup>53</sup>**

Aggregated SIIS data would supplant or supplement other data sources for critical CDPH functions. As an example, each primary school in California collects paper immunization records as a legal requirement for matriculation. CDPH currently uses these records to retrospectively assess immunization rates around the state. When a child enters kindergarten, his or her immunization information is transcribed onto a form ("Blue Card") that is placed into that child's school file. Blue Card data are reviewed by CDPH to determine immunization status at 24 months of age, approximately three years prior to kindergarten entry. Aggregated SIIS data would allow real-time assessment of a child's immunization status in the SIIS, instead of the current three year lag time due to the review of the Blue Card, when evaluating the effects of specific immunization programs or policies.

CDPH also obtains immunization rate estimates from the CDC's annual National Immunization Survey (NIS), a random telephone sampling from all states. However, the NIS' use of a limited sample precludes analysis of many important subgroups in California. Continued use of the NIS is threatened by increasing costs from increased exclusive usage of cellular telephones, requiring more dialing to achieve the desired sample and potentially introducing bias into the results. Some states are starting to use their immunization registries to augment or possibly replace NIS.

Aggregated SIIS data would be valuable to CDPH for epidemiological studies and legislative and public health reports. It would also support improved monitoring and accountability of publicly-financed vaccines for children enrolled in Medi-Cal.

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<sup>53</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

#### **D. Typical Business Processes<sup>54</sup>**

A typical business process starts with a family's visit to an immunization provider for routine childhood immunizations or a request for a copy of immunization records (e.g., Yellow Cards and Blue Cards). These records are required for a variety of activities, some required by law, most notably admission to school.

Participating providers search the regional registry to review prior immunizations given to a patient, determine the immunizations needed at that particular visit (if any) based on the registry's immunization algorithm and the provider's clinical guidelines, administer any required immunizations, and produce a copy of the immunization record for the family (see Figure 4-2). Each regional registry currently contains information on residents of that specific region but no other regions.

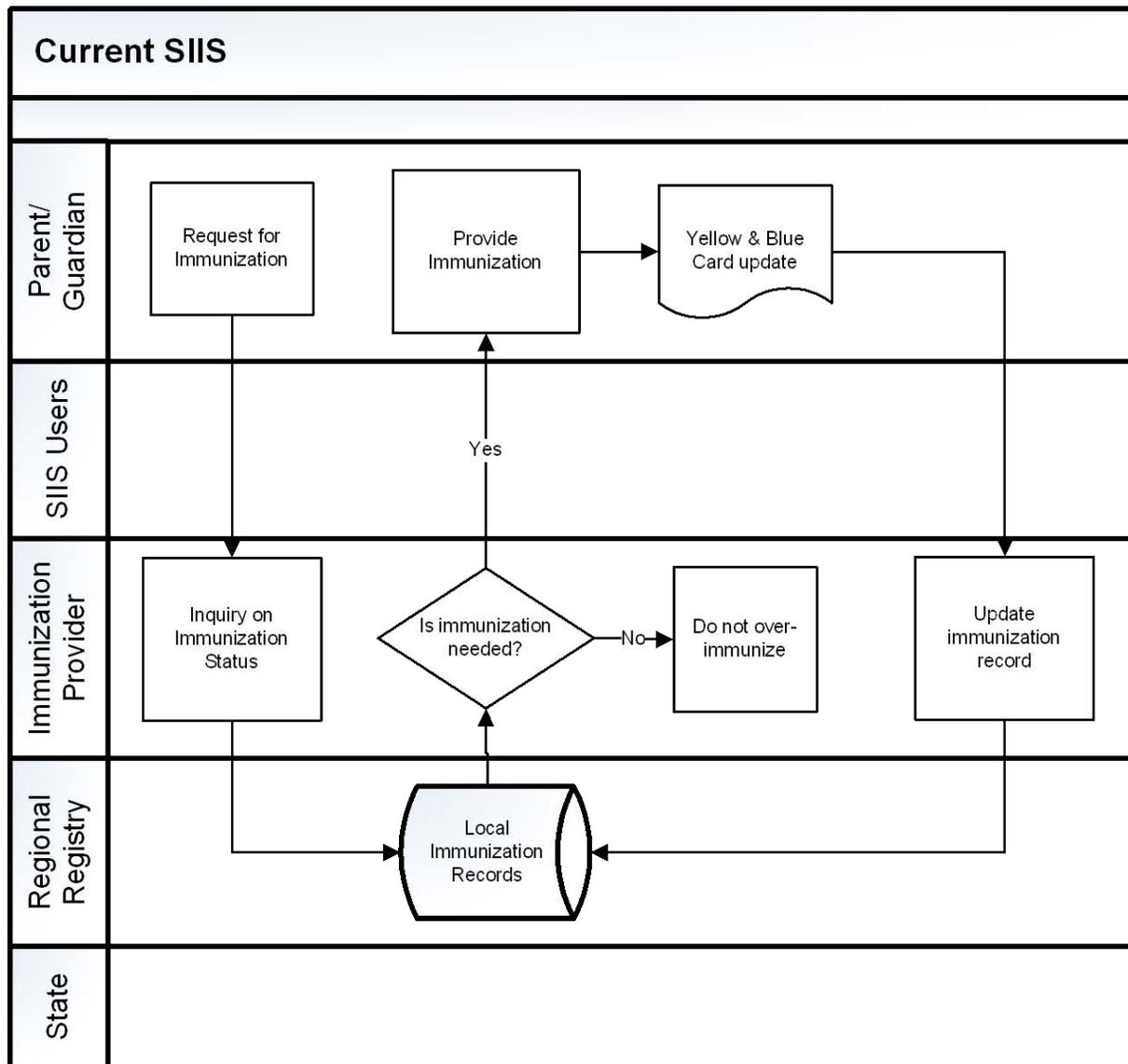
Regional registries encourage providers to use the registry to:

- Immunize patients completely and on time.
- Collect and manage immunization data.
- Administer the correct immunization based on a consistent interpretation of increasingly-complicated clinical guidelines.
- Simplify immunization vaccine inventory management.
- Monitor and improve the delivery of age-appropriate immunizations by avoiding over- and under-immunization.
- Provide copies of standard records (Yellow or Blue Cards) to families more accurately and efficiently than through hand transcription.

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<sup>54</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

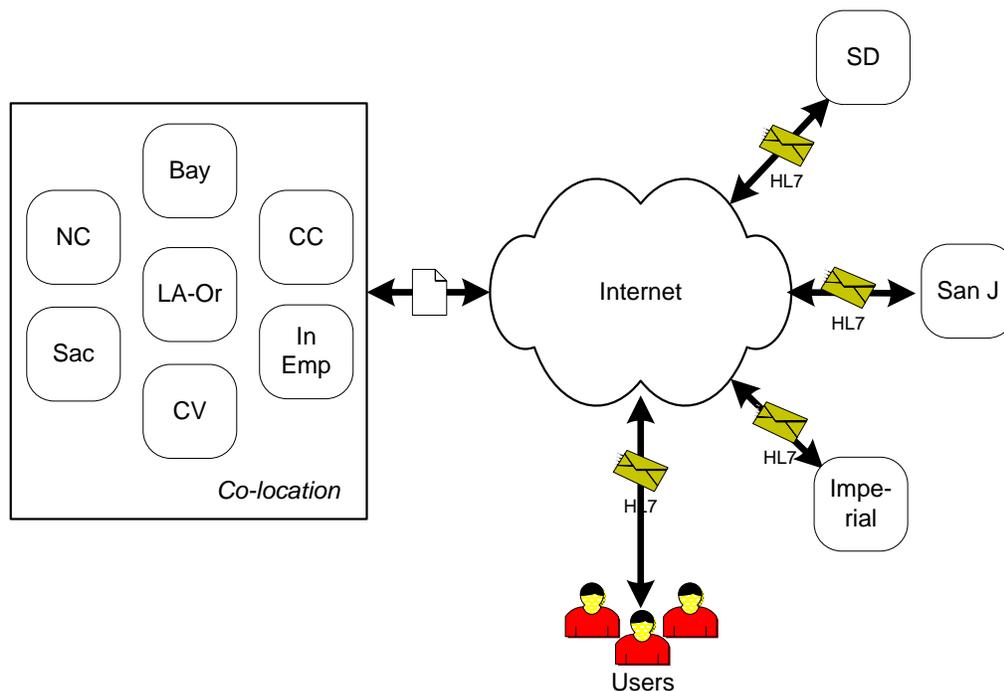
Figure 4-2: Immunization Work Flow



### 4.1.1 Current High-Level CAIR Architecture

All CAIR regions are currently utilizing web-based registry applications. The seven CAIR Software Regions are using a standardized single instance of the CAIR Software Application. The other three independent regions are using their own registry software. The servers for the CAIR Software Regions are all co-located at the U.C. Berkeley Data Center; however the databases are not consolidated. The regional registries currently do not have the capacity to easily share information with one another (see Data Exchange description in section 3.1.1.1 for more information). See Figure 4-3.

**Figure 4-3: Current High-Level CAIR Architecture**



**Legend**

<b>NC:</b> Northern California	<b>La-Or:</b> Los Angeles-Orange
<b>Bay:</b> Bay Area	<b>SD:</b> San Diego
<b>CC:</b> Central Coast	<b>San J:</b> San Joaquin Valley
<b>In Emp:</b> Inland Empire	<b>Imperial:</b> Imperial County
<b>CV:</b> Central Valley	<b>HL7:</b> Health Level Seven
<b>Sac:</b> Greater Sacramento Area	

**4.1.1.1 Key Attributes**

Key attributes of the current CAIR architecture include the following:

- Nine separate, isolated regional registries (plus Imperial) that cannot exchange data with one another.
- Seven regions use one product (CAIR software) co-located in one facility at the U.C. Berkeley Data Center.
- CAIR software is developed with older, unsupported tools.
- Flat-file data exchange (as depicted by the white paper icon in Figure 4-3) is enabled with providers, but it does not meet MU objectives.
- All registries are Internet accessible.
- All regions have demonstrated HL7 messaging exchange capability, but either do not have HL7 capability fully implemented (CAIR Software Regions) or are implemented but not prepared or ready for scale-up (Imperial, San Joaquin, San Diego).

**4.1.1.2 Current CAIR Requirements Scorecard**

The high-level requirements the current CAIR architecture meets are depicted in “scorecards”. A legend for the requirements scorecards is in Figure 4-4.

**Figure 4-4: Requirements Scorecard Legend**

○	Does not meet requirement
◐	Partially meets requirement
●	Fully meets requirement

With the current CAIR architecture, only some of the high-level requirements are fully met as depicted in Figure 4-5.

**Figure 4-5: Current CAIR Requirements Scorecard**

State-wide consolidated records	○
Data export and analysis	○
Continuous operations	●
Standards-based exchange	◐
Security and privacy of data	●
Support for clinical operations	●
Store required data	●
Enable Meaningful Use	○
Support HIE Core Services	○
Stable, well-supported technology	○

#### 4.1.1.3 Advantages/Disadvantages

The advantages and disadvantages for the current CAIR architecture are listed in Table 4-1 below.

**Table 4-1: Current CAIR Architecture: Advantages/Disadvantages**

Advantages	Disadvantages
<ul style="list-style-type: none"> <li> Leverages and supports local policies and practices</li> <li> Software is richly functional for clinicians</li> <li> Most regional software meets most, but not all, of CDC's Minimum Functional Standards for IIS</li> </ul>	<ul style="list-style-type: none"> <li> Redundancy in staff and technology prevents best leverage of funds as each region operates somewhat independently</li> <li> No consistent support for standards-based data interoperability between EHR systems and IIS</li> <li> Disparate data across regional databases prevents single, consolidated record from being assembled</li> <li> Does not enable MU due to lack of support for standards-based interoperability</li> <li> Discourages largest providers who want a single point of connection for submitting data</li> <li> CAIR software based on old products which are difficult to enhance and modify and must be updated to the current sustainable technology</li> <li> Does not address incompatibility with MAC browser</li> </ul>

## 4.1.2 Objectives of the Current Method

Objectives of the current method include the following:<sup>55</sup>

- To improve immunization rates for all California children.
- To provide rapid access to providers and other authorized users a complete, up-to-date, accurate immunization record for individuals residing anywhere in the State of California.
- To provide rapid access to expert vaccine forecasting.
- To eliminate both missed opportunities to immunize and unnecessary duplicate immunizations.
- To meet Healthy People 2020 objectives (see section 3.1.1.1).

## 4.1.3 Ability of System to Meet Workload

The existing CAIR Software Application is able to meet the current program and workload requirements. The most activity in the CAIR Software Application takes place in the first week of each calendar month as reported by the CAIR Software Application's Technical Team. Patient search activity by clinical users from January 2011 to March 2011 has steadily increased from the same period in the prior year as depicted in Table 4-2 below.

**Table 4-2: Patient Search Activity by Clinical Users, January 2011 – March 2011**

Measure	#	% Change (since January 2010-March 2010)
Patient Lookups	47,639,702	+45%
Clinical Organizations	4,710	+18%
Average Lookups per Clinical Organization per day	169	+23%
CAIR-wide Lookups per Minute (8 hour workday)	1654	+45%

There are currently no performance issues, processing backlogs or anticipated issues with the existing CAIR Software Application's ability to meet current workload requirements.

## 4.1.4 Level of User and Technical Staff Satisfaction

While there have been no formal feedback mechanisms such as surveys on the level of user and technical staff satisfaction, informal feedback has shown the response to the CAIR Software Application and independent registries to be positive.

Users have commended the CAIR Software Application's Technical Team on their performance and have provided positive feedback on how the CAIR Software Application saves time and helps with decision support. Some users reported they would never go back to manual Yellow and Blue Cards or attempting to decipher written materials when they could easily use the CAIR Software Application to determine a patient's immunization needs and print out Yellow and Blue cards. Given the recent budget cuts, some users have even tried to seek funding sources for the CAIR Software Application on their own. The number of tickets submitted to the Help Desk and enhancements (implemented or currently under implementation) may also provide some

<sup>55</sup> State of California. Department of Public Health. CAIR. 19 April 2011  
<<http://cairweb.org/cair-mission-statement/>>.

indication of the level of user satisfaction. See Figure 4-6 for the number of tickets per Help Desk ticket type for the nine month period between July 2010 and April 2011 as well as the number of system enhancements (implemented or currently under implementation) between January 2010 and April 2011.

**Figure 4-6: Help Desk Ticket Types (7/31/2010 – 4/22/2011) and System Enhancements (1/1/2010 – 4/28/2011)**

Help Desk Ticket Types from 7/13/2010 to 4/22/2011	
Authorization to release records	72
Login Issues	581
Merge Accounts	378
Merge Patient Accounts	36
New Provider Accounts	77
Other Requests	612
Password Resets	1836
Patient Merge Accounts	69
Provider Accounts	162
User Accounts	883

System Enhancements from 1/1/2010 to 4/28/2011	
	243

The CAIR Software Application’s Technical Team has also reported that they have no imminent concerns with the current system.

Level of user and technical staff satisfaction data was not available from the independent regions at the time of the writing of this FSR.

#### 4.1.5 Data Input, Processing, and Output Characteristics

CAIR is populated by providers who directly enter data into the web-based registry applications or submit data via data exchange. Electronic import of immunization data via flat file to the CAIR Software Application is available to participating health care providers. Import files may be submitted to the CAIR Software Application via secure File Transfer Protocol (sFTP). For more information on the electronic import of immunization data to the CAIR Software Application, refer to the CAIR v3.x Flat File Data Exchange Specifications<sup>56</sup>. See also section 3.1.1.3 for more information on the submission/retrieval of immunization information.

<sup>56</sup> California Immunization Registry. *CAIR v3.x Flat File Data Exchange Specifications*. October 19, 2010: Document Version 6.1. 25 April 2011  
<[http://www.cairweb.org/images/docs/CAIR\\_DataExchangeSpecification\\_v6\\_1.pdf](http://www.cairweb.org/images/docs/CAIR_DataExchangeSpecification_v6_1.pdf)>.

Health plans can request data outputs from the CAIR Software Application in the form of a HEDIS report. For more information on the process to request data for HEDIS, see the HEDIS Data Request Process<sup>57</sup>. Batch outputs from CAIR for input into provider EHR systems are also produced for a handful of providers who have requested them.

#### **4.1.6 Data Characteristics**

The seven CAIR Software Regions each have an independent database, all with similar structures. The databases are all relational databases running on SQL Server 2005 with the latest service packs and security features installed. SQL Server was chosen because it is widely supported for importing of data by other software packages such as spreadsheets, word processors, report generators, database managers, etc. The databases are designed to support users (see section 3.1.1.5 for users) as well as staff to maintain consistency of immunization records.

The databases capture information to support clinical operations, decision support, data analysis and reporting. Information stored and maintained in the databases includes but are not limited to the following:

- Patient demographic (e.g., name, date of birth, address, parent/guardian)
- Immunization (e.g., immunization history, administered date and vaccine type, administering provider)
- Disease history (e.g., disease, onset date)
- Provider information (e.g., name, address)
- Vaccine inventory (e.g., manufacturer, lot number, expiration date)  
(For additional details on the data model for the CAIR Software Application, see Appendix D – CAIR Software Application version 3.30 Entity Relationship Diagram.)

Because data is stored in relational databases, information can be analyzed and reports generated in various ways including but not limited to the following:

- By age group
- By geopolitical area
- By demographics
- By number of immunizations recorded within various timeframes

However, due to the fragmentation of data not only within the CAIR Software Regions' databases, but also across California's disparate regional immunization registries, comprehensive data analysis and reporting on, and access to, consolidated, up-to-date, accurate, complete immunization information on individuals is difficult to achieve.

#### **4.1.7 System Provisions for Security, Privacy, and Confidentiality**

CDPH, authorized users in the CAIR Software Regions, and the independent registries, meet local, state and federal security, privacy and confidentiality requirements, including the

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<sup>57</sup> California Immunization Registry. *HEDIS Data Request Process*. Version September 2010. 25 April 2011 <[http://www.cairweb.org/images/docs/HEDIS\\_Matching\\_Process.pdf](http://www.cairweb.org/images/docs/HEDIS_Matching_Process.pdf)>.

California Health and Safety Code Section 120440<sup>58</sup> law which allows the following access to CAIR<sup>59</sup>:

- Health care providers
- Health plans
- California Work Opportunities and Responsibility to Kids (CalWORKs) programs
- State and local health departments
- WIC programs
- State/County foster care agencies
- Schools
- Child care facilities

CAIR complies with HIPAA and state law to protect patient privacy.<sup>60</sup> Providers and CAIR staff must abide by confidentiality agreements in order to share patient records. Each viewing of patient records is tracked to maintain an audit trail. Moreover, CAIR software has security features to protect confidential data from being accessed and/or viewed by unauthorized sources.<sup>61</sup>

Specifically, the following rules govern the use of CAIR<sup>62</sup>:

### **HIPAA**

- HIPAA allows public health entities such as immunization registries to securely exchange personal health information (PHI) related to immunizations with authorized agencies.

### **California Health and Safety Code Section 120440**

- This code was specifically established to govern who can access registries, what information can be maintained, and how this information can be used.
- CAIR conforms to all requirements of this code.

CAIR has established policies to further ensure the privacy and security of client information.

### **Privacy**

- All participating agencies and individual users must adhere to confidentiality agreements.
- All users receive training related to protecting the confidentiality of client data.

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<sup>58</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>59</sup> "Provider Bulletin." Community Health Plan Los Angeles County November 25, 2009: No. 09-23. 19 April 2011  
<[http://chp.dhs.lacounty.gov/pdf/ProviderBulletins/PB\\_09\\_23.pdf](http://chp.dhs.lacounty.gov/pdf/ProviderBulletins/PB_09_23.pdf)>.

<sup>60</sup> State of California. Department of Public Health. *CA State letter affirming immunization registries comply with HIPAA and State law*. 19 April 2011  
<[http://cairweb.org/images/docs/Appendix\\_J\\_HIPAA\\_Ltr-signed11-19-03.doc](http://cairweb.org/images/docs/Appendix_J_HIPAA_Ltr-signed11-19-03.doc)>.

<sup>61</sup> State of California. Department of Public Health. *CAIR Frequently Asked Questions (FAQ) about Immunization Registries (Health Care Providers)*. 19 April 2011  
<<http://cairweb.org/provider-faq-english/#q9>>.

<sup>62</sup> "Provider Bulletin." Community Health Plan Los Angeles County November 25, 2009: No. 09-23. 19 April 2011  
<[http://chp.dhs.lacounty.gov/pdf/ProviderBulletins/PB\\_09\\_23.pdf](http://chp.dhs.lacounty.gov/pdf/ProviderBulletins/PB_09_23.pdf)>.

- Unique passwords are required to access data in CAIR.

### **Security**

- Software used by the CAIR network has been designed, and is updated regularly, to meet industry standards to protect client information from being shared with unauthorized sources.
- CAIR adheres to strict security standards.
- Authorized users access CAIR through a secure Internet connection, and servers are secured by firewalls.

## **4.1.8 Equipment Requirements**

The minimum system requirements for accessing the CAIR Software Application include the following<sup>63,64</sup>:

- Computer(s) with 1.2 GHz processor or higher\*
- 256 MB RAM (512 MB or higher is strongly recommended)
- 1 GB Free Disk Space at all times
- Operating system of Windows 2000 with the latest updates applied (Windows XP or above recommended)
- Anti-Virus Software
- SVGA 1024x768 dpi Display
- DSL/Cable Internet Service or higher connection (e.g., T1/T3 line)
- Broadband Network Adaptor (10/100 Mbps) or faster
- Configured to run TCP/IP protocol
- Microsoft Internet Explorer Version 6.0 or higher, Service Pack 1 (SP1) or higher
- Laser Printer

\* Macintosh/Apple computers are not currently compatible with the CAIR software unless they are configured to run Internet Explorer. Systems with processors slower than 1 GHz may experience decreased performance and may not have the capacity to handle future upgrades of the CAIR software.

See Figure 4-7 for the CAIR Software Regions' hardware inventory.

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<sup>63</sup> State of California. Department of Public Health. *CAIR Quick Technology Self-Assessment Form*. 19 April 2011  
<<http://cairweb.org/images/docs/IMM-928.pdf>>

<sup>64</sup> "Provider Bulletin." Community Health Plan Los Angeles County November 25, 2009: No. 09-23. 19 April 2011  
<[http://chp.dhs.lacounty.gov/pdf/ProviderBulletins/PB\\_09\\_23.pdf](http://chp.dhs.lacounty.gov/pdf/ProviderBulletins/PB_09_23.pdf)>

**Figure 4-7: CAIR Software Regions' Hardware Inventory**

UCB Servers		C drive capacity	D drive capacity	Operating System	Processor	# of Processors	Ram
DB Server	HPDB5	299GB	7.27TB	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon X5570 2.93GHz	4 Quad core CPUs	64GB
DB Server	HPDB6	299GB	7.27TB	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon X5570 2.93GHz	4 Quad core CPUs	64GB
Witness Server	HOFFA	9.83GB	24.05GB	Windows Server 2003 service pack 2	Intel Pentium III 1.2 GHZ	1 CPU	512MB
Web Server	CVIIS	33.9GB	203GB	Windows Server 2003 R2 Standard Edition service pack 2	Intel Xeon CPU 3.00GHz	2 CPUs	2GB
Web Server	BARR	33.9GB	203GB	Windows Server 2003 R2 Standard Edition service pack 2	Intel Xeon 3.00GHz	2 CPUs	2GB
Web Server	LINK	135GB		Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon CPU 3.20GHz	2 CPUs	6GB
Web Server	IE	25GB	111GB	Windows Server 2003 Standard Edition service pack 2	Intel Xeon CPU 3.00GHz	2 CPUs	3GB
Web Server	CCIR	20.4GB	115GB (f: drive)	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon CPU 3.00GHz	4 CPUs	3GB
Web Server	HCIC	33.8GB		Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Pentium III 1266MHz 1.26 GHz	1 CPU	1GB
Web Server	INNC	9.76GB	73.2GB	Windows 2000 Service Pack 4	Intel Xeon CPU 3.20GHz	2 CPUs	2GB
Hosting.Com Servers		C drive capacity	D drive capacity	Operating System	Processor	Number of Process	Ram
Firewall	Netscreen SSG520						
Switch	Cisco SR2024C 24 port Gig Switch						
Switch	Netgear 24						
Switch	Dell PowerConnect 2608						
Web/DB Server	Dell PowerEdge 2650 Regiontest	67.7GB		Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon CPU 2.40GHz	2 CPUs	1GB
Web/DB Server	HP DL 380 Cair2	22GB	11.9GB	Windows 2000 Server	Intel Xeon 3.00 GHz	1 CPU	3GB
Web/DB Server	HP DL 380 FTP IZ1 Server	33.9GB	203GB	Windows Server 2003 R2 Standard Edition service pack 2	Intel Xeon 3.00 GHz	1 CPU	2GB
Blade System	BL680 DB1	136GB	683GB	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon E7340 2.4GHz	4 Quad core CPUs	32GB
Blade System	BL680 DB2	136GB	683GB	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon E7340 2.4GHz	4 Quad core CPUs	32GB
Blade System	BL680 DB3	136GB	1.36TB	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon E7450 2.4GHz	4 Six core CPUs	48GB
Blade System	BL680 DB4	136GB	1.36TB	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon E7450 2.4GHz	4 Six core CPUs	48GB
Blade System	BL460 Web1	136GB	-	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon E5450 3.0GHZ	2 Quad core CPUs	16GB
Blade System	BL460 Web2	136GB	-	Windows Server 2003 R2 Enterprise Edition service pack 2	Intel Xeon E5450 3.0GHZ	2 Quad core CPUs	16GB
Blade System	BL460 on order						
Blade System	BL460 on order						
HP PDU (Power Distribution Unit)	220-volt						
HP PDU (Power Distribution Unit)							

#### 4.1.9 Internal and External Interfaces

CAIR can currently be interfaced with provider EHR systems via HL7 messaging (independent registries) or bi-directional flat file exchange (CAIR Software Regions). The CAIR Software Regions are also in the process of implementing HL7 data exchange capabilities via a state messaging system. In addition, an interface to receive HL7 messages from IHS has been

implemented. See section 3.1.1.1 for the HL7 interface capabilities within the CAIR Software Regions and between the CAIR Software Regions, independent registries, and providers.

Users can also interface with the registries through direct input into the user interfaces of their respective region's registry applications. See section 3.1.1.4 for more information on submission/retrieval of immunization information.

The CAIR Software Application is currently interfaced with provider EHR systems via bi-directional flat file exchange. Immunization data from the provider is extracted from the EHR systems and sent to the CAIR Software Application via sFTP (see Appendix E for the CAIR Software Application's Import Entity Relationship Diagram). CAIR Software Application users also have the option of having immunization data extracted from the CAIR Software Application and downloaded to the providers' EHR systems.<sup>65</sup>

#### 4.1.10 Personnel Requirements

The CAIR Software Region Technical Team has personnel to accommodate the responsibilities of central management of the CAIR Software Regions' regional databases. Personnel include fourteen staff, including a CAIR Manager, a Provider Support Coordinator, a Database Administrator, two Data Quality Staff, two Data Systems Specialists, two Software Programmers, three Help Desk Staff, and two Data Exchange Support Staff. Data Exchange Support Staff manage the increasing number of providers in the seven CAIR Software Regions who want to exchange data electronically.<sup>66</sup>

Provider Recruitment, Training, Retention and Support Staff were historically hired independently by each region using funds provided to each region. This provided regional autonomy, but was inherently duplicative and could not avail itself to any economies of scale.<sup>67</sup>

The CAIR Software Region Provider Recruitment, Training, Retention and Support Staff under a revised, more efficient model are included in Table 4-3. The San Joaquin and San Diego regions will continue to receive a population-based share of the provider support dollars as regional funding. Imperial County has chosen to decline funding support. See section 3.1.1.1 for a description of the Provider Recruitment, Training, Retention and Support model.

**Table 4-3: Registry Field Staff by VFC Region**

Status	CAIR Region	VFC Region	Senior Staff (supervisory)	VFC Field Staff	Registry Field Staff (FTEs)
CAIR Software Regions	Northern California/ Greater Sacramento Area	Northern California	1	2	1
	Bay Area	Bay Area	1	3	2
	Central Valley	Central Valley	1	3	1

<sup>65</sup> State of California. Department of Public Health. *CAIR Data Exchange Tech Support*. 19 April 2011 <<http://cairweb.org/data-exchange-tech-support/>>

<sup>66</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

<sup>67</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

Status	CAIR Region	VFC Region	Senior Staff (supervisory)	VFC Field Staff	Registry Field Staff (FTEs)
	Los Angeles-Orange	Los Angeles	1	5	3
	Los Angeles-Orange / Inland Empire/ Central Coast	Southern California	1	3	3
Independent	San Joaquin	Central Valley			0*
Independent	San Diego	Southern California			0.5*
<b>Totals</b>			<b>5</b>	<b>16</b>	<b>10</b>

\*San Joaquin and San Diego each commit 0.7 FTEs to help desk support and San Diego has an additional 0.5 FTEs of local provider support (registry field staff) for outreach/training.

### 4.1.11 System Documentation

The CAIR 3.30 User Manual (Document version 3.30, 6/28/2008) is an online manual for the CAIR Software Application available on all CAIR Software Regions' web servers.

Additionally, there are a set of the following Data Entry Guides available on the CAIR website<sup>68</sup>:

- CAIR Quick Guide: tip sheet for log-in, search & printing reports (6/09)
- CAIR Data Entry Guidelines (7-Page Guide) (2/10)
- Vaccine Acronyms and Abbreviations (8/10)

The CAIR website<sup>69</sup> also includes various training materials such as:

- Documentation to set-up and conduct training.
- Post-training certificates for new CAIR users.
- Documentation to evaluate user skills/training effectiveness.
- Thirteen automated short and self-paced training modules<sup>70</sup> which can be viewed to learn specific tasks of the CAIR Software Application.

The Data Entry Guides and training materials listed above are either in Portable Document Format (PDF) or in Microsoft Word documents (.doc).

### 4.1.12 Failures of Current System

Disparate data across the regional databases prevents a single, consolidated immunization record for individuals from being assembled. This leads to challenges in clinical operations at the point of care, data analysis, and reporting. Since each region is operating somewhat independently, there is also expensive redundancy in staff and technology. Additionally, the lack of unified records and disparate systems is discouraging to the largest providers who want a

<sup>68</sup> State of California. Department of Public Health. *CAIR Training Tools*. 19 April 2011 <<http://cairweb.org/training-tools/>>.

<sup>69</sup> State of California. Department of Public Health. *CAIR Training Tools*. 19 April 2011 <<http://cairweb.org/training-tools/>>.

<sup>70</sup> State of California. Department of Public Health. *CAIR Training Tools*. 19 April 2011 <<http://cairweb.org/cair-training-modules-clinical/>>.

single point of connection for submitting data to the registry, and a single point of query for receiving data back in return.

While the independent registries support standards-based HL7 data exchange, the CAIR Software Regions have not yet completed implementation of HL7 data exchange and therefore do not enable MU (see Data Exchange description in section 3.1.1.1 for more information). The CAIR Software Application is also based on aging technologies which are increasingly becoming challenging and more costly to support and are non-compliant with current State standards and policies (see section 3.2).

See also section 4.1.1.3.

## **4.2 Technical Environment**

### **4.2.1 Expected Operational Life of Proposed Solution**

The expected operational life of the proposed solution is ten years.

### **4.2.2 Interaction of Proposed Solution with other Systems**

The proposed solution for a consolidation of data in the CAIR Software Regions with new registry software, leveraging a patient indexing function and HL7 messaging capability is described in section 5. The seven CAIR Software Regions consolidated into one database will exchange information with provider EHR systems and the independent registries via HL7 messaging (version 2.3.1 or higher). Interaction with systems such as Vital Records Systems, the MMIS and its data warehouse, HIEs, and other local, state and federal public health systems will be possible via standards-based interoperability (see section 3.4.4). HL7 messages might also be routed through a local or regional HIE, of which the new CAIR software will be an authorized trading partner.

See sections 3.4.2, 3.4.5, and 3.4.7 for the requirements for interaction with Vital Records systems.

### **4.2.3 State-Level Information Processing Policies**

State IT policy, standards, instructions, and [California Technology Agency](#) guidelines are provided in:

- The State Administrative Manual (SAM)
- The Statewide Information Management Manual (SIMM)
- IT Policy Letters (ITPL)

#### 4.2.4 Financial Constraints

The 60% reduction in FY2010-2011 CAIR funding has forced the nine regions which accepted State funds to downsize local staff or to halt operations altogether.<sup>71</sup> The independent registries are still providing partial funding with local dollars.

The total budget for the Immunization Branch is \$2.9 million in federal funds, of which \$1.4 million is for personnel (see section 4.1.10), \$0.5 million is for operations, and \$1 million is for local provider support, mostly for personnel. Due to the budget constraints, roles at CDPH were eliminated which warranted the expansion of responsibilities in other existing roles. Additionally, limited funds must be leveraged in order to continue providing IIS provider recruitment, training, retention, and support activities. (See section 3.1.1.1 for a description of the Provider Recruitment, Training, Retention and Support model.)

#### 4.2.5 Legal or Public Policy Constraints

California law authorizes the operation of immunization registries (H&SC 120440) and defines who is authorized to submit and access immunization data. Patients must be disclosed or made aware of the registry before immunization information is entered into the registry. Immunization data can be manually entered into the registry through a web interface or imported into it via electronic files. Normally, incoming data has the 'disclosure' and 'permission to share' fields set to 'Yes', which allows the data to be shared with other CAIR users. If the patient decides that they don't want their submitted information shared, they can either inform the provider, who then sets the patient 'permission to share' field to 'No' or they fill out and submit an official state 'opt out' form to CAIR staff, who go in and manually set the patient 'permission to share' field to 'No'. Records with 'permission to share' or the 'disclosure' fields set to 'No' can only be viewed by the healthcare provider who submitted the data. Currently, about 1 in every 20 patients in CAIR has chosen to 'opt out' of data sharing, so that 95% of the immunization data in the registry is accessible to CAIR users.

Schools must comply with the Family Educational Rights and Privacy Act (FERPA) with respect to CAIR since FERPA considers school medical records to be covered educational records as well. Schools must disclose to parents and obtain signed consent from parents to allow their children's records to be placed in CAIR.

Tuberculosis data can be stored in CAIR but currently it requires Health Officers approval before inclusion in CAIR.

Under the current governance of CAIR, sharing of vital records data across counties is prohibited. Some counties in California currently receive birth data in their registries, from their County Vital Records<sup>72</sup> Offices. Vital record data use is governed by Health and Safety Code (H&SC) 102230 and 102231, which prohibits re-release of vital records data. If the CAIR system were transferred under the governance of CDPH, the requirements for interaction with Vital Records systems could be enabled in accordance with H&SC 102230 (see sections 3.4.2, 3.4.5, and 3.4.7).

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<sup>71</sup> State of California. Department of Public Health. *California Immunization Registry (CAIR) System Business Plan 2011-2012*. August, 2010.

<sup>72</sup> Vital records include birth certificates, death records, marriage licenses, and divorce decrees.

See also description of legal implications in section 3.1.1.1, vital records interfaces in section 3.1.1.4 and security, privacy, and confidentiality provisions in section 4.1.7.

## **4.2.6 Agency Policies and Procedures**

CDPH policy and procedures related to IT are provided in the Public Health Administrative Manual (PHAM) chapter 9, available on the CDPH Intranet.

## **4.2.7 Anticipated Changes**

Anticipated changes in the current CDPH IT infrastructure are driven by Executive Order (EO) S-03-10 see [California Technology Agency](#), and include statewide email consolidation, statewide network consolidation, data center consolidation, server virtualization, and reduction in electrical power usage.

## **4.2.8 Availability of Personnel Resources**

See section 4.1.10.

## **4.2.9 Existing Infrastructure**

The Department of Health Care Services (DHCS) and CDPH Information Technology Standards document (available on the CDPH Intranet) describes the existing CDPH technology infrastructure, including:

- Desktop, Laptop, Printer, and Mobile Computing Standards
  - Desktop and Laptop Hardware Standards
  - Monitor Standards
  - Printer Standards
  - Software Standards – Tier 1
  - Software Standards – Tier 2 & Tier 3
  - Software Standards – Administration Utilities
  - Mobile Computing Standards
- Network Server Technology Standards
  - Server Hardware Standards
  - Server Software Standards – Tier 1
  - Server Software Standards – Tier 2
  - Server Environmental Standards
- Network and Data Communication Standards
  - Telecommunication Standards
  - Network Topology Standards
  - Network Topology and Equipment Standards
  - Data Cabling & Connector Standards
  - Communications Protocols and Addressing Standards
  - Network Management Standards
  - Virtual Private Network (VPN) Standards
  - Enterprise Video Conferencing Standards
- Naming Standards
  - E-mail Address Standards

- User Id Naming Standards
- PC Naming Standards
- Network Printer Naming Standards
- Server Naming Standards
- Group Naming Standards
- Group Policy Object Naming Standards
- Domain Name System (DNS) Naming Standards
- Programming Standards
  - Development Languages

#### **4.2.9.1 Application Development Methodology**

The CDPH application development methodology, standards, and best practices are described in the Web Based Application Architecture Center (available on the CDPH Intranet).

#### **4.2.9.2 Project Management Methodology**

The CDPH utilizes the California Project Management Methodology (CA-PMM) (see [California Technology Agency](#)), also known as (aka) SIMM section 17, as described in section 6 of this FSR.

## 5.0 Proposed Solution

The CDPH proposes the initiation of a procurement seeking a technical solution from vendors to implement a partial consolidation of CAIR, California's SIIS. (Note: The proposed solution is Alternative #2: Option B described in section 5.3.2.) The resulting system would be hosted at the Office of Technology Services (OTech) leveraging their Tenant Managed Services - Premium hosting model.

The procurement will encourage the most competitive pool of offers possible, and will allow vendors to propose a variety of creative technical solutions. CDPH will select the best value offer in terms of features, technology, cost, compliance with CDPH and OTech technical and security standards, and ability to most effectively accomplish the objectives and requirements identified in section 3 of this FSR.

Project decision makers and project business and information technology partners evaluated each of the alternatives considered with respect to the needs, business objectives, and functional requirements presented in this FSR, along with stakeholder feedback obtained via a series of three stakeholder webinars and follow-on survey tool. The proposed solution and alternatives considered are described in subsequent sections of this FSR.

### 5.1 Solution Description

The CDPH proposes the initiation of a procurement seeking a technical solution from vendors to implement a partial consolidation of CAIR, California's SIIS, by consolidating the CAIR Software Regions. While stakeholders considered full consolidation preferable, partial consolidation was chosen as the best option because CDPH does not have the power to induce the independent registries to join the larger group. This option also allows for the independent registries to migrate to the consolidated system if they choose. The existing software used by the CAIR Software Regions would be replaced with new software (i.e., internally developed, commercial-off-the shelf (COTS) software, public domain software, or another registry's software), with the addition of a patient indexing function and HL7 messaging capability. The proposed solution will also offer enhanced capability for data export, analysis and reporting. Careful consideration of each registry software solution, regardless of the platform on which it operates, will provide CDPH the greatest flexibility in choosing the best system for California registry users.

In general, the vendor solution must be aligned with the CAIR vision and goal:

**Vision:** *Any authorized user anywhere in the state of California can immediately obtain comprehensive immunization information on any California child.*

**Goal:** *The goal of CAIR is to improve immunization rates for all California children through an innovative public-private partnership. CAIR is a collaborative effort involving regional immunization registry services, with the support of their local health departments, the California Department of Public Health Immunization Branch, and a spectrum of key stakeholders across the state. CAIR is working to develop an integrated, secure, readily-accessible statewide network of computerized immunization information systems to make each child's full immunization history available to providers and other authorized users, such as schools, foster care, and juvenile detention centers. The system will ensure that users have rapid access to complete and up-to-date immunization records, as well as expert vaccine forecasting. A major objective is to eliminate both missed opportunities to immunize and unnecessary duplicate immunizations.*

For an additional description of the proposed solution, see Alternative #2: Option B in section 5.3.2.

### **5.1.1 Hardware**

The proposed solution will require the virtual servers to be installed and set-up at the OTech Tenant Managed Services - Premium environment:

- Four (4) Web Service servers (for development/testing, training, staging, and production)
- Eight (8) Application servers (two each for development/testing, training, staging, and production)
- Four (4) SQL Database servers (for development/testing, training, staging, and production)

The solution will leverage existing Active Directory servers for the intranet and extranet.

The specific hardware requirements will be finalized following the selection of the Project Implementation vendor.

## 5.1.2 Software

Working in conjunction with OTech, CDPH will purchase the necessary software and services in support of CAIR. The typical software needed for the proposed solution is identified in Table 5-1. The specific software requirements will be finalized following the selection of the Project Implementation vendor and solution.

**Table 5-1: Software Type and Function**

Software Type	Function	Quantity
Windows server	Operating System	16*
SQL Server	Database	4
.NET	Application environment; business logic environment	1
Integration Engine (e.g. Microsoft BizTalk or Orion Rhapsody)	To support incoming and outgoing message translation, consumption, and extraction	1

\*Without addressing redundancy or disaster recovery. Quantity could increase if multiple servers are needed for increased scalability.

## 5.1.3 Technical Platform

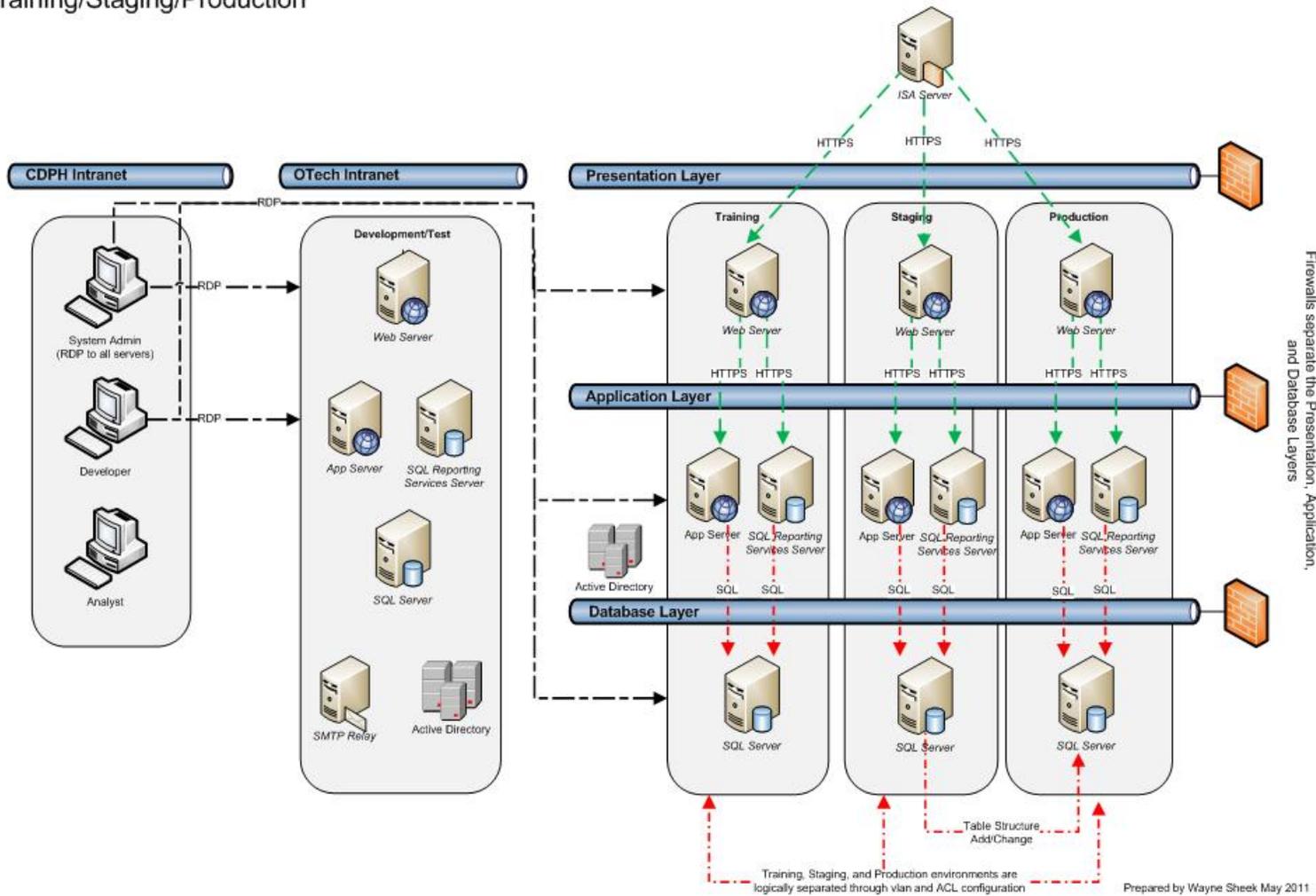
The proposed solution will use hardware and operating system software that complies with CDPH and OTech standards, which are widely supported in the marketplace.<sup>73</sup>

See Figure 5-1 for the application architecture of the proposed solution. See also Figure 5-9 in section 5.3.2 for connectivity between the environments.

<sup>73</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

Figure 5-1: Proposed Solution – Application Architecture

**CAIR Architecture**  
Intranet  
Dev/Test  
Training/Staging/Production



### 5.1.4 Development Approach

The Information Technology Services Division (ITSD) Project Management Office will assign a State Project Manager (PM) to oversee the development of CAIR 2.0. A detailed implementation approach will be finalized following the selection of the Project Implementation Vendor. Initial market research has revealed some Modified Off the Shelf (MOTS) solutions on the market that meet the CAIR 2.0 requirements listed in this FSR. Based on this first assessment a MOTS solution is possible.

**Table 5-2: Estimated Percentage of Development**

Select and estimate percentage of each:				
<input checked="" type="checkbox"/> COTS <u>90</u> %	<input checked="" type="checkbox"/> MOTS <u>10</u> %	<input type="checkbox"/> Custom Development <u> </u> %	<input type="checkbox"/> Other	<input type="checkbox"/> None
Additional Narrative: CDPH will procure a Project Implementation Vendor (also referred to as the Solution Vendor or Solution Integrator). The selected Project Implementation Vendor will include, as a part of their technical solution, the methodology to be utilized in implementing the solution as well as their experience in using the methodology. Methodologies can include, but are not limited to a standard Systems Development Life Cycle (SDLC) approach which will require requirements identification and validation, system design, build, test and implementation, agile methodologies, or some other methodology as described in the Project Implementation Vendor's technical solution. Implementation will be managed following State standards and guidelines and using Project Management Institute (PMI) best practices.				

### 5.1.5 Integration Issues

The consolidated database used by the CAIR Software Regions must be able to support standards-based interoperability with the independent registries and provider EHR systems. CDPH and the Project Implementation Vendor will be responsible for ensuring successful standards-based, bi-directional data exchange.

### 5.1.6 Procurement Approach

The CDPH understands and appreciates the importance of project procurement planning. The PM will work closely with the Department of General Services (DGS) and the assigned CDPH acquisition specialist to detail a procurement strategy. The overall plan to manage and accomplish the acquisitions required for this project will be formally documented in the project management plan.

The CAIR 2.0 solution vendor agreement will be a fixed price, deliverables based contract. The State will pay the vendor for deliverables identified in the contract upon completion and State approval of those deliverables. The CDPH Sponsor, CDPH CIO, CDPH contract manager, DGS, Technology Agency, and the CDPH PM will work collaboratively on this RFP procurement.

All information technology procurements associated with the project will follow the Information Technology Acquisition Planning (ITAP) requirements and process described in ITPL 11-3. ([http://www.cio.ca.gov/Government/IT\\_Policy/pdf/TL\\_11-3\\_ITAP\\_Rescission\\_12-6-11.pdf](http://www.cio.ca.gov/Government/IT_Policy/pdf/TL_11-3_ITAP_Rescission_12-6-11.pdf))

The project manager (PM) will work closely with the CDPH business and technical teams and with DGS to develop the RFP and the proposal evaluation and selection criteria.

### 5.1.6.1 Prime Vendor Procurement

The below tables show the prime vendor procurement vehicle(s) and contract type for the Solution Vendor product and/or services.

**Table 5-3: Proposed Prime Vendor Procurement Vehicle(s)**

Procurement Vehicle:					
<input checked="" type="checkbox"/> RFP	<input type="checkbox"/> IFB	<input type="checkbox"/> RFO - CMAS	<input type="checkbox"/> RFO - MSA	<input type="checkbox"/> Other	<input type="checkbox"/> None
Additional Narrative Vendor proposals may include Commercial off the Shelf (COTS) software, public domain software, or another registry's software. Configuration and development services along with training will be included.					

**Table 5-4: Proposed Prime Vendor Contract Type**

Contract Type:				
<input checked="" type="checkbox"/> Fixed Price	<input type="checkbox"/> Time and materials	<input type="checkbox"/> Percentage of Benefit	<input type="checkbox"/> Others	<input type="checkbox"/> None
Additional Narrative: The contract will be Deliverable Based.				

### 5.1.6.2 Market Research

Market research combined with informal user evaluations have revealed several Modified off the Shelf (MOTS) solutions on the market that meet the CAIR 2.0 requirements listed in this FSR so that a MOTS solution is very likely. The CDPH Sponsor, CDPH CIO, CDPH contract manager, DGS, Technology Agency, and the CDPH project manager will work collaboratively on this procurement. This will ensure all procurement considerations are addressed during the development of the RFP document.

**Table 5-5: Other Procurement Considerations**

Consideration	Description
GC 19130 Justification	The services contracted are not available within civil service, cannot be performed satisfactorily by civil service employees, or are of such a highly specialized or technical nature that the necessary expert knowledge, experience, and ability are not available through the civil service system
SB & DVBE Efforts	Follow certified small businesses, microbusinesses and/or certified DVBEs DGS requirements.
Contract Terms	One year maintenance following implementation of the system
Types of IT Goods and Services	COTS software, public domain software, another registry's software, or other solution that best meets business requirements and provides best value to the state.

**5.1.6.3 All Procurements for Project**

Sections 6.5.9 and 6.5.10 of this FSR explain the procurement and contract management plan for the CAIR 2.0 project. These plans use the CA-PMM methodology. The overview of all procurements for this project are shown in the below table.

**Table 5-6: Contract Table**

Contract Number	TBD	TBD	TBD
Type of Contract	RFP	CMAS	Office of Technology Services (OTech) Service Request
Has the contract been awarded? (Y/N)	N	N	N
If so, what is the date of the award? If not, what is the planned award?	March 2014	March 2014	December 2014
Start date of Contract (planned)	April 2014	April 2014	January 2015
End date of Contract (planned)	November 2015	November 2015	Ongoing
Total Value of Contract (planned)	\$2,400,000	\$116,667	\$26,180 (one-time) \$154,590 (continuing/yearly)
Is this an Interagency Acquisition? (Y/N)	N	N	Y – Service Request
Is it performance based? (Y/N)	Y (Deliverable-based)	Y (Deliverable-based)	Y (Deliverable-based)
Competitively awarded? (Y/N)	Y (Formal)	Y (Leveraged)	N – Service Request
What, if any, alternative financing option(s) are being used? (i.e., Loan, grant, or other)	Immunization Registry Funds, Health Statistics Special Fund, and Reimbursement Federal Centers for Medicare and Medicaid (CMS) through Department of Health Care Services (DHCS).	Immunization Registry Funds, Health Statistics Special Fund, and Reimbursement Federal CMS through DHCS.	Immunization Registry Funds, Health Statistics Special Fund, and Reimbursement Federal CMS through DHCS.

#### **5.1.6.4 California Government Code 19130 Compliance**

The CDPH will conduct a procurement asking vendors to propose a cost-effective solution to achieve the objectives described in this FSR. From our market research of available solutions and similar implementations in other states, it is very likely that the selected solution will require staff with expert knowledge of the solution to implement it effectively. The specific skills required will depend on the selected solution, and are unlikely to be available from state civil service staff.

The PM will follow the established, formal CDPH approval process for any contracts which involve “personal services”. The approval process includes the requirement to justify why state civil service staff cannot perform the services. The PM will justify personal services contracting based on one or more of the following conditions allowed in Government Code (GC) 19130 (b):

- Services are not available in civil service.
- Services cannot be performed satisfactorily by civil service employees.
- Services are of such a highly specialized or technical nature that the necessary expert knowledge, experience and ability are not available through the civil service system.
- Training services for which no qualified civil service instructors are available.
- Services are so urgent, temporary, or occasional that the use of the civil service system is impractical and would frustrate its very purpose.

The CDPH Legal Office will ensure the department is meeting all appropriate authorizations before entering into a contract.

#### **5.1.6.5 Performance Bond**

To protect the State’s investment and ensure adequate contractor performance, CDPH will require a performance bond if the selected vendor will receive progress payments. The vendor shall provide proof of bondability. The proof of bondability must state that the bonding company will bond the vendor for thirty percent (30%) of the value of the contract and that this bond shall be held in effect until successful completion of the vendor contract, which includes the warranty. The bonding company must be a surety insurer, licensed to do business in the State of California.

CDPH will require the actual performance bond to be delivered to the State within twenty-one (21) calendar days of contract award and will be returned to the Contractor upon successful completion of the Contract.

#### **5.1.7 Technical Interfaces**

The consolidated database used by the CAIR Software Regions must be able to support standards-based interoperability with the independent registries and provider EHR systems. The independent registries will need to scale-up their HL7 data exchange capabilities to support larger scale query of immunization data across regions throughout the state. This interoperability includes the ability to interface with a patient indexing function via HL7 to facilitate searching for records in other regions.

The Project Implementation Vendor in conjunction with CDPH will design, build, and test all technical interfaces between the consolidated CAIR Software Regions, independent registries and provider EHR systems.

### **5.1.8 Accessibility**

The proposed system will be in compliance with California Government Code § 11135:California Code – Section 11135 and Section 508<sup>74</sup> regarding access to online applications for the disabled.

### **5.1.9 Data Migration Plan**

The PM has the ultimate responsibility for data migration. The PM will work closely with the acquisition specialist and CDPH technical experts to ensure the selection of a vendor with the necessary skills and experience to accomplish data migration successfully. The contract will detail the vendor responsibilities and CDPH expectations/requirements regarding data migration. The vendor will be responsible for data migration planning, documentation, and execution. Vendor deliverables will include a formal Data Migration Plan compliant with the applicable best practice Data Item Description (DID) from the Office of System Integration<sup>75</sup>. As described in the DID, the Plan will detail the data migration objectives, strategy, preparation and procedures. CDPH subject matter experts (SMEs) will be made available to ensure timely response to vendor questions and requests for information related to data migration.

The following diagram (Figure 5-2: Data Migration Map) shows the phased-approach-plan of consolidating the data. Data migration is expected to be relatively straightforward, as the seven databases (seven regions) have the same database schema. Most of the data consolidation work is expected to be focused on removing duplicate records and not correcting a wide variety of data anomalies.

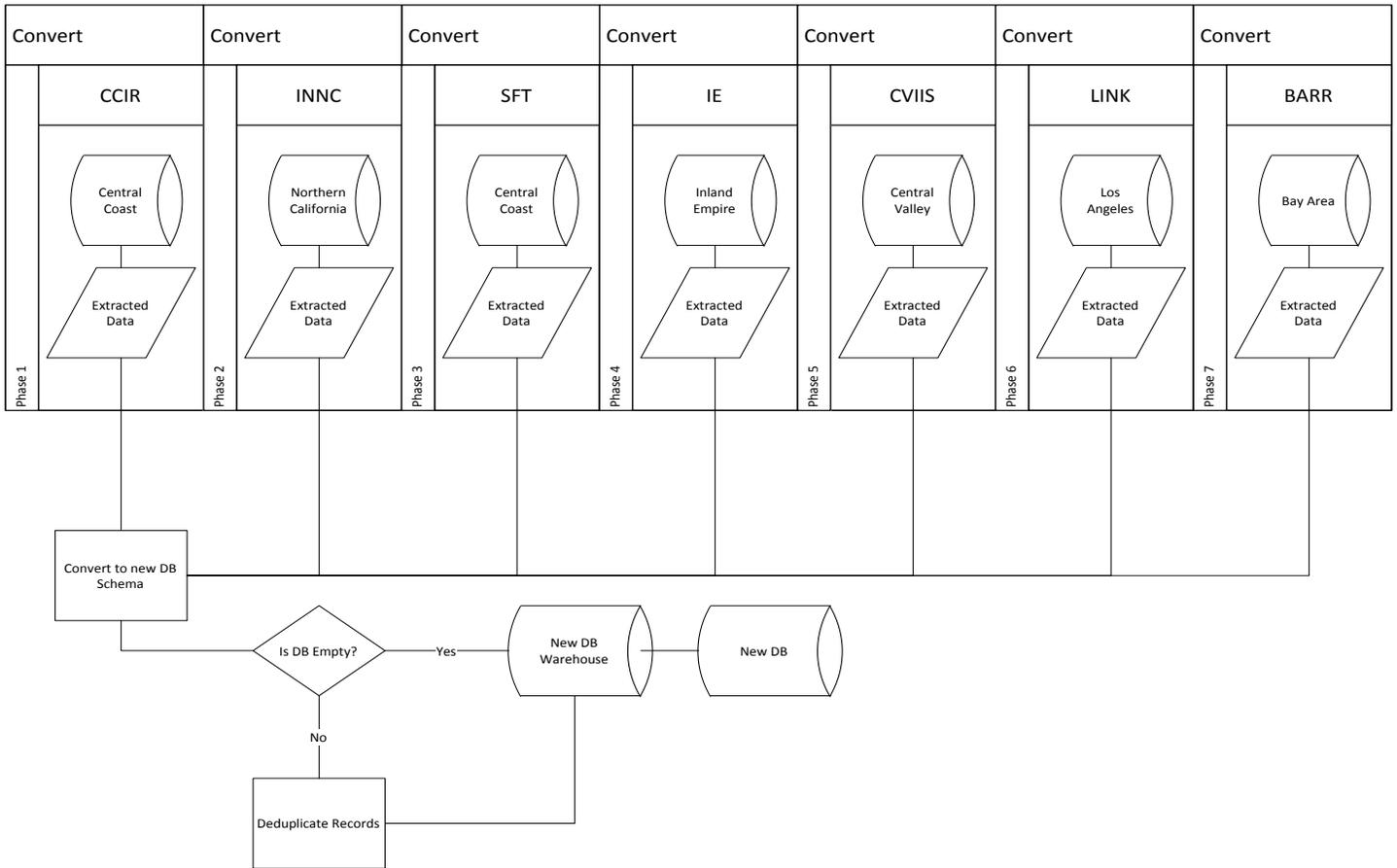
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<sup>74</sup> "Section 508," 21 April 2011  
<<http://www.section508.gov/>>.

<sup>75</sup> See <http://www.bestpractices.osi.ca.gov/sysacq/documents/Data%20Conversion%20Plan%20-%20DID.doc>

**Figure 5-2: Data Migration Map**

The Data Migration Map is a high level view of region data conversion in the CAIR 2.0 project.



### **5.1.10 Testing Plan**

The Project Implementation Vendor, Technical Lead, Internal IT Tech Support, Business Lead, Project and Subject Matter Experts (SMEs) will play a significant role in the testing activities of the proposed solution. Testing will include, but is not limited to, unit testing, functional testing, performance testing, and user acceptance testing. Additional tests may be included as per the Project Implementation Vendor's proposed testing approach.

Unit testing will be performed by the Project Implementation Vendor on the development environment. Functional testing will be performed on a test environment by the Project Implementation Vendor and CDPH staff who will assume the various roles of providers, epidemiologists, public health officials, and other authorized users of the system. Performance testing will be conducted by the Project Implementation Vendor in conjunction with CDPH staff. User acceptance testing will either be conducted on the same test environment used for functional testing or on a different user acceptance testing environment and will be performed by CDPH staff where each component of the system will be tested before it is accepted. CDPH will describe the necessary tests to be performed, the expected results, and will report the actual test results. Documentation for review and discussion will be based on completed tests. The tests will refer to the Requirements Traceability matrix (see Table 3-12) to ensure all requirements are being tested and include a description of the function being tested, initial conditions required to be present, and the test scripts to be used to do the test.<sup>76</sup>

Once functional and user acceptance testing has been completed successfully on their respective environments, deployment to the production environment and the official acceptance process will begin. CDPH personnel will provide training to the authorized users taking part in the acceptance testing. Any issues identified during the official acceptance testing will be reported back to the Project Implementation Vendor and designated CDPH staff. The Project Implementation Vendor will fix program defects, while other issues or enhancement requests will be logged as a part of the identified Change Control process.<sup>77</sup>

A detailed Testing Plan will be finalized following the selection of the Project Implementation Vendor.

### **5.1.11 Resource Requirements**

State staff resources required for this project are detailed in paragraph 8.2.1.1 One-Time Project Staff Costs, and 8.2.2.1 Continuing Project Staff Costs.

### **5.1.12 Training Plan**

The Project Implementation Vendor will develop the training plan, training schedule and the necessary training materials to conduct Train-the-Trainer sessions for the Registry Field staff (see section 3.1.1.1 for a description of the Provider Recruitment, Training, Retention and

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<sup>76</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

<sup>77</sup> State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.

Support model). Training documentation will also be developed by the Project Implementation Vendor for technical staff to develop, operate, and maintain the system. Potential sources for training include the face-to-face, distance learning, and online training modules.

A detailed Training Plan and schedule will be finalized following the selection of the Project Implementation Vendor.

### **5.1.13 Ongoing Maintenance**

Ongoing operations and maintenance of the proposed system will be managed by a vendor in collaboration with existing Immunization Branch Staff: a CAIR Manager, a Provider Support Coordinator, and two Data Exchange Support Staff. Hardware operations and maintenance will be provided by CDPH Information Technology Services staff. The Immunization Branch will be responsible for the maintenance patching, backup, etc. of the proposed system. Additional needs for operations and maintenance will be determined following the selection of the Project Implementation Vendor.

See also section 6.5.12 for the Maintenance & Operations Transition Plan and section 3.4.3 for Continuous Operations Requirements.

### **5.1.14 Information Security**

The project will follow the information security policies, as applicable, provided by:

- CDPH Information Security Office (ISO) Security Requirements for Projects (SR1)
- OTech Information Security Standards
- The State Administrative Manual (SAM)
- The CDPH Information Security Policy

### **5.1.15 Confidentiality**

All persons that will be working with CDPH personal and confidential information (PCI), or protected health information (PHI), must sign a confidentiality statement. The statement must include at a minimum, General Use, Security and Privacy safeguards, Unacceptable Use, and Enforcement Policies. The statement must be signed by the workforce member prior to access to CDPH PCI. The statement must be renewed annually. The Contractor shall retain each person's written confidentiality statement for CDPH inspection for a period of three (3) years following contract termination.

### **5.1.16 Impact on End Users**

The user interface, i.e., the screens, utilized by the independent registries is not expected to change. However, the user interface utilized by the CAIR Software Regions will change due to the acquisition of new software for the partial consolidation. This will require additional training as per the Training Plan (see section 5.1.12).

End users will be able to access more complete, up-to-date, accurate immunization information on individuals as well as query and submit immunization information in a standards-based format with other regions. It will also be easier for end users to search for and locate records in other regions with the assistance of a patient indexing function.

### 5.1.17 Impact on Existing System

The existing system will be impacted such that it will support standards-based interoperability. Additionally, the seven separate databases utilized by the CAIR Software Regions will be consolidated into one database. Data will need to be migrated to the consolidated system with Alternative #2: Option B (Adapt new software) (see section 5.3.2.1.1) or if the independent regions decide to join the consolidated system. Data conversion issues will need to be addressed as a part of the migration plans and activities.

### 5.1.18 Consistency with Overall Strategies

This proposed project aligns with the State's strategic direction for information technology, CDPH Strategic Business Plan and Agency Information Management Strategy (AIMS) in support of the business needs of the CDPH.

#### 5.1.18.1 Alignment with Statewide Strategic Plan

The proposed project is aligned with Goals 1-3 of the 2011 California Information Technology Strategic Plan:

- **Goal 1:** Make Government Transparent, Accessible, and Secure
- **Goal 2:** Drive Innovation and Collaboration
- **Goal 3:** Make Information Technology Reliable and Sustainable through Consolidated Platforms and Shared Services

#### 5.1.18.2 Alignment with CDPH Strategic Plan

Implementation of this system addresses Goals 1 and 3 of CDPH's 2008-2010 Strategic Plan<sup>78</sup> and the Healthy People 2020 Objectives (see section 3.1.1.1).

- **Goal 1:** Increase Quality and Years of Healthy Life, Reduce Disparities, and Promote Health Equity
- **Goal 3:** Improve Quality and Availability of Data to Inform Public Health Decision-Making

#### 5.1.18.3 Alignment with AIMS

The proposed project is aligned with AIMS Goal 1.

- **Goal 1:** Treat Information as an asset and create an environment to maximize its value to the Department and its partners and customers.

### 5.1.19 Impact on Current Infrastructure

The existing information technology infrastructure will be changed to support the consolidation of the seven CAIR Software Region databases into one, to support HL7 interoperability, and to support new CAIR software.

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<sup>78</sup> State of California. Department of Public Health. *Strategic Plan 2008-2010*. 21 April 2011. <<http://www.cdph.ca.gov/Documents/CDPH-Strategic-Plan.pdf>>.

Detailed infrastructure needs will be determined following the selection of the Project Implementation Vendor.

### 5.1.20 System Hosting/Data Center Consolidation

Use the check boxes and identify the entity planned to host the system in the table below:

**Table 5-7: System Hosting**

Hosting	
<input type="checkbox"/> OTech Managed Services	<input checked="" type="checkbox"/> OTech Tenant Managed Services - Premium
<input type="checkbox"/> Agency/Dept.	<input type="checkbox"/> Outsourced/Other
<p>Additional Narrative</p> <p>This solution will be hosted at the OTech data center in the Tenant Managed Service – Premium environment. This information is included in the Economic Analysis Workbook (EAW) as part of this FSR. This solution is consistent with the data center consolidation.</p>	

### 5.1.21 Disaster Recovery

Disaster recovery requirements are as specified by the CDPH Disaster Recovery Plan.

### 5.1.22 Public Access

Authorized users will have real-time access to patient data via their registry interface. (See section 3.1.1.5 for registry users.) In addition, authorized sites will have access to data through standards-based interoperability provided through web services technology.

For data safeguards, see section 4.1.7.

### 5.1.23 Cost and Benefits

The estimated one-time and continuing costs of implementing the proposed solution are identified in Table 5-8 below.

**Table 5-8: Proposed Solution\* – One Time & Ongoing Expenses**

ONE-TIME COST	
Staff (Salaries & Benefits)	\$851,547
Software Customization	\$2,400,000
IV&V Contract Services	\$116,667
Other Contract Services <sup>&amp;</sup>	\$1,255,000
Data Center Services	\$26,180
<b>TOTAL ONE-TIME COST</b>	<b>\$4,649,394</b>
CONTINUING COST	
Staff (Salaries & Benefits)	\$219,163
Contract Services	\$1,741,667
Data Center Services	\$386,475
<b>TOTAL CONTINUING COST</b>	<b>\$2,347,305</b>
<b>YEARLY CONTINUING COST</b>	<b>\$1,393,009</b>
<b>TOTAL PROJECT COSTS</b>	<b>\$6,996,699</b>

\* The Proposed Solution is Alternative #2/Option B which corresponds to the cost tables in section 8 named "Proposed Alternative" or "ALT (P)". Annual Continuing Costs include Data Center Services cost of \$154,590.

<sup>&</sup> 'Other Contract Services' represents the project costs of existing CAIR Technical staff who are CDPH contract employees.

A more detailed explanation of costs and assumptions used is presented in section 8. See section 5.3.2.3 for the benefits of the proposed solution.

### 5.1.24 Sources of Funding

The proposed solution is expected to be funded primarily with Federal funds and may be funded by CMS through the Medi-Cal Program with a potential 90%/10% match of Federal funding/Special funding pending the submission (to be completed at a future date) and approval of an Implementation Advanced Planning Document (IAPD) request for federal financial participation (FFP). Currently, the Immunization Branch and VFC Program receive an annual budget from the CDC through Section 317<sup>79</sup> funding which may be increased to accommodate

<sup>79</sup> Centers for Disease Control and Prevention. *Immunization Grant Program (Section 317)*. 25 April 2011 <<http://www.cdc.gov/vaccines/programs/vfc/downloads/grant-317.pdf>>.

the needs of implementing the proposed solution.

## 5.2 Rationale for Selection

This section describes the rationale for the selection of Alternative #2: Partial Consolidation + Software Changes (see section 5.3.2). In comparison to the other four alternatives considered, Alternative #2: Option B is the most feasible and relevant at this point in time for California. A brief summary is presented below including the reasons why the other four alternatives were not selected.

Alternative #1: Connect Regions via HL7 (see section 5.3.1) was deemed by project decision makers and project business and information technology partners, with input from stakeholders, as not providing much added value over the current CAIR architecture, i.e., the status quo. There was no further consideration of Alternative #1. The main differentiating aspect between the current CAIR architecture and Alternative #1 is support for standards-based HL7 data exchange, where with the current CAIR architecture, all regions support limited scale HL7 data exchange and with Alternative #1 all regions would support scalable HL7 data exchange.

Alternative #3: Full Consolidation (see section 5.3.3) was deemed by project decision makers and project business and information technology partners, with input from stakeholders, as the ideal approach, resulting in the creation of a single, central consolidated database, a single web-based application, and a single unified record. Alternative #3, Options A or B (see section 5.3.3.1.1) meets all the requirements and objectives stated in this FSR and would appear to be the alternative to be selected; however, this alternative was not perceived as achievable unless all the independent registries agree to join the consolidation, which at this time is not mandated by the State and not likely on a volunteer basis.

Alternative #4: Connect through HIEs (see section 5.3.4) was deemed by project decision makers and project business and information technology partners, with input from stakeholders, to be similar to Alternative #1, but dependent on HIEs which are still emerging and distributed in nature. There were concerns that regions without a connection to a HIE would be unable to participate and leverage the benefits of this alternative. Thus, there was no further consideration for Alternative #4. Project decision makers, project business and information technology partners, and stakeholders all understand that the emergence of HIEs will increasingly play a role in registries and that some aspects of connecting through HIEs could be utilized with respect to any of the alternatives presented.

Alternative #5: Expanded IIS/Integrated Systems (see section 5.3.5) is easiest/best enabled with a fully consolidated system. CAIR is not and may never be fully consolidated, and therefore this alternative was deemed by project decision makers and project business and information technology partners, early on in the evaluation of the alternatives to be too complex and was rejected as a potential alternative for further consideration at this point in time.

The remaining alternative is Alternative #2: Partial Consolidation + Software Changes (see section 5.3.2) which brings CAIR closest to a full consolidation without mandating regional participation. Alternative #2 consolidates the data from the seven CAIR Software Regions, with the other three regions continuing to use their existing software or migrating to the consolidated system if they so choose. Interoperability is enabled via HL7 amongst the consolidated region, remaining regions, and providers.

Most of the high-level requirements and objectives will be fully met with the software options (see section 5.3.2.1.2) for Alternative #2. Alternative #2 is aligned with stakeholder feedback on the need to further consolidate and obtain information from other regions in a standards-based format while still respecting the independent registries wishes to remain independent. Additionally, while this alternative does not eliminate redundancy in staff and technology, it minimizes it. Alternative #2 comes closest to producing a unified record in the absence of a full consolidation and is likely to encourage the largest providers to submit and query for data and participate in the registry due to the minimized points of connection for submitting data to the registry and querying the registry. Additionally, while Alternative #2 is not a full consolidation, most of the data for California's zero through five year-olds will be included in the consolidated database since the seven CAIR Software Regions cover 87% of California's zero through five year-olds, with the remaining 13% of children being located in the regions covered by the still-independent registries. The 87% could increase if other regions decide to join the consolidation.

Alternative #2 was deemed by project decision makers and project business and information technology partners, with input from stakeholders, as the selected alternative. The greatest level of enthusiasm was expressed by stakeholders for a partial consolidation with new software (Option B). Based on discussions during the stakeholder webinars, independent regions supported the idea of a consolidated registry but were cautious about joining the effort unless they were assured the functionality, benefits, and support of the selected solution meets or exceeds what they currently provide.

Below are a summary of the requirements and objective scorecards (see Figure 5-3 and Figure 5-4) used to evaluate each alternative presented in section 5.3. With the progression through each alternative, there are additional high-level requirements and objectives that are envisioned to be fully met as compared to its previous alternative.

**Figure 5-3: Summary of Requirements Scorecards\***

	#2: Partial Consolidation					#3: Full Consolidation				
	Current	#1: Connect	Use Modified		Use Current	Use Modified	Use Current		#4: HIE	#5: Expanded
		Regions	CAIR Software	New Software	CAIR Software		CAIR Software	New Software	CAIR Software	
State-wide consolidated records	○	⊙	⊙	⊙	⊙	●	●	●	⊙	●
Data export and analysis	○	○	⊙	⊙	⊙	●	●	⊙	○	●
Continuous operations	●	●	●	●	●	●	●	●	●	●
Standards-based exchange	⊙	●	●	●	●	●	●	●	●	●
Security and privacy of data	●	●	●	●	●	●	●	●	●	●
Support for clinical operations	●	●	●	●	●	●	●	●	●	●
Store required data	●	●	●	●	●	●	●	●	●	●
Enable Meaningful Use	○	●	●	●	●	●	●	●	●	●
Support HIE Core Services	○	⊙	●	●	⊙	●	●	⊙	●	●
Stable, well-supported technology	○	○	●	●	○	●	●	○	○	●

\* See Figure 4-4 for the Requirements Scorecard Legend.

**Figure 5-4: Summary of Objectives Scorecards\***

	#2: Partial Consolidation					#3: Full Consolidation				
	Current	#1: Connect	Use Modified		Use Current	Use Modified	Use Current		#4: HIE	#5: Expanded
		Regions	CAIR Software	New Software	CAIR Software		CAIR Software	New Software	CAIR Software	
Objective 1/2: State-wide consolidated records	○	⊙	⊙	⊙	⊙	●	●	●	⊙	●
Objective 3: Store required data	●	●	●	●	●	●	●	●	●	●
Objective 4: Standards-based exchange	⊙	●	●	●	●	●	●	●	●	●
Objective 5/6: Data export and analysis	○	○	⊙	⊙	⊙	●	●	⊙	○	●
Objective 7: Support HIE Core Services	○	⊙	●	●	⊙	●	●	⊙	●	●
Objective 8: Stable/supportable/accessible SIIS	○	○	●	●	○	●	●	○	○	●

**Figure 5-5: Objectives Scorecard Legend**

○	Does not meet objective
⊙	Partially meets objective
●	Fully meets objective

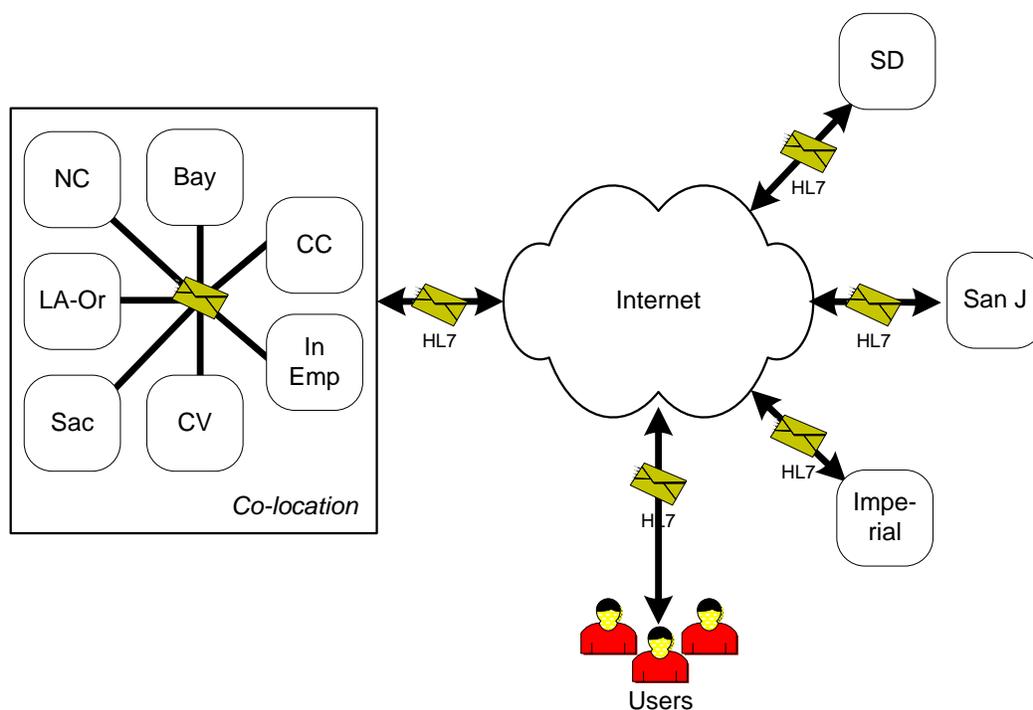
## 5.3 Alternatives Considered

### 5.3.1 Alternative #1: Connect Regions via HL7

#### 5.3.1.1 Description

This alternative is for the regions to largely remain as-is, continuing use of their existing software, but to enable and fully implement interoperability between them via a standards-based format. Interoperability is envisioned to be enabled via HL7, not only between the CAIR Software Regions, but also with the independent registries and with providers. See Figure 5-6.

Figure 5-6: Alternative #1: Connect Regions via HL7



#### Legend

**NC:** Northern California

**Bay:** Bay Area

**CC:** Central Coast

**In Emp:** Inland Empire

**CV:** Central Valley

**Sac:** Greater Sacramento Area

**La-Or:** Los Angeles-Orange

**SD:** San Diego

**San J:** San Joaquin Valley

**Imperial:** Imperial County

**HL7:** Health Level Seven

#### 5.3.1.1.1 Key Attributes and Software Options

Key attributes of Alternative #1 include the following:

- Regional registries continue to operate independently using their existing software.
- All regions now support HL7 which enables interoperability between regions and with providers for query and data submission.
- Regions not using the CAIR software can migrate if they choose.
- No other changes are made to infrastructure or operations.

### 5.3.1.1.2 Alternative #1 Scorecards

With Alternative #1, many of the high-level requirements will be fully met as depicted in Figure 5-7 and only some of the objectives will be met as depicted in Figure 5-8.

**Figure 5-7: Alternative #1: Requirements Scorecard\***

State-wide consolidated records	⊙
Data export and analysis	○
Continuous operations	●
Standards-based exchange	●
Security and privacy of data	●
Support for clinical operations	●
Store required data	●
Enable Meaningful Use	●
Support HIE Core Services	⊙
Stable, well-supported technology	○

\* See Figure 4-4 for the Requirements Scorecard Legend.

**Figure 5-8: Alternative #1: Objectives Scorecard**

Objective 1/2: State-wide consolidated records	⊙
Objective 3: Store required data	●
Objective 4: Standards-based exchange	●
Objective 5/6: Data export and analysis	○
Objective 7: Support HIE Core Services	⊙
Objective 8: Stable/supportable/accessible SIIS	○

\* See Figure 5-4 for the Objectives Scorecard Legend.

### 5.3.1.2 Costs

In reviewing this alternative with project decision makers and project business and information technology partners, Alternative #1 was deemed to be unfeasible, warranting no cost analysis.

### 5.3.1.3 Benefits

In addition to the advantages in described in section 5.3.1.4, benefits include:

- Uniform data quality and data standards.
- Greater access to data by providers across regions may improve patient care.
- Expedite restorative efforts in wide-spread emergencies increasing the availability of accurate and timely data during a disaster or pandemic.
- Enable California to efficiently and promptly provide other states with immunization data on children and families displaced by disaster.
- Guide the development of the SIIS in meeting the CDC Minimum Functional Standards, or core functions, for an IIS.
- Enable clinicians to easily share information with one another to provide accurate, complete, up to date immunization information on a patient.
- Enable EHR systems to query for or submit immunization information to the SIIS.
- Leveraging HIE services provided by the State such as the Trust Framework, Entity Level Provider Directory (ELPD), Individual Level Provider Directory (ILPD), Services

Registry, and Connectivity Services may minimize duplicative efforts and align utilization of HIE services with national efforts.

### 5.3.1.4 Advantages and Disadvantages

The advantages and disadvantages for Alternative #1 are listed in Table 5-9 below.

**Table 5-9: Alternative #1: Advantages/Disadvantages**

Advantages	Disadvantages
<ul style="list-style-type: none"> <li> Leverages and supports local policies and practices</li> <li> Software is richly functional for clinicians</li> <li> Most regional software meets most, but not all, of CDC's Minimum Functional Standards for IIS</li> <li> Less effort to implement because of minimal changes compared to other alternatives</li> <li> <b>Enables MU through standards-based interoperability</b></li> <li> <b>Regional registries can now query each other to potentially build a consolidated record, but results may be limited</b></li> </ul>	<ul style="list-style-type: none"> <li> Redundancy in staff and technology prevents best leverage of funds as each region operates somewhat independently</li> <li> Disparate data across regional databases prevents single, consolidated record from being assembled</li> <li> <b>Better solution needed to match patient identity between registries and for managing duplicates and corrections</b></li> <li> May still discourage largest providers who want a single point of connection for submitting data</li> <li> CAIR software based on old products which are difficult to enhance and modify and must be updated to the current sustainable technology</li> <li> Does not address incompatibility with Mac browser.</li> </ul>

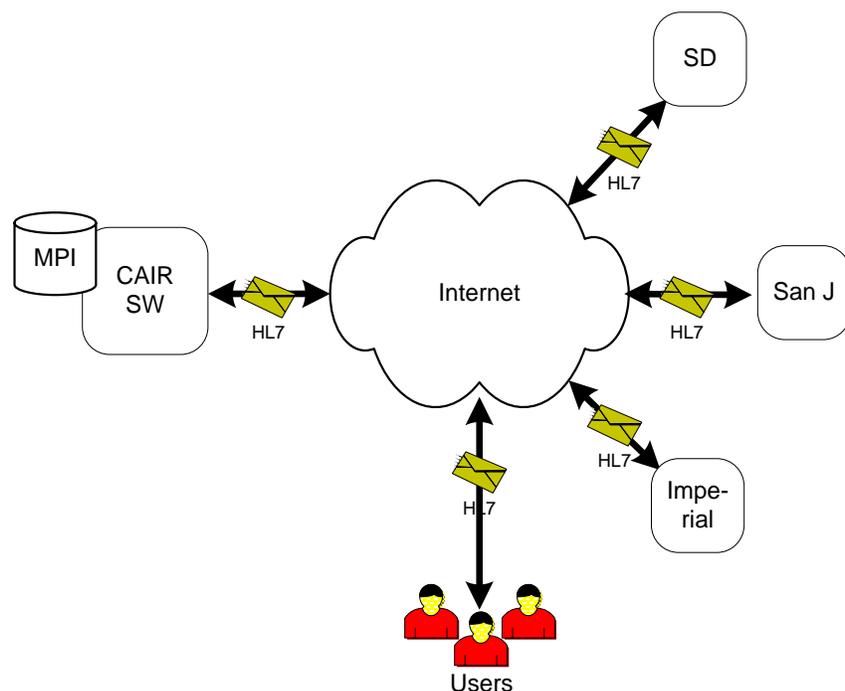
Note: **Bold** in the table above indicates an advantage or disadvantage that is different from the current CAIR architecture described in section 4.1.1. Disadvantages related to the current CAIR architecture are primarily the same with the exception that MU is now enabled between the CAIR Software Regions and between the CAIR Software Regions, independent registries and providers with Alternative #1.

## 5.3.2 Alternative #2: Partial Consolidation + Software Changes

### 5.3.2.1 Description

This alternative is to consolidate the data from the seven CAIR Software Regions, with the other three regions continuing to use their existing software or migrating to the consolidated system if they so choose. Interoperability is enabled via HL7 amongst the consolidated region, remaining regions, and providers. The added impact of different software options is also considered. See Figure 5-9.

**Figure 5-9: Alternative #2: Partial Consolidation**



**Legend**

**MPI:** Master Patient Index  
**CAIR SW:** CAIR Software  
**HL7:** Health Level Seven

**SD:** San Diego  
**San J:** San Joaquin Valley  
**Imperial:** Imperial County

### 5.3.2.1.1 Key Attributes & Software Options

Key attributes of Alternative #2 include the following:

- Database from the seven regions running the CAIR software are consolidated into one database which covers 87% of California's zero through five year-olds.
- Other regions may continue with their own products, or migrate to the consolidated system if they choose.
- If other regions stay independent, the patient indexing functioning typically included within IIS can be utilized to facilitate searching for records in other regions. Alternatively, a MPI could also be implemented if feasible, which would contain all demographic records from all regions to facilitate searching for records. The other regions would register their patient demographic records with the MPI so that the MPI could be queried to find data for patients located in other regions.
- All software is Internet accessible.
- Enable HL7 between new centralized system and providers for query and submission; stand-alone regions would need to scale-up their existing HL7 capabilities.
- Enhanced capability for data export, analysis and reporting.

Software options for this alternative include:

- **Option A:** Modify the current CAIR software to use more current tools and to comply with State software requirements.

- **Option B:** Adapt new software, either COTS software, public domain software, or software from another registry.
- **Option C:** Continue to use the current CAIR software.
  - In reviewing this software option with project decision makers and project business and information technology partners, it was deemed to be unfeasible, warranting no further consideration.

### 5.3.2.1.2 Alternative #2 Scorecards

With Alternative #2, many of the high-level requirements will be fully met with the software options as depicted in Figure 5-10 and many of the objectives will be met with Software Option A or B as depicted in Figure 5-11.

**Figure 5-10: Alternative #2: Requirements Scorecard\***

	Use Modified CAIR Software	New Software	Use Current CAIR Software
State-wide consolidated records	○	○	○
Data export and analysis	○	○	○
Continuous operations	●	●	●
Standards-based exchange	●	●	●
Security and privacy of data	●	●	●
Support for clinical operations	●	●	●
Store required data	●	●	●
Enable Meaningful Use	●	●	●
Support HIE Core Services	●	●	○
Stable, well-supported technology	●	●	○

\* See Figure 4-4 for the Requirements Scorecard Legend.

**Figure 5-11: Alternative #2: Objectives Scorecard\***

	Use Modified CAIR Software	New Software	Use Current CAIR Software
Objective 1/2: State-wide consolidated records	○	○	○
Objective 3: Store required data	●	●	●
Objective 4: Standards-based exchange	●	●	●
Objective 5/6: Data export and analysis	○	○	○
Objective 7: Support HIE Core Services	●	●	○
Objective 8: Stable/supportable/accessible SIIS	●	●	○

\* See Figure 5-4 for the Objectives Scorecard Legend.

### 5.3.2.2 Costs

#### Alternative #2: Option A

The estimated one-time and continuing costs of implementing Alternative #2: Option A are identified in Table 5-10 below.

**Table 5-10: Alternative #2/Option A\* – One Time & Ongoing Expenses**

<b>ONE-TIME COST</b>	
Staff (Salaries & Benefits)	\$1,166,418
Software Customization	\$2,400,000
IV&V Contract Services	\$186,667
Other Contract Services &	\$1,855,000
Data Center Services	\$39,580
<b>TOTAL ONE-TIME COST</b>	<b>\$5,647,665</b>
<b>CONTINUING COST</b>	
Staff (Salaries & Benefits)	\$106,120
Contract Services	\$1,741,667
Data Center Services	\$1,000,968
<b>TOTAL CONTINUING COST</b>	<b>\$2,848,754</b>
<b>TOTAL PROJECT COSTS</b>	<b>\$8,496,419</b>

\* Alternative #2/Option A corresponds to the cost tables in section 8 named "Alternative #1" or "ALT (1)".

& 'Other Contract Services' represents the project costs of existing CAIR Technical contract staff who will serve as subject matter experts (SMEs)

**Alternative #2: Option B**

The estimated one-time and continuing costs of implementing Alternative #2: Option B are identified in Table 5-11 below.

**Table 5-11: Alternative #2/Option B\* – One Time & Ongoing Expenses**

<b>ONE-TIME COST</b>	
Staff (Salaries & Benefits)	\$851,547
Software Customization	\$2,400,000
IV&V Contract Services	\$116,667
Other Contract Services &	\$1,255,000
Data Center Services	\$26,180
<b>TOTAL ONE-TIME COST</b>	<b>\$4,649,394</b>
<b>CONTINUING COST</b>	
Staff (Salaries & Benefits)	\$219,163
Contract Services	\$1,741,667
Data Center Services	\$386,475
<b>TOTAL CONTINUING COST</b>	<b>\$2,347,305</b>
<b>TOTAL PROJECT COSTS</b>	<b>\$6,996,699</b>

\* Alternative #2/Option B correspond to the cost tables in section 8 named “Proposed Alternative” or “ALT (P)”.

& ‘Other Contract Services’ represents the project costs of existing CAIR Technical contract staff who will serve as subject matter experts (SMEs).

A more detailed explanation of costs and assumptions used is presented in section 8.

**Alternative #2: Option C**

In reviewing this alternative with project decision makers and project business and information technology partners, Alternative #2: Option C was deemed to be unfeasible, warranting no cost analysis.

**5.3.2.3 Benefits**

In addition to the advantages in described in section 5.3.2.4, benefits include:

- Reduce inefficiencies and duplicative efforts by staff and in technology.
- Leverage use of limited funds.
- Minimize risk in moving to a partial consolidation from lessons learned from other states.
- Information of where children are under- or over-immunized in California by geographic and demographic breakdowns.

- Increased completeness of records, to reduce the barrier of unknown immunization status, minimize over immunization, reduce under immunization, and enhance the efficiency and cost-effectiveness of national immunization efforts.
- Uniform data quality and data standards.
- Greater access to data by providers across regions may improve patient care.
- Expedite restorative efforts in wide-spread emergencies increasing the availability of accurate and timely data during a disaster or pandemic.
- Enable California to efficiently and promptly provide other states with immunization data on children and families displaced by disaster.
- Guide the development of the SIIS in meeting the CDC Minimum Functional Standards or core functions, for an IIS.
- Enable clinicians to easily share information with one another to provide accurate, complete, up to date immunization information on a patient.
- Enable EHR systems to query for or submit immunization information to the SIIS.
- Facilitate the efficiency in determining the impact of a new vaccine or immunization outreach strategy.
- Readily identify who has received specific lots of vaccine in case of spoilage or improper manufacture.
- Cost-efficiently and effectively identify children at risk during a vaccine preventable disease outbreak in a community.
- Enable obtaining and using immunization data from the SIIS more easily, efficiently and in a timely manner.
- Leveraging HIE services provided by the State such as the Trust Framework, Entity Level Provider Directory (ELPD), Individual Level Provider Directory (ILPD), Services Registry, and Connectivity Services may minimize duplicative efforts and align utilization of HIE services with national efforts.
- Comply with current State security, software and hosting standards.

#### **5.3.2.4 Advantages and Disadvantages**

The advantages and disadvantages common to the software options described above for Alternative #2 are listed in Table 5-12 below. Additionally, best practices from other states have shown re-branding of the SIIS may ease the transition to consolidation and a new product. This may be beneficial for California as CAIR currently has two different meanings, either as the CAIR Software Application or as the collective SIIS comprised of all regions regardless of whether they use the CAIR Software Application or not.

**Table 5-12: Alternative #2: Advantages/Disadvantages Common to all Software Options**

Advantages	Disadvantages
<ul style="list-style-type: none"> <li> <b>Relatively easy to consolidate data from like systems and come closer to producing a unified record</b></li> <li> Enables Meaningful Use through standards-based interoperability</li> <li> <b>Enables better provider query and submission across regions through data consolidation</b></li> <li> <b>Likely to encourage largest providers to submit data and participate</b></li> <li> <b>Greater legitimacy as a statewide registry makes it more attractive to providers</b></li> <li> <b>Reduces ongoing development needs since working only on a few or one system</b></li> </ul>	<ul style="list-style-type: none"> <li> Some redundancy in staff and technology remains</li> <li> Some fragmentation of data remains as some regions continue to operate with their own databases</li> <li> Better solution needed to match patient identity between registries and for managing duplicates and corrections</li> <li> <b>Need greater technical support (whether employed at state or regional level)</b></li> <li> <b>Independent regions likely will not join unless the new system functions as well as, or better, than their current system</b></li> </ul>

Note: **Bold** in the table above indicates an advantage or disadvantage that is different from previous alternatives presented. Alternative #2 comes closer to meeting the requirements and objectives stated in this FSR as opposed to Alternative #1. Alternative #2 builds off of Alternative #1. While the advantages for Alternative #2 are similar to those of Alternative #1, the magnitude of those advantages is *increased* in Alternative #2. While the disadvantages for Alternative #2 are similar to those of Alternative #1, the magnitude of those disadvantages is *decreased* in Alternative #2.

The advantages and disadvantages specific to each software option for Alternative #2 are listed in Table 5-13 below.

**Table 5-13: Alternative #2: Software Option Advantages/Disadvantages**

Implementation Option	Advantages	Disadvantages
<p><b>Option A:</b> Modify CAIR Software</p>	<ul style="list-style-type: none"> <li> Removes dependency on older software, reducing costs in the long run and improving product stability</li> <li> Redesign of user interface to current web standards will facilitate user experience</li> <li> May be quicker to implement over a completely new product</li> <li> Easier to consolidate data into an existing database structure</li> </ul>	<ul style="list-style-type: none"> <li> Current code base may be a poor foundation upon which to re-build the product</li> <li> The more that changes, the more the “advantages” are reduced</li> <li> Requires retraining of users</li> <li> May be more challenging to bring together data from regions using other products</li> <li> CA still “on its own” with a unique product</li> <li> May be more expensive than acquiring a new product, especially one developed in</li> </ul>

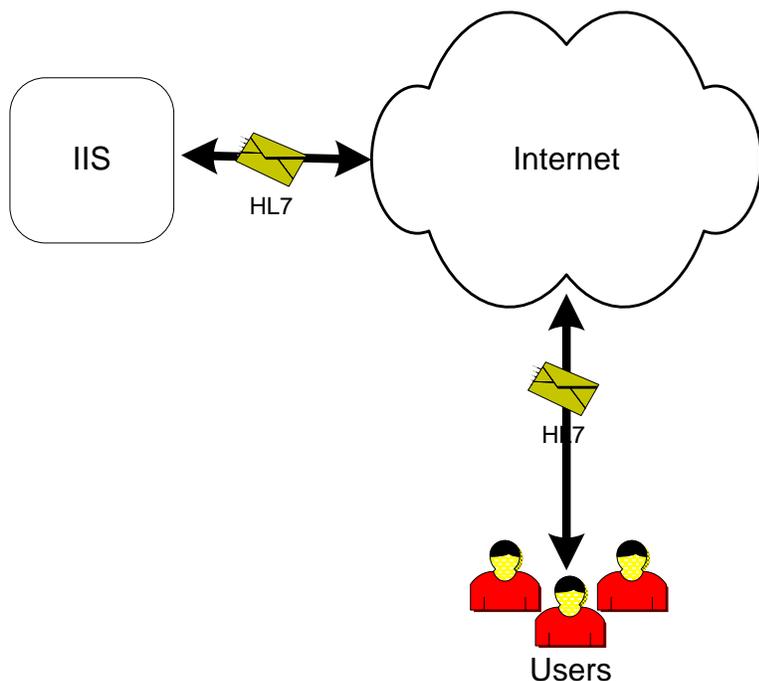
Implementation Option	Advantages	Disadvantages
<p><b>Option B:</b> Adopt New Software</p>	<ul style="list-style-type: none"> <li>👍 Removes dependency on older software, reducing costs in the long run and improving product stability</li> <li>👍 May enable smoother re-launch of CAIR through the use of a new product</li> <li>👍 Lessons learned from other states' experiences (NY, MN, MI) may reduce the risks of consolidation</li> <li>👍 Use of a product from elsewhere may lower overall support cost through leverage</li> </ul>	<p>another agency</p> <ul style="list-style-type: none"> <li>👎 May take longer to acquire and deploy compared to staying with an existing product</li> <li>👎 May be more challenging to migrate data into a completely new product</li> <li>👎 Requires re-training of users</li> <li>👎 May require choices to be made in desired functionality: different products may not function the same way the CAIR software does today</li> <li>👎 Need to budget for ongoing cost and resources for a new software and system which cannot be supported with current level of resources</li> </ul>
<p><b>Option C:</b> Use Current CAIR Software</p>	<ul style="list-style-type: none"> <li>👍 Little to no retraining of users</li> <li>👍 Quicker to implement</li> <li>👍 Easier to consolidate data into an existing database structure</li> </ul>	<ul style="list-style-type: none"> <li>👎 Continues investment in old products which must be updated to current, sustainable technology and which may not scale for statewide use</li> <li>👎 Need to train users who were not using the CAIR software</li> <li>👎 May be more challenging to bring together data from regions using other products</li> <li>👎 CA still "on its own" with a unique product</li> <li>👎 Key business requirements may not be met</li> </ul>

### 5.3.3 Alternative #3: Full Consolidation

#### 5.3.3.1 Description

This alternative is to consolidate the data from all regions, i.e., collapse the seven CAIR Software Regions and the three independent registries into one system, resulting in the creation of a single, central consolidated database and a single web-based application. Interoperability is enabled via HL7 between the one consolidated system and provider EHR systems. See Figure 5-12.

**Figure 5-12: Alternative #3: Full Consolidation**



**Legend**

IIS: Immunization Information System

HL7: Health Level Seven

### 5.3.3.1.1 Key Attributes & Software Options

Key attributes of Alternative #3 include the following:

- All regional registry databases consolidated into one central database.
- Requires agreement of independent registries, though not mandated.
- All users use the same web-based application.
- HL7 enabled between new centralized system and providers for query and submission (likely using web services and/or NwHIN Direct).

The software options for Alternative #3 are the same as for Alternative #2.

### 5.3.3.1.2 Alternative #3 Scorecards

With Alternative #3, most of the high-level requirements and objectives will be fully met with Option C, and all the high-level requirements and objectives will be fully met with Options A and B, as depicted in Figure 5-13 and Figure 5-14, respectively.

**Figure 5-13: Alternative #3: Requirements Scorecard\***

	Use Modified		Use Current
	CAIR Software	New Software	CAIR Software
State-wide consolidated records	●	●	●
Data export and analysis	●	●	⊙
Continuous operations	●	●	●
Standards-based exchange	●	●	●
Security and privacy of data	●	●	●
Support for clinical operations	●	●	●
Store required data	●	●	●
Enable Meaningful Use	●	●	●
Support HIE Core Services	●	●	⊙
Stable, well-supported technology	●	●	○

\* See Figure 4-4 for the Requirements Scorecard Legend.

**Figure 5-14: Alternative #3: Objectives Scorecard\***

	Use Modified		Use Current
	CAIR Software	New Software	CAIR Software
Objective 1/2: State-wide consolidated records	●	●	●
Objective 3: Store required data	●	●	●
Objective 4: Standards-based exchange	●	●	●
Objective 5/6: Data export and analysis	●	●	⊙
Objective 7: Support HIE Core Services	●	●	⊙
Objective 8: Stable/supportable/accessible SIIS	●	●	○

\* See Figure 5-4 for the Objectives Scorecard Legend.

### 5.3.3.2 Costs

#### Alternative #3: Option A

In reviewing Alternative #3: Option A with project decision makers and project business and information technology partners, it was deemed to be unfeasible because the independent registries are not mandated to join the consolidation, therefore warranting no cost analysis.

**Alternative #3: Option B**

Although Alternative #3: Option B was deemed to be unfeasible because the independent registries are not mandated to join the consolidation, cost analysis was performed for additional comparison with the other alternatives. The estimated one-time and continuing costs of implementing Alternative #3: Option B are identified in Table 5-14 below.

**Table 5-14: Alternative #3/Option B\* – One Time & Ongoing Expenses**

<b>ONE-TIME COST</b>	
Staff (Salaries & Benefits)	\$842,135
Software Customization	\$2,800,000
IV&V Contract Services	\$116,667
Other Contract Services &	\$1,255,000
Data Center Services	\$39,580
<b>TOTAL ONE-TIME COST</b>	<b>\$5,053,382</b>
<b>CONTINUING COST</b>	
Staff (Salaries & Benefits)	\$106,120
Contract Services	\$1,741,667
Data Center Services	\$721,806
<b>TOTAL CONTINUING COST</b>	<b>\$2,569,592</b>
<b>TOTAL PROJECT COSTS</b>	<b>\$7,622,974</b>

\* Alternative #3/Option B corresponds to the cost tables in section 8 named “Alternative #2” or “ALT (2)”.

& ‘Other Contract Services’ represents the project costs of existing CAIR Technical contract staff who will serve as subject matter experts (SMEs).

**Alternative #3: Option C**

In reviewing this Alternative #3: Option C with project decision makers and project business and information technology partners, it was deemed to be unfeasible because the independent registries are not mandated to join the consolidation, therefore warranting no cost analysis.

**5.3.3.3 Benefits**

In addition to the advantages in described in section 5.3.3.4, the benefits for Alternative #3 are the same as for Alternative #2 (see section 5.3.2.3).

**5.3.3.4 Advantages and Disadvantages**

The advantages and disadvantages common to the software options described above for Alternative #3 are listed in Table 5-15 below. Additionally, best practices from other states have

shown that the primary driver to centralize was the desire to reduce the cost of redundancy and a clear set of requirements should drive any new solution. In California’s case, this is aligned with some of the key drivers in re-examining its SIIIS strategy—budget cuts and inefficiencies due to redundancy in staff and technology across regions.

**Table 5-15: Alternative #3: Advantages/Disadvantages Common to all Software Options**

Advantages	Disadvantages
<ul style="list-style-type: none"> <li> <b>Enables the creation of a single, consolidated record which is the “gold standard”</b></li> <li> <b>Eliminates redundancy in staff and technology as there is only one statewide registry to operate</b></li> <li> Enables MU through standards-based interoperability</li> <li> Largest providers should be willing to submit data and participate</li> <li> CAIR is positioned to make use of State core services when available</li> </ul>	<p>No common disadvantages across software options</p>

Note: **Bold** in the table above indicates an advantage or disadvantage that is different from previous alternatives presented. Software options A and B for Alternative #3 meet all the requirements and objectives stated in this FSR. Alternative #3 builds off of Alternative #2 such that it is a full consolidation of data from *all* regions.

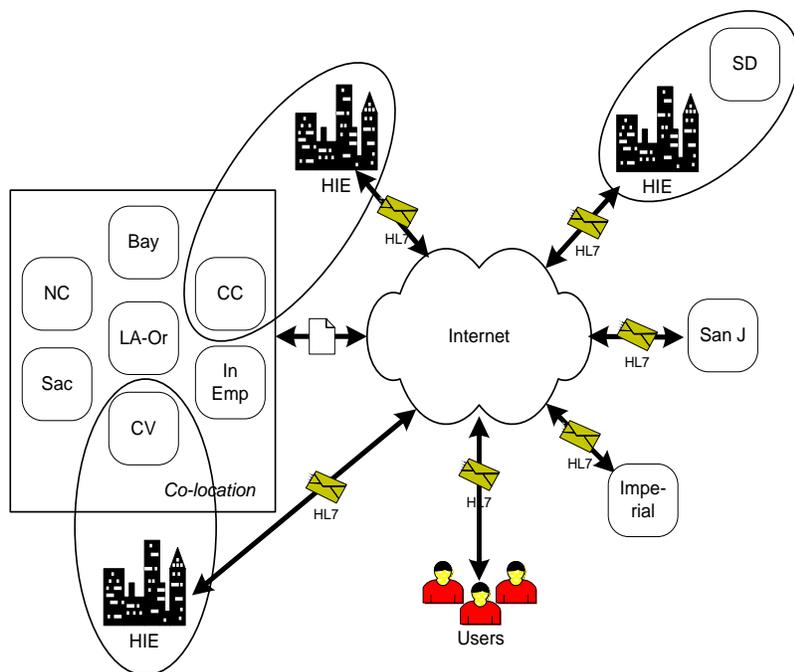
The software option advantages/disadvantages for Alternative #3 are the same as for Alternative #2 (see Table 5-13 in section 5.3.2.4).

### 5.3.4 Alternative #4: Connect through HIEs

#### 5.3.4.1 Description

This alternative is designed to leverage HIE development in the state. It is envisioned that the existing regional registries would connect to local HIEs where available. The regional registries would interoperate with the local HIEs, and then the HIEs would interoperate with one another when immunization data needs to pass between regions. The regions largely remain as-is, continuing use of their existing software which now needs to support HL7. Interoperability is enabled between the regions and providers via HL7 and is supported by the HIEs when interfaces from the registries to the HIEs are implemented. See Figure 5-15.

**Figure 5-15: Alternative #4: Connect through HIEs**



**Legend**

- |                                     |   |
|-------------------------------------|---|
| <b>NC:</b> Northern California      | <b>La-Or:</b> Los Angeles-Orange        |
| <b>Bay:</b> Bay Area                | <b>SD:</b> San Diego                    |
| <b>CC:</b> Central Coast            | <b>San J:</b> San Joaquin Valley        |
| <b>In Emp:</b> Inland Empire        | <b>Imperial:</b> Imperial County        |
| <b>CV:</b> Central Valley           | <b>HIE:</b> Health Information Exchange |
| <b>Sac:</b> Greater Sacramento Area | <b>HL7:</b> Health Level Seven          |

**5.3.4.1.1 Key Attributes**

Key attributes of Alternative #4 include the following:

- Regional registries stay in place but become connected to local HIEs where available.
- HIEs provide interoperability support between regions and with providers for query and submission via HL7.
- Current registry software products need to scale-up their HL7 capabilities.

**5.3.4.1.2 Alternative #4 Scorecards**

With Alternative #4, most of the high-level requirements will be fully met as depicted in Figure 5-16 and only some of the objectives will be met as depicted in Figure 5-17.

**Figure 5-16: Alternative #4: Requirements Scorecard\***

State-wide consolidated records	⊙
Data export and analysis	○
Continuous operations	●
Standards-based exchange	●
Security and privacy of data	●
Support for clinical operations	●
Store required data	●
Enable Meaningful Use	●
Support HIE Core Services	●
Stable, well-supported technology	○

\* See Figure 4-4 for the Requirements Scorecard Legend.

**Figure 5-17: Alternative #4: Objectives Scorecard\***

Objective 1/2: State-wide consolidated records	⊙
Objective 3: Store required data	●
Objective 4: Standards-based exchange	●
Objective 5/6: Data export and analysis	○
Objective 7: Support HIE Core Services	●
Objective 8: Stable/supportable/accessible SIIS	○

\* See Figure 5-5 for the Objectives Scorecard Legend.

### 5.3.4.2 Costs

In reviewing this alternative with project decision makers and project business and information technology partners, Alternative #4 was deemed to be unfeasible due to the dependence on HIEs which are still emerging and may not cover all geographic areas in the state, therefore warranting no cost analysis.

### 5.3.4.3 Benefits

In addition to the advantages described in section 5.3.4.4, benefits include:

- Increased completeness of records, to reduce the barrier of unknown immunization status, minimize over immunization, reduce under immunization, and enhance the efficiency and cost-effectiveness of national immunization efforts.
- Uniform data quality and data standards.
- Greater access to data by providers across regions may improve patient care.
- Expedite restorative efforts in wide-spread emergencies increasing the availability of accurate and timely data during a disaster or pandemic.
- Enable California to efficiently and promptly provide other states with immunization data on children and families displaced by disaster.
- Guide the development of the SIIS in meeting the CDC Minimum Functional Standards or core functions, for an IIS.
- Enable clinicians to easily share information with one another to provide accurate, complete, up to date immunization information on a patient.
- Enable EHR systems to query for or submit immunization information to the SIIS.

### 5.3.4.4 Advantages and Disadvantages

The advantages and disadvantages for Alternative #4 are listed in Table 5-16 below. Additionally, as a best practice, the recent national focus on HIE is worth some consideration in the statewide immunization registry planning.

**Table 5-16: Alternative #4: Advantages/Disadvantages**

Advantages	Disadvantages
<ul style="list-style-type: none"> <li> Software remains in place with the least re-training for users</li> <li> <b>Leverages distributed nature of HIE development in the state</b></li> <li> <b>Simplifies connectivity for providers by focusing on HIE interfaces – fewer connections yields lower cost</b></li> <li> <b>Promotes community data exchange</b></li> <li> <b>Incentives and investment in HIEs is supporting their development</b></li> <li> Enables MU, at least for some</li> </ul>	<ul style="list-style-type: none"> <li> Redundancy in staff and technology remains which prevents best leverage of funds as each region operates somewhat independently</li> <li> <b>Only enables interoperability for regions connected to local HIEs which do not yet cover the entire state</b></li> <li> Disparate data across regional databases preventing a single, consolidated record from being assembled without queries between HIEs</li> <li> May still discourage largest providers who want a single point of connection as they still need to work with multiple regions</li> <li> Continues investment in old products which must be updated to the current sustainable technology</li> </ul>

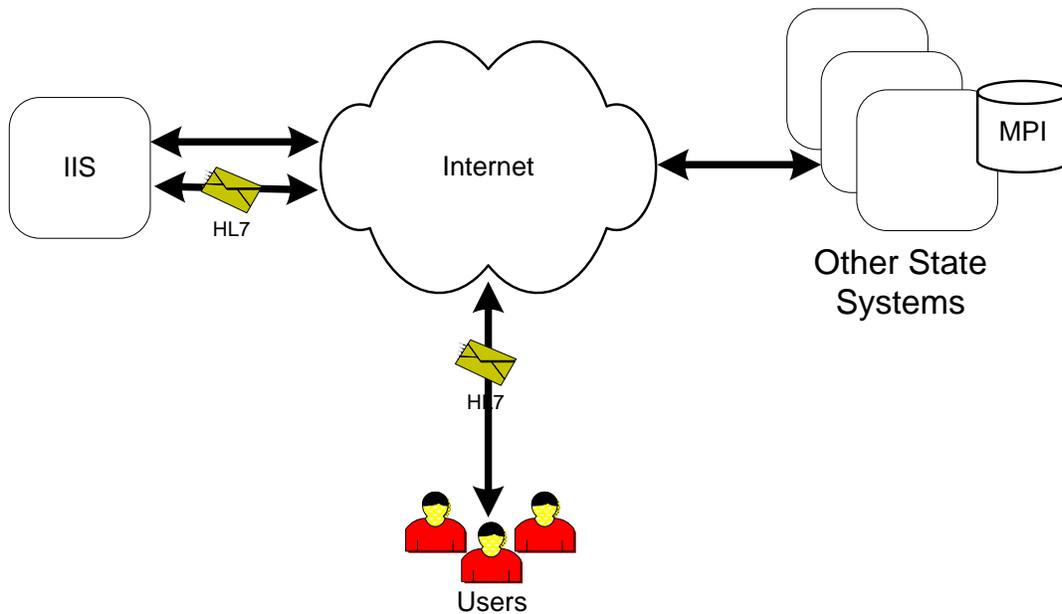
Note: **Bold** in the table above indicates an advantage or disadvantage that is different from previous alternatives presented. Alternative #4 is similar to Alternative #1 in that the regional registries stay in place with the difference in connectivity method—through HIE interfaces with Alternative #4 and through registry interoperability with Alternative #1.

## 5.3.5 Alternative #5: Expanded IIS/Integrated Systems

### 5.3.5.1 Description

This alternative is designed to embellish the IIS with other data types and functions from other State or local public health programs and is easiest/best enabled with a fully consolidated system. See Figure 5-18.

**Figure 5-18: Alternative #5: Expanded IIS/Integrated Systems**



**Legend**

**IIS:** Immunization Information System  
**MPI:** Master Patient Index  
**HL7:** Health Level Seven

**5.3.5.1.1 Key Attributes**

Key attributes of Alternative #5 include the following:

- Most feasible and easiest to enable with a fully consolidated system.
- IIS functionality enhanced by inclusion of other data and/or integration with other state and/or county systems.
- Requires strong leadership and clear vision.

**5.3.5.1.2 Alternative #5 Scorecards**

With Alternative #5, all of the high-level requirements and objectives will be fully met as depicted in Figure 5-19 and Figure 5-20, respectively.

**Figure 5-19: Alternative #5: Requirements Scorecard\***

State-wide consolidated records	●
Data export and analysis	●
Continuous operations	●
Standards-based exchange	●
Security and privacy of data	●
Support for clinical operations	●
Store required data	●
Enable Meaningful Use	●
Support HIE Core Services	●
Stable, well-supported technology	●

\* See Figure 4-4 for the Requirements Scorecard Legend.

**Figure 5-20: Alternative #5: Objectives Scorecard\***

Objective 1/2: State-wide consolidated records	●
Objective 3: Store required data	●
Objective 4: Standards-based exchange	●
Objective 5/6: Data export and analysis	●
Objective 7: Support HIE Core Services	●
Objective 8: Stable/supportable/accessible SIIS	●

\* See Figure 5-4 for the Objectives Scorecard Legend.

### 5.3.5.2 Costs

In a technical review with project business and information technology partners, Alternative #5 was deemed to be too complex and was rejected as a potential alternative for further consideration, therefore warranting no cost analysis.

### 5.3.5.3 Benefits

In addition to the advantages in described in section 5.3.5.4, the benefits for Alternative #5 are the same as for Alternative #2 (see section 5.3.2.3).

### 5.3.5.4 Advantages and Disadvantages

The advantages and disadvantages for Alternative #5 are listed in Table 5-17 below. Additionally, best practices from other states have shown that expanded IIS/integrated systems require careful planning and cooperation between programs.

**Table 5-17: Alternative #5: Advantages/Disadvantages**

Advantages	Disadvantages
<ul style="list-style-type: none"> <li> Subsumes all strengths of a full consolidation approach</li> <li> Enriches functionality of IIS with more data from other programs, potentially improving service to clients and enabling more sophisticated surveillance</li> <li> Broadens integration of data in support of Agency objectives</li> <li> Increases attractiveness of IIS for some providers as more data is available</li> </ul>	<ul style="list-style-type: none"> <li> Inter-program integration may be difficult to negotiate, especially in a time of lean financing</li> <li> May detract from IIS' main mission of Immunization Program support</li> <li> Integration may require additional software and staff investments, though functional and programmatic improvements may justify this investment</li> </ul>

## 6.0 Project Management Plan

The CDPH Immunization Branch is committed to a structured, methodical approach to project management and recognizes that this is required to ensure a successful outcome for this project. The intent of this FSR document is to secure approval and funding to initiate the procurement process and solicit vendor proposals that describe viable solutions to meet the specified needs, objectives and requirements described in this document. This section describes components of the Project Management Plan (PMP) to help ensure a successful implementation and is compliant with the State's Information Technology Project Management Methodology, the CA-PMM, managed by the Technology Agency. The Technology Agency website is [California Technology Agency](#).

After the project has been approved, the PM will develop a PMP for review and approval by the Steering Committee. The plan will describe the project schedule and the methods and approaches to be taken for project management activities, including change management, quality control, human resources, communications, and risk management. Plans requested and submitted by the vendor will follow a standard deliverable review/acceptance process.

### 6.1 Project Manager Qualifications

Leveraging the CA-PMM Complexity Assessment Toolkit, the project characteristics of complexity/risk, duration, budget, and team size are evaluated to determine the recommended PM skill set and level of oversight appropriate for the project. A qualified experienced PM is critical to the success of any project, and it is envisioned that this project's complexity and risk levels will warrant an experienced PM, assigned by the Planning and Project Management Branch (PPMB), working collaboratively with a Design, Development & Implementation (DD&I) lead, identified by the selected Project Implementation Vendor, and a Business Lead and Technical Lead assigned by DCDC.

Understanding the project's complexity helps in assembling the right sponsors, project leadership and team and provides the measure of oversight required for the project. This project's complexity scores, provided in Table 6-1 below, identify a level two PM and warrant assessment of complexity be done periodically every two to three months and/or at the conclusion of each phase of the project.

The following table indicates the complexity scores for this project. The Complexity Assessment detail can be found in Appendix C of this document.

**Table 6-1: Complexity Scores**

Business Complexity:	<b>2.4</b>	Technical Complexity:	<b>2.8</b>
Project Zone (Oversight Required on Zone IV):		<input type="checkbox"/> I <input checked="" type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV	
PM Skill Set Level Recommendation based on CA-PMM:		<b>PM Level 2</b>	

Consistent and professional project management techniques and policies are necessary to complete this project. The PPMB-Project Management Office (PMO), in collaboration with the CDPH Immunization Branch, will assign a well-qualified state PM to the project. The PM will be responsible for managing the project schedule, budget, quality, scope, assessing deliverables, tracking issues, managing risks and confirming that the appropriate Immunization Branch staff

members and resources are involved with the project. To assure project success, the PM will have proven experience planning and managing California IT projects of equivalent scope and complexity.

The assigned PM will have, at a minimum, the qualifications required by the CA-PMM for a level II PM:

- Experience: Three to five years as a key team member on a medium or large IT project or as a Project Manager on a small or medium IT project. Technical experience commensurate with the proposed technology.
- Professional Knowledge: Strong working knowledge of the CA-PMM, department's methodology, SDLC. Familiar with CA Budgeting, Procurement, and Contracting processes.

## 6.2 Project Management Methodology

The PM will adhere to the following guidelines:

1. CA-PMM, SIMM Section 17.
2. The recommended project management and risk management practices from the State's IT Project Oversight Framework, SIMM Section 45.
3. The Project Management Body of Knowledge (PMBOK), latest edition, from the PMI.

The CA-PMM provides an approach to successfully manage the challenges of IT systems implementation. These management challenges arise from such factors as the complexity of the core business, specific customer needs, technology alternatives, and scarce resources. CA-PMM project management process groups or stages include project Concept, Initiating, Planning, Executing, and Closing. Monitoring and controlling occur throughout the project. After the Closing stage, maintenance and operations (M&O) are included to round out the full life cycle of a project.

Within each stage, the project work plan, risk management plan, communication plan, and contracts must be carefully monitored to mitigate changes to project scope, budget, and resource requirements. Adhering to a sound project management methodology at each stage of the project – from planning to evaluation – ensures that the project will achieve desired business outcomes, meet end-user expectations, and conclude on schedule and within budget.

The specific project management activities will include:

- Project Planning
- Execution, Management and Governance
- Change Control
- Resource Allocation
- Project Reporting – of progress made with project phases, milestones, and scheduled tasks
- Product Review and Approval – identifying acceptance criteria
- Project Evaluation and other Closeout Activities

The PM will develop project management deliverables, including the Project Charter and the PMP and will provide written status reports regularly to the Executive Sponsor and Steering

Committee. The PM will, at a minimum, implement the required project management practices specified in SIMM 17 and 45 for reportable projects and will be responsible for the following tasks:

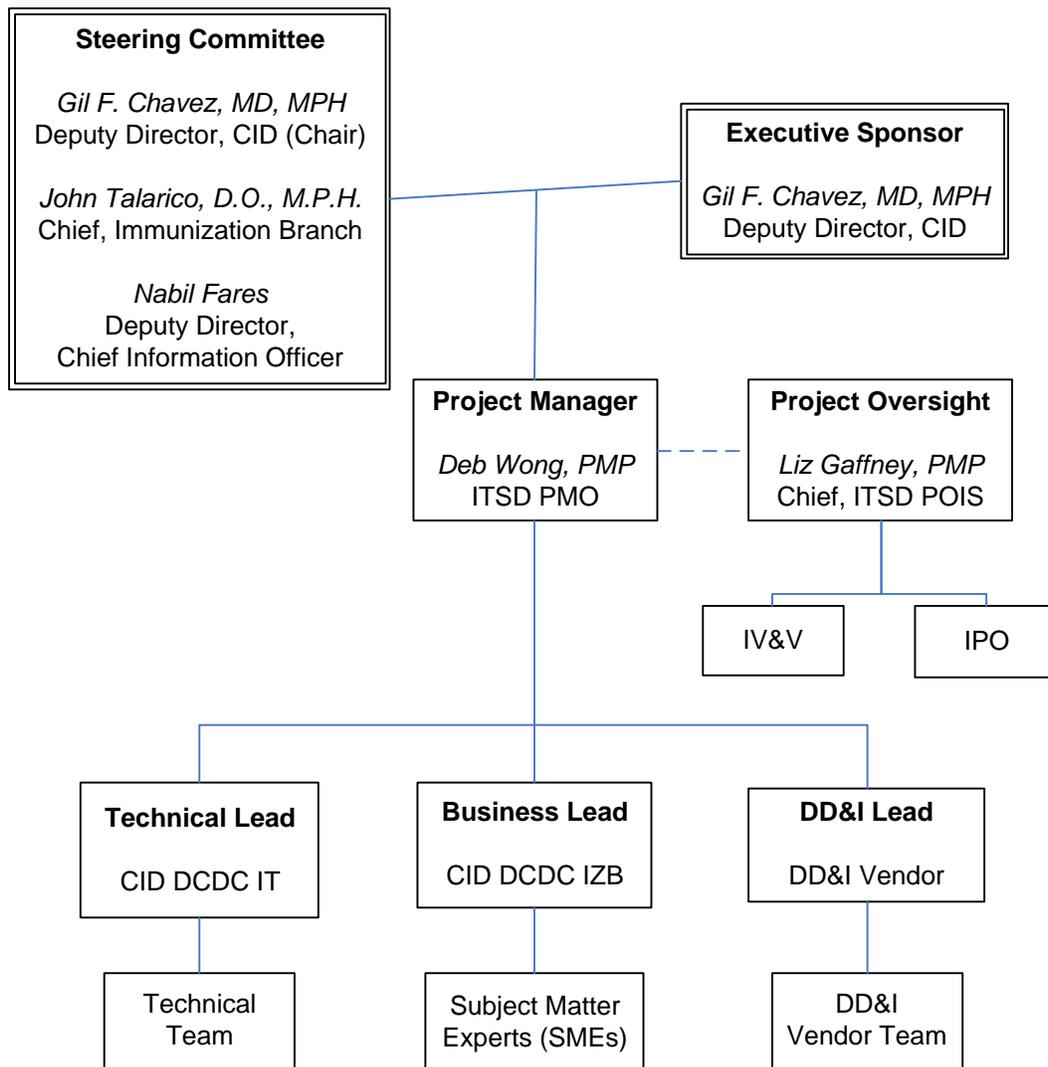
- Developing and maintaining the Project Charter to be approved by the Steering Committee and Project Sponsor. The Charter defines project goals and objectives, roles and responsibilities, scope, high-level milestones and deliverables and gives the PM the authority to initiate the project.
- Developing and maintaining a detailed PMP.
- Developing and maintaining a detailed project schedule, to be approved by the Steering Committee. The project schedule defines the phases, activities, timeframe, resources, dependencies, milestones and deliverables, and monitors planned versus actual performance.
- Maintaining and managing the approved project budget.
- Performing resource, quality, and configuration planning and management.
- Utilizing rigorous issue management, risk management, and change management processes.
- Developing monthly project status reports.
- Identifying and documenting successful system implementation criteria.
- Utilizing a predefined structured governance approach to review and obtain approval of project deliverables.
- Conducting ongoing performance reviews and taking corrective actions as needed.

Additional project management activities are described in section 6.5.3, Project Team Roles and Responsibilities.

## **6.3 Project Organization**

This section describes the Project Team and Oversight Organization. The following figure represents the project structure to be refined once the Project Implementation Vendor and solution are selected. A description of the Project Team roles and responsibilities is provided in section 6.5.3, Project Team Roles and Responsibilities.

Figure 6-1: Project Team Structure



## 6.4 Project Priorities

All projects have three components that must be managed:

- Schedule
- Scope
- Resources

Each of these is interrelated; a change in any one component will almost certainly impact the others. Prior to beginning the project, it is important to determine the relative importance and flexibility of each. The terminology used is defined as:

- **Improved:** The component is most flexible, and will probably change if needed.
- **Constrained:** The component is least flexible, and is least likely to change.
- **Accepted:** The component is somewhat flexible, and may change somewhat if needed.

The following table below represents the trade-off matrix for the project schedule, scope, and resources.

**Table 6-2: Project Trade-off Matrix**

Schedule	Scope	Resources
Accepted	Improved	Constrained

## 6.5 Project Planning

During the Planning stage of the project, the PM will develop a PMP. The PMP includes the following key subsidiary plans:

- Scope Management Plan
- Configuration/Change Control Plan
- Resource Management Plan
- Communication Plan
- Risk Management Plan
- Cost Management Plan
- Quality Management Plan
- Schedule Management Plan
- Procurement Plan
- Contract Management Plan
- Organization Change Management Plan
- Maintenance and Operations (M&O) Transition Plan

The PMP helps ensure the timely and successful completion of the project goals and objectives through the definition of the activities and resources required to accomplish them and the means used to perform them. The project plan defines each major task, estimates the time and resources required and provides a framework for tracking, monitoring, and reporting the progress to goals.

### 6.5.1 Scope Management Plan

Scope Management is a means to ensure the project design is followed and a formal process is undertaken when changes are necessary. The high-level requirements described in this document provide the basic scope of the project. The Scope Management Plan in the PMP defines the processes and procedures to manage the scope of the project and effect changes in the scope using a structured change control process. Scope management processes will include:

- Verify and confirm the business and functional requirements of the project at each successive project stage.
- Analyze impact of changes to the project scope and manage such changes through a standardized approved change control process.
- Manage vendor contracts in accordance to the vendor contract specifications and State policy.
- Continuously evaluate project scope against time, cost, functionality and requirements.

The scope of this project will consist of the activities required to address the functional requirements listed in Section 3.4, Business Functional Requirements, including:

- Procuring vendor services for:
  - IV&V
  - DD&I Services for solution implementation.
- Performing detailed business requirements analysis.
- Performing data migration from the current system and databases, as necessary.
- Providing Project Oversight (PO).
- Performing unit, system, and user acceptance testing.
- Providing system and user documentation.
- Performing training and knowledge transfer to users, maintenance, and support staff.
- Providing a specified period of maintenance and operation support as needed.

## 6.5.2 Configuration/Change Control Plan

Effective configuration management requires an effective and well-defined configuration management organization. The configuration management organization is responsible for:

- Defining who will be responsible for and have authority over configuration management.
- Setting standards, procedures and guidelines for the full project team to follow.
- Defining tools, resources and facilities to be used for configuration management.
- The detailed configuration/change control management information represented as a summary in the PMP.

Change is an inevitable occurrence in any project. A change is defined as any alteration to the scope of the project including direction, requirements, hardware, software, application, network, operations or environment that adds to, deletes from, or in any way modifies the scope of work. In order to effectively manage change for this project, a Change Management Plan will define the process, procedures, and outputs for all change-related project activities. The plan will identify the parties responsible for identifying, resolving, supporting, approving, making, tracking, and reporting project changes. The major goal of this change management strategy is to ensure changes are made using a standardized consistent methodology and procedures that minimize negative impacts and maximize positive impacts to the requirements, design, development, implementation, and maintenance of the system.

The change management process will define the processes and procedures for reporting an identified need for change; how the change request will be analyzed and documented; how the change will be acted upon for review, approval or denial; and, how the change will be incorporated into the PMP. The plan is designed to:

- Minimize project risk.
- Provide documentation for all changes.
- Minimize disruption to the project due to rework.
- Measure project volatility.
- Provide open disclosure of changes.
- Communicate changes and status of changes to stakeholders.
- Maximize system/application value.
- Minimize unanticipated impacts to schedule and/or budget.

The implementation of a change management plan ensures that all changes are evaluated for potential scope, cost, and schedule impacts. The process allows decision-makers the opportunity to evaluate changes in a systematic manner that becomes a component of the overall project risk management strategy. Without a method for evaluating, prioritizing, and implementing changes, schedule delays, poorly defined requirements and/or cost overruns are potential results for any system development effort. Alternatively, a well-defined and properly utilized change management process reduces risk and increases the likelihood of project success.

The change management process for the project will provide a mechanism for the review and approval of changes or additions to the scope, requirements, or design of the various systems. This process will allow the Immunization Branch, ITSD, and the Project Implementation Vendor to jointly discuss, review, prioritize and approve changes to requirements and design through all phases of the project. Changes impacting the hosting environment will be coordinated and scheduled through ITSD's change management process and tools.

The change management process will track all proposed changes to the system software and hardware. All requested changes will be analyzed with respect to cost and benefit. Change requests that have received recommended approvals from the project manager will be presented to a Change Control Board (CCB) for approval. This process ensures that changes are documented and applied in a controlled manner with participation from relevant project stakeholders from initiation through closure.

CCB approved changes will be included in an updated and approved schedule and assigned to the responsible party for execution. Project documentation will be updated in accordance with the approved document management process and the initial request and approval will be logged and stored in the project repository for reference.

### **6.5.3 Human Resource Plan**

Human Resource Planning or Resource Management is a critical component of the PMP. Identifying the key activities and tasks, the skill sets required to complete the tasks, the duration – length of time the resources will be needed and allocation – the percentage of their time needed to complete the tasks, will ensure the commitment of having the right people in the right role and identify any gaps in personnel.

For this project, it is envisioned that personnel resources from the Immunization Branch and ITSD will be involved in various activities of the project phases including, but not limited to: business requirements analysis, technical requirements analysis, acceptance testing and training, but it is also expected that key project team members will be contracted through a procurement process and subsequently engaged through the selection of a Project Implementation Vendor.

To ensure an understanding of the various roles and responsibilities of the primary project participants, they have been outlined in Table 6-3 below.

**Table 6-3: Project Team Roles & Responsibilities**

ROLE	RESPONSIBILITIES	REPRESENTATIVE
Executive Sponsor	<ul style="list-style-type: none"> <li>• Ensures an appropriately skilled PM, Technical Lead, and Business Lead are assigned to the project. Appraises the performance of the PM, Technical Lead, and Business Lead as needed.</li> <li>• Approves Project Charter and PMP.</li> <li>• Champions the project.</li> <li>• Commits time and political capital to the project.</li> <li>• Empowers the PM with the appropriate authority.</li> <li>• Owns the project and ensures sustained buy-in at all levels.</li> <li>• Ensures timely availability of needed resources including administrative support.</li> <li>• Follows up to ensure that targeted benefits are realized.</li> <li>• Approves the goals, scope, schedule, and budget for the project and significant changes to them.</li> <li>• Keeps informed about project status.</li> <li>• Guides project through and minimizes the political minefields.</li> <li>• Provides feedback on performance vs. expectations.</li> <li>• Provides direction and guidance for key organizational strategies.</li> <li>• Resolves strategic and major issues and makes major decisions.</li> <li>• Shields project teams from unrealistic customer demands.</li> <li>• Understands project complexity.</li> </ul>	Deputy Director, CID
Steering Committee	<ul style="list-style-type: none"> <li>• Assists with prioritizing and resolving business priorities related to the project.</li> <li>• Provides advice and leadership regarding consistency with Program-wide strategies, direction, and policies. Provides advice and recommendations to Executive Sponsor and project team.</li> <li>• Participates as a member of the CCB.</li> <li>• Publicly supports the project by communicating the project's goals and objectives and working to reduce barriers and mitigate risk.</li> <li>• Allocates and commits project resources for duration of project.</li> <li>• Makes major decisions and resolves issues and disputes regarding scope, cost, schedule, and quality that could not be resolved at lower levels.</li> <li>• Facilitates communication and decision-making across organizational lines.</li> </ul>	Deputy Director, CID Chief, Immunization Branch (IZB) Chief Information Officer

ROLE	RESPONSIBILITIES	REPRESENTATIVE
PM	<ul style="list-style-type: none"> <li>• Complies with State, CDPH, and PPMB project management processes, procedures, standards, and best practices.</li> <li>• Accountable to the Executive Sponsor and PPMB for all project management related activities.</li> <li>• Determines the appropriate project structure and governance model is used based on the size and complexity of project.</li> <li>• Prepares the Project Charter and obtains approval from the PPMB, Executive Sponsor, and Steering Committee.</li> <li>• Identifies and plans for milestones, deliverables, and functionality to be achieved as defined in the Project Charter and subsequent project plans.</li> <li>• Plans the project and prepares the PMP. Coordinates and manages inputs to the project plan. Obtains approval from the Executive Sponsor and Steering Committee.</li> <li>• Develops and/or coordinates the development of the master project schedule and other project work schedules. Identifies and manages dependencies and risks in the project schedule.</li> <li>• Identifies and acquires resources needed for the project and ensures resources assigned to the project are effectively managed according to the schedule and plan.</li> <li>• Tracks progress against the project schedule. Tracks progress on contractor's schedules.</li> <li>• Creates processes for quality assurance and ensures that they are present and executed on the project.</li> <li>• Escalates decisions and issues as needed to the Steering Committee and Executive Sponsor.</li> <li>• Manages risks and risk mitigation/contingencies on the project. Leads risk identification sessions for the project.</li> <li>• Administers the deliverable review and approval process.</li> <li>• Plans, guides, and oversees the day-to-day activities that support the project. Fosters communication across the project. Organizes and facilitates project team meetings. Prepares and distributes status reports as required in the Project Plan.</li> <li>• Monitors and manages the defined project scope, cost, quality, and schedule during the course of the project.</li> <li>• Oversees and coordinates the change request process and ensures that change requests adhere to specified quality and configuration standards.</li> <li>• Leads and manages implementation of the project solution including planning, organizing, coordinating, and monitoring implementation activities.</li> <li>• Oversees management of the project and verifies that sound project management principles and processes are used to achieve project success.</li> <li>• Develops and maintains all project management related</li> </ul>	ITSD PMO

ROLE	RESPONSIBILITIES	REPRESENTATIVE
	<p>documents including the Project Charter, Project Plan, and schedule.</p> <ul style="list-style-type: none"> <li>• Ensures that milestones, deliverables and functionality are achieved as defined in the Project Charter and project plans.</li> <li>• Identifies and resolves issues and risks. Escalates decisions and issues to Steering Committee and Executive Sponsor as needed.</li> <li>• Coordinates project related issues with other efforts and projects.</li> <li>• Ensures that effective quality control and assurance processes are used in the project.</li> <li>• Coordinates high-level risk management activities for risks that cross project boundaries or are beyond the project's control.</li> <li>• Serves as the primary liaison of the project to the Executive Sponsor and Steering Committee.</li> <li>• Manages development of vendor solicitation and procurement documents.</li> <li>• Integrates procurement activities for the project. Ensures consistency and continuity throughout the procurement process and conformity to procurement standards, rules, and regulations.</li> <li>• Prepares and maintains the Procurement Plan.</li> <li>• Manages evaluation of vendor proposals or offers and the selection of vendors. Coordinates contract negotiations.</li> <li>• Manages the preparation of procurement documents.</li> <li>• Acts as the principle interface to contractors. Manages and tracks contracts.</li> <li>• Negotiates contract amendments, reviews work authorizations and invoices, and ensures that all contractual terms and deliverables are met.</li> </ul>	
<p>Technical Lead</p>	<ul style="list-style-type: none"> <li>• Manages the technical discipline of the project.</li> <li>• Provides technical direction to the PM, project team members and others to establish and execute the technical standards, policies, processes, and procedures needed for the project.</li> <li>• Partners with IT managers to acquire appropriate technical assistance needed for the design, development, testing, implementation and support of the new system.</li> <li>• Provides leadership and support to technical staff that are assigned to the project. Interfaces directly with project team members, including contractors, to ensure technical obligations satisfy all objectives and expectations. Responsible for the day-to-day activities of technical staff who are engaged in the technical aspects of the project.</li> <li>• Manages application design sessions and walkthroughs.</li> <li>• Monitors application development and support and ensures</li> </ul>	<p>DCDC IT Manager</p>

ROLE	RESPONSIBILITIES	REPRESENTATIVE
	<p>that quality control is maintained.</p> <ul style="list-style-type: none"> <li>• Prepares and implements test plans and processes and monitors, supports, and evaluates testing activities.</li> <li>• Coordinates the testing of the system, including any system developed by a contractor.</li> <li>• Coordinates interface tests with other organizations as needed.</li> <li>• Works with testing and program staff to design test cases and data that will best represent "real-life" scenarios for the system.</li> <li>• Maintains and updates the requirements document during the design, development, implementation, and operations stages.</li> <li>• Administers the configuration management process for the system. Coordinates and controls the system configuration. Maintains and updates system configuration documentation.</li> <li>• Coordinates and oversees the maintenance and operations of the new system. Manages resolution of system and operations support problems.</li> <li>• Monitors system service levels and metrics.</li> <li>• Manages application change management processes and acceptance testing of application changes.</li> <li>• Works with stakeholders for approval to release programs and configuration modifications into production.</li> <li>• Assists the customer with special requests or problems.</li> <li>• Participates in the procurement process to secure an implementation vendor and to ensure that the selected vendor and its approach meets project and State technical standards.</li> </ul>	
Internal IT Technical Support	<ul style="list-style-type: none"> <li>• Participates in the procurement process to secure a project implementation vendor and to ensure that the selected vendor and its approach meets project technical standards.</li> <li>• Supports the PM in managing tasks and resources in the project work plan related to technical requirements and ITSD staff involvement.</li> <li>• Assists the PM in providing assessment and evaluation of the project from a technical perspective, to identify and mitigate program risks.</li> <li>• Assists the PM in tracking technical project risks, issues, and change management requirements.</li> <li>• Assists the PM in reviewing technical deliverables from the project implementation vendor.</li> <li>• Assists in developing test cases for user acceptance testing.</li> <li>• Supports subject matter experts (SMEs) to ensure appropriate and complete system and acceptance testing.</li> <li>• Assist the PM in defining project success criteria.</li> </ul>	DCDC IT, ITSD

ROLE	RESPONSIBILITIES	REPRESENTATIVE
	<ul style="list-style-type: none"> <li>• Updates the Operational Recovery Plan (ORP).</li> <li>• Participates in training, knowledge transfers, and transition.</li> </ul>	
Business Lead	<ul style="list-style-type: none"> <li>• Coordinates and ensures that business organizational, policy, and procedure changes are developed and implemented according to the project schedule.</li> <li>• Ensures business requirements are comprehensive and approved by business stakeholders.</li> <li>• Coordinates and ensures that SMEs are engaged appropriately and timely.</li> <li>• Provides the customer perspective. Prioritizes problems and issues.</li> <li>• Responsible for the day-to-day activities of the business program staff who are engaged in the program aspects of the project.</li> <li>• Ensures that appropriate resources are engaged for User Acceptance Testing and Product Acceptance.</li> <li>• Participate in the project implementation vendor procurement process to help ensure that the selected vendor and its proposed approach best meet the needs of program stakeholders.</li> </ul>	IZB
SMEs	<ul style="list-style-type: none"> <li>• Ensure that relevant program staff are identified and involved in the project solution functional requirements definition, acceptance testing, and training.</li> <li>• Help the PM to identify and track program project issues and risks, as well as change management requirements.</li> <li>• Provide assessment and evaluation of the project from a business perspective to mitigate program risks.</li> <li>• Assist in the identification of information requirements impacted by the project solution and develop new business rules to ensure data quality.</li> <li>• Assist in the identification and validation of business functional requirements and process flows impacted by the project solution implementation.</li> <li>• Assist the project implementation vendor in defining functional and technical requirements.</li> <li>• Assist in establishing process targets and key performance indicators for the project solution user acceptance criteria.</li> <li>• Perform user acceptance testing, including development of test process flow cases and testing of the solution.</li> <li>• Assist in developing training materials by identifying specific training needs.</li> <li>• Define success criteria for system implementation.</li> <li>• Participate in lessons learned sessions.</li> <li>• Review vendor deliverables to ensure program needs are met.</li> <li>• Monitor process metrics and ongoing user acceptance issues.</li> </ul>	SMEs from the IZB and other stakeholders

ROLE	RESPONSIBILITIES	REPRESENTATIVE
	<ul style="list-style-type: none"> <li>• Recommend functional improvements involving process and/or system changes.</li> <li>• Review and sign-off to accept project deliverables.</li> </ul>	
DD&I Lead	<ul style="list-style-type: none"> <li>• Develop a detailed work breakdown structure (WBS) for project tasks of the projects requirements to be reviewed and approved by the PM.</li> <li>• Validate and implement the project solution according to the documented functional and technical requirements in the RFP.</li> <li>• Coordinate task scheduling with the PM.</li> <li>• Identify current process functions and sub-functions to be in the scope of the project solution.</li> <li>• Work with the IZB to establish process targets and key performance indicators for use as solution acceptance criteria.</li> <li>• Consult with ITSD on system technology architecture.</li> <li>• Develop the technical project tasks and resource requirements for project plans.</li> <li>• Maintain an integrated technical development project schedule managed by the PM</li> <li>• Perform walkthroughs of prototypes with stakeholders.</li> <li>• Perform and assist in functional team training, unit testing, system testing, and UAT until system is accepted by the IZB.</li> <li>• Provide weekly updates on project status.</li> <li>• Ensure CDPH and State technical standards and requirements are followed.</li> <li>• Manage project implementation vendor team resources and assignments, and adhere to the detailed work plan approved by the PM and Steering Committee.</li> <li>• Assist in identifying potential risks and issues related to the project solution and report these to the PM.</li> <li>• Monitor the development and testing of deliverables according to the project quality assurance plan.</li> <li>• Provide user manuals and systems documentation.</li> <li>• Develop training materials and conduct training to ensure smooth system transition.</li> <li>• Participate in the Steering Committee as needed.</li> </ul>	Project Implementation Vendor

IV&V	<ul style="list-style-type: none"> <li>• Serves as an independent expert to provide oversight and recommendations for technical activities critical to the project's success.</li> <li>• Evaluates technical products of the project to ensure that each product satisfies the requirements levied on it, and that the final result of the project will meet the objectives and requirements described in section 3 of this FSR.</li> <li>• Provides an independent, unbiased assessment of the technical aspects of the project to the PM and Steering Committee.</li> <li>• Develops and maintains the project Requirements Traceability Matrix.</li> <li>• Independently identifies and evaluates technical risks.</li> <li>• Prepares monthly IV&amp;V reports.</li> <li>• Oversees the project in accordance with (Institute of Electrical and Electronic Engineers – IEEE) standard 1012-2004, tailored as appropriate for the project.</li> <li>• Validates system requirements adhere to CDPH IT standards.</li> </ul>	ITSD Project Oversight and Initiation Section (POIS)
Independent Project Oversight (IPO)	<ul style="list-style-type: none"> <li>• Provides adherence to SIMM 45, IT Project Oversight Framework.</li> </ul>	ITSD POIS

### 6.5.4 Communication Management Plan

The Immunization Branch recognizes that open project communication between stakeholders is critical to the success of the project and plans to incorporate best practices for developing the communication management strategy for the project. This will include the processes required to ensure timely and appropriate generation, collection, dissemination, storage, and ultimate disposition of project information. The PM will ensure compliance in implementing, at a minimum, project communication activities and strategies in alignment with the State's IT Project Oversight Framework.

The PM will use existing forums and planned methods of exchanging information both within the project team and to stakeholders and interested parties outside of the project. This will ensure effective communications of a consistent message and information among control agencies, project team members, and internal and external stakeholders. Critical elements of the project communication strategy include the following:

- Communication Planning
- Issue and Action Item Tracking
- Issue Resolution
- Escalation Process
- Problem/Defect Tracking
- Status Reporting
- Vendor Deliverable Reviews

The PM will communicate with the project stakeholders continuously throughout the project to help ensure the ultimate success of the project.

### **6.5.5 Risk Management Plan**

The Risk management Plan is described in section 7 of this FSR document.

### **6.5.6 Cost Management Plan**

Cost management includes the processes involved in planning, estimating, budgeting, and controlling costs so that the project can be completed within the approved budget.<sup>80</sup>

The project budget will be continually tracked during the life of the project. The budget will show the approved baseline cost, actual expenditures against the baseline cost, and the remaining balance in each cost category.

The project expenditures cannot be allowed to exceed the approved baseline cost estimate without approval from the Executive Sponsor (if expenditures exceed ten percent of the original estimate) or through the CDPH budgetary process.

If project costs change by ten percent or more, the variance will be reported to Technology Agency via a SPR for approval.

The PM must track the costs of all resources required to complete all project activities. The PM and stakeholders are challenged to look at the whole picture and take a broader view of the project life cycle and not just the development efforts. Cost reductions in development may equal greater costs in either operations or maintenance, thereby reducing the project's overall value to the organization. This highlights the critical nature of considering all stakeholders in estimating, budgeting, and controlling the project costs.

### **6.5.7 Quality Management Plan**

Quality Management planning is the process of identifying which quality standards are relevant to the project and determining how to satisfy them. Fundamentally, quality and quality management are planned, designed, and incorporated within the process and not added as an afterthought.<sup>81</sup> No amount of inspection – after a product is produced – can put quality into a product. In order to have a quality product, a test plan and approach will be developed to include systems and business test activities. Quality planning, assurance, and control apply to both the product and the project management components of the project.

### **6.5.8 Schedule Management Plan**

The Schedule Management Plan establishes how the project schedule will be managed and controlled. Estimating the duration of activities is the principal work. Activity duration estimating

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<sup>80</sup> *A Guide to the Project Management Body of Knowledge*, Third Edition, (Pennsylvania: Project Management Institute, Inc. 2004)158.

<sup>81</sup> *Ibid.*, p.183-184.

is the process of “estimating the number of work periods that will be needed to complete individual schedule activities”<sup>82</sup>. Number of periods refers to the hours, days, or weeks that it will take to perform the activity, taking into account elapsed time. The purpose for duration estimating is to develop an approximation of time (usually expressed in a range of time) and an understanding of the magnitude of the effort.

The purpose of the Schedule Management Plan is to provide for the timely completion of the project activities that meet the business needs, objectives, and requirements. The initial sections of the Schedule Management Plan describe what tool is going to be used to manage the schedule, how a baseline schedule will be established, how often the schedule will be updated, how changes to the schedule will be proposed, approved and communicated, and how and where the schedule will be kept.

The following project schedule includes the major milestones associated with this project to be refined further once the Project Implementation Vendor and solution are selected.

**Table 6-4: High-Level Project Schedule**

<b>Project Activities</b> Major Milestones shown in Shaded Cells.		<b>Planned Start Date</b>	<b>Planned Completion Date</b>
<b>STAGE I: INITIATION AND PLANNING</b>			
		<b>Project Start</b>	<b>December 2012</b>
1	Create Project Charter / Project Management Plan	December 2012	January 2013
<b>STAGE II: EXECUTION</b>			
<b>PROCUREMENT</b>			
2	Solicitation Document Preparation		May 2013
3	Conduct Solicitation		September 2013
4	Evaluate Responses		December 2013
5	Acquisition Approval		March 2014
<b>Vendor On-Board</b>		<b>April 2014</b>	
<b>ANALYSIS &amp; DESIGN</b>			
7	Requirements Gathering and Analysis	April 2014	July 2014
<b>Requirements Specifications Complete</b>		<b>July 2014</b>	
8	Design Documentation Process: General Design, Architectural Diagram, and Detail Design	August 2014	October 2014
<b>Design Documents Complete</b>		<b>October 2014</b>	

<sup>82</sup> Ibid., p. 359.

<b>BUILD</b>			
9	Hosting Configuration and Deployment: Submit Service Requests and Establish Hosting Environment	October 2014	December 2014
10	Application Program Build/Configuration	January 2015	April 2015
<b>System Build Complete</b>		<b>April 2015</b>	
<b>TEST</b>			
11	Integration and System Testing	May 2015	June 2015
<b>System Testing Complete</b>		<b>June 2015</b>	
12	User Acceptance Testing	July 2015	September 2015
<b>User Acceptance Testing Complete</b>		<b>September 2015</b>	
<b>TRAIN</b>			
13	User Training / Knowledge Transfer	October 2015	November 2015
<b>Training Complete</b>		<b>November 2015</b>	
<b>IMPLEMENT</b>			
14	Data Migration	July 2015	September 2015
15	Transition to Maintenance & Operation	October 2015	November 2015
<b>System Go Live</b>		<b>November 2015</b>	
<b>STAGE III: CLOSE OUT</b>			
<b>Formal Product Acceptance</b>			
16	Administrative / Contract Closure	November 2015	November 2015
17	Conduct "Lessons Learned"	November 2015	November 2015
18	Decommission Old System	November 2015	November 2015
19	Product Acceptance	November 2015	November 2015
<b>Project Complete</b>		<b>November 2015</b>	
20	Prepare and Submit Post Implementation Evaluation Report (PIER)	November 2015	November 2016
<b>PIER</b>		<b>November 2016</b>	

### 6.5.9 Procurement Management Plan

The project will utilize a competitive RFP procurement process for the Project Implementation Vendor. The contract will be a fixed price, deliverables based contract. The State will pay the vendor for deliverables identified in the contract upon completion and State approval of those deliverables.

The project will utilize a RFO process, soliciting firms on the California IT CMAS or IT Multiple Service Award (MSA) contract lists to acquire any additional vendor services as needed such as IV and V.

The Procurement Plan involves determining which project needs can best be met by purchasing or acquiring products, services, or results outside the project organization and which project needs can be accomplished by the project team during project execution. It is during this process that “make or buy” decisions are made and includes the following:

- A determination of what is required to meet the needs.
- A review of the associated risks.
- Whether or not it should be purchased.
- Consideration of potential sellers.
- How much is required.
- When it needs to be acquired.
- What type of contract is best suited?

Specific components of the Procurement Plan include:

- Process to contract with vendors.
- Acquisition Plan.
- Category – Hardware, Software, Other.
- Item – the item being purchased.
- Approximate cost of the item being purchased.
- The type of solicitation instrument being used.
- The type of procurement being used (CMAS, MSA, etc.).
- The reasoning behind the choice of procurement type.
- A list of any known vendors who can provide the goods or services.
- The WBS ID# for the item being purchased.
- The date by which procurement approval must be received.

### **6.5.10 Contract Management Plan**

The Contract Management Plan documents the products, services, and results requirements needed to meet a project’s objectives<sup>83</sup>. The following components will be included in the Contract Management Plan:

- Location of contract documents
- Performance Monitory Process
- Deficiencies/Disputes Management
- Status and Progress Reporting Process
- Contractor Staffing Monitoring Process
- Contractor Staff Replacement Process
- Invoice Processing
- Invoice Metrics
- Contract Amendment Process
- Closing Process
- Final Work Products
- Contractor Performance Review
- Final Invoice Processing

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<sup>83</sup> Ibid., p.290.

- Contract Records Archive

### **6.5.11 Organizational Change Management Plan**

Projects by their very nature generate changes in an organization – from a people, process, and/or technology perspective. A project that has been approved, even with a strong champion, does not mean there will be no resistance within the organization.

The Change Management Plan dovetails with the Communication Management Plan and stakeholder analysis. Identified stakeholders are assessed in terms of their awareness of the project, the influence they can exert, determination of any resistance or concerns they may have, identification of optimum communication, and a summary of actions to be taken.

Time spent proactively making the case for change to an organization – understanding how various stakeholders will be impacted by the change being introduced and identifying ways to ease their transition, will significantly reduce resistance and risks. Stakeholders with little resistance to the change may be good change agent candidates.

Resistors of change must be prioritized. Every effort must be made to understand the sources of their resistance. Articulating a strategy and identifying best channels of communication for resistors is at the heart of the organizational change management.

### **6.5.12 Maintenance and Operations (M&O) Transition Plan**

Projects must include a plan for how they will be transitioned to the operation team that will ultimately own the new system. Projects enter maintenance and operations when the new system is implemented into production. Until that time, there needs to be a bridge built between the project team executing development, the transition team, and the operations team. Throughout the life cycle all change management activities need to be mapped to either existing change management processes or, if they are going to follow any unique procedures at any given point in the life cycle, they need to be documented and justified in this plan.

## **6.6 Project Monitoring**

Project monitoring activities will encompass the monitoring and controlling of the project's schedule, budget, and scope. The process for tracking and reporting on the status of project deliverables, project schedule, and project budget is described in this section.

### **6.6.1 Overall Project Monitoring**

The PM is responsible for overseeing all aspects of the project. Specific requirements of the PM are defined in Section 6.1, Project Manager Qualifications and Table 6-3, Project Team Roles & Responsibilities.

### **6.6.2 Team Meetings**

On a consistent basis, the PM will conduct project status meetings with various constituents, distributing a standing agenda for review of the project plan and deliverable schedule, upcoming events (e.g., interviews and working sessions), issue/risk logs and other relevant topics.

- Weekly meetings will be scheduled with the project team.
- Monthly Project Executive Management Meetings (Steering Committee) will be held.

### **6.6.3 Status Reporting**

To enable the project team to distribute timely information to stakeholders, the PM will develop a monthly Project Status Report to be reviewed and approved by the Steering Committee. This report will include updates on accomplishments, activities in progress, upcoming activities, issues, and deliverable status. These reports will indicate whether scheduled activities or deliverables will meet their due dates or if those dates are at risk. Incidental issues will be included as attachments to the report. An issue tracking tool will be used to identify responsible parties and due dates for resolution of any issues. The weekly report will include status updates for these outstanding issues.

Project teams will use a simple, streamlined method of communicating status report to various stakeholders throughout the life of the project. The information contained in the report is proportional to the complexity of the project. The format, degree, and extent of reporting will be based on the project's delegation authority (see to Section 6.7).

The PM will track and report on project status on an ongoing basis and will conduct regularly scheduled status meetings with the Project Implementation Vendor and team members to discuss project progress, issue resolution, change requests, and next steps.

The following standard reporting mechanisms will be used in the duration of the project:

- Status Reports
- Issue Management (including logs)
- Risk Management (including logs)
- Project Management Reports

The nature of the project warrants the need for formal monitoring. A core component of the project plan will necessitate identifying deliverables, scheduling, and assigning them to vendor or project staff members. Actual delivery dates will be compared with scheduled due dates to aid in tracking and control. The project plan will also mandate the distribution of status updates and the scheduling of checkpoint meetings.

The PM will be responsible for monitoring the success of the system implementation within scheduling and fiscal constraints. The project will utilize the department's existing budgeting and procurement mechanisms to track and control progress. The PM will maintain copies of all budgetary and procurement documents related to the project and post them to a centralized project repository for reference.

## **6.7 Authorization Required**

Project authorization is dependent upon several factors. The following table indicates the criteria reviewed to determine whether a project is Delegated or Reportable. Authorization for this project will follow a Reportable Project process with authority as described in the shaded column below:

**Table 6-5: Authorization Matrix**

	<b>Delegated Projects</b>	<b>Reportable Projects</b>
<b>Criteria</b>	Less than \$500,000 one-time cost	Greater than \$500,000; or Mandated by state statute; or Technology Agency determines reportable
<b>Authorization</b>	Sponsoring Deputy Director CIO	Sponsoring Deputy Director CIO Budget Officer CDPH Director CHHS Agency Technology Agency

## 7.0 Risk Management Plan

### 7.1 Risk Management

The Risk Management Plan describes the methods that the project will use to manage risks throughout the life of the project.

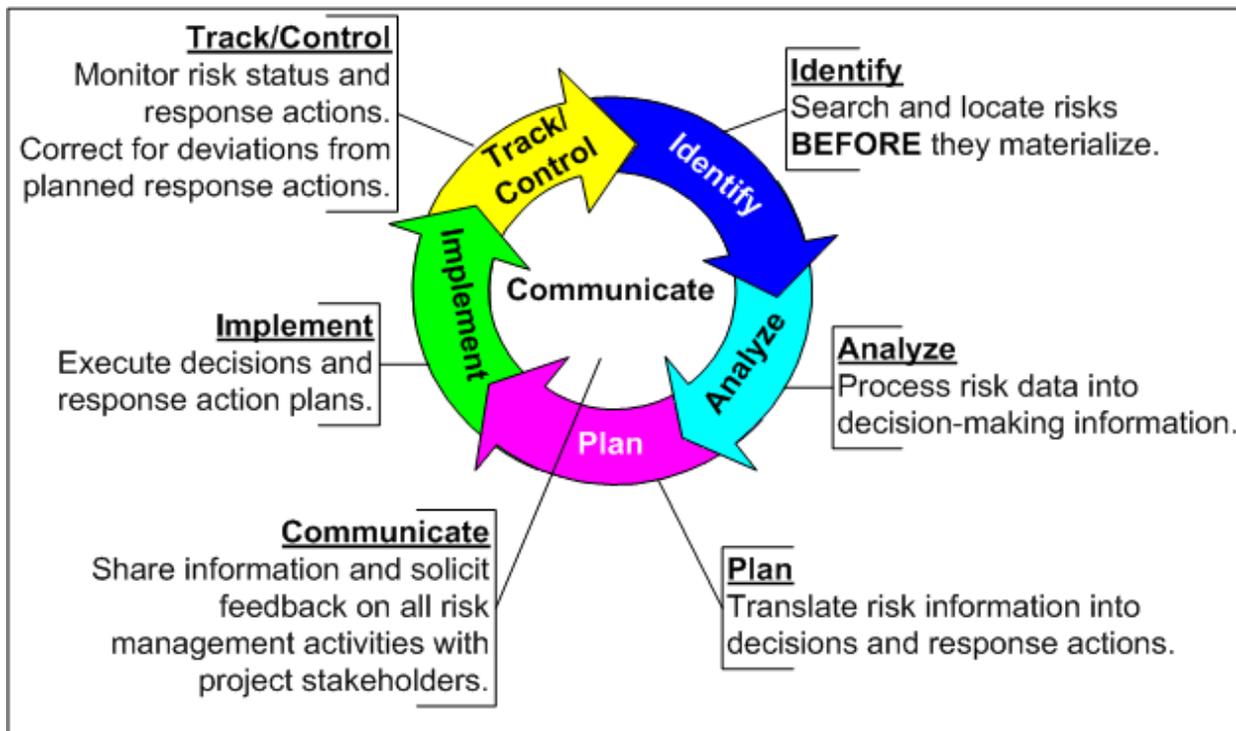
Risks are defined as uncertain conditions or events that may impact (negatively or positively) the project scope, schedule, cost, and/or quality.

Risk management planning includes the following components:

- Risk Identification
- Risk Escalation
- Risk Analysis
- Risk Register
- Risk Response Planning
- Risk Response Assessment

The continuous cycle of risk management activity is depicted graphically below in Figure 7-1.

**Figure 7-1: Cycle of Risk Management Activity**



#### 7.1.1 References Consulted

- Project Management Institute's Project Management Book of Knowledge (PMBOK), 4<sup>th</sup> Edition, Chapter 11 (Project Risk Management)

- Technology Agency's Information Technology Project Oversight Framework, Section 5 (Risk Management and Escalation Procedures)
- State Information Management Manual (SIMM), Section 17A, The CA-PMM Reference Manual, Section 3.1.6 (Risk Management Plan)

## **7.1.2 Goals and Objectives**

The goal of the Risk Management Plan is to improve the probability of success of the project by providing a roadmap for:

- Ongoing identification and assessment of potential problems.
- The opportunity to make adjustments to avoid or lessen the impact of those problems before they occur.

The objectives of the Risk Management Plan are the continuous identification, assessment, and documentation of:

- The risks faced by the project.
- The estimated probability of each risk.
- The consequences in terms of impact on project scope, schedule, cost, and quality should the risk events occur.
- The priority of each risk for response action and escalation.
- The owner of each risk.
- The plan of action for responding to and/or tracking each risk.
- The thresholds and procedures for escalating risks.

## **7.1.3 Scope**

The Risk Management Plan includes the activities to support the continuous identification, assessment, plan, communication, implementation and monitoring of known and/or potential risks for the duration of the project.

Leveraging the information from the Complexity Assessment in Section 6.1, Project Manager Qualifications, the business or technical attributes should be evaluated as a potential risk to the project and be managed through the Risk Management Plan to reduce the risk potential.

## 7.1.4 Roles and Responsibilities

The table below identifies the project stakeholders and their related risk management responsibilities.

**Table 7-1: Risk Management Roles and Responsibilities**

Title	Role/Responsibilities
Technology Agency	<ul style="list-style-type: none"> <li>• Review monthly IPO Reports to assess project risk management practices.</li> <li>• Provide feedback and direction as needed.</li> </ul>
Steering Committee	<ul style="list-style-type: none"> <li>• Final approval of Risk Management Plan.</li> <li>• Review escalated high and medium severity risks.</li> <li>• Provide direction when needed.</li> <li>• Determine if risks have become unacceptable for the project to continue.</li> </ul>
POIS	<ul style="list-style-type: none"> <li>• Provide general risk management assistance as requested.</li> <li>• Review escalated high and medium severity risks.</li> <li>• Provide feedback and suggestions as needed.</li> <li>• Manage the IPO and IV&amp;V efforts.</li> <li>• Provide an ongoing independent review and analysis of project risk management practices.</li> <li>• Independently identify and analyze project risks.</li> <li>• Develop IPO Reports for submission to project management and the Technology Agency.</li> </ul>
Risk Manager (PM)	<ul style="list-style-type: none"> <li>• Overall responsibility for risk management.</li> <li>• Develop the Risk Management Plan.</li> <li>• Determine which risk candidates represent actual risks.</li> <li>• Assign Risk Owners and communicate the plan to project team and stakeholders.</li> <li>• Maintain the Risk Management Forms.</li> <li>• Maintain the Risk List and review risks at weekly team status meetings.</li> <li>• Escalate risks as needed.</li> </ul>
Risk Owners (Project team members as assigned)	<ul style="list-style-type: none"> <li>• Assign risk attributes.</li> <li>• Determine risk tolerance level.</li> <li>• Determine risk priority and response strategy.</li> <li>• Develop risk response action plan.</li> <li>• Execute risk response actions.</li> <li>• Track and report risk status and response activity.</li> </ul>
Project Team Members	<ul style="list-style-type: none"> <li>• Identify risk candidates.</li> <li>• Serve as Risk Owners as assigned.</li> </ul>
IPO / IV&V	<ul style="list-style-type: none"> <li>• Review and evaluate technical risks.</li> <li>• Independently identify and analyze technical risks.</li> <li>• Coordinate with the Risk Manager and POIS to ensure that technical risks are tracked and escalated as needed.</li> </ul>

## 7.2 Risk Identification

Risk identification is the process of discovering those risks which could potentially negatively impact the project scope, quality, cost, and/or schedule. It would be impossible to identify all possible risks to the project, therefore emphasis is on identifying risks that are at least somewhat likely to occur and that could have a significant impact on the project. All project team members and the POIS are responsible for identifying potential risks to the project. Regularly scheduled project management meetings must include a standing agenda item for raising new risk candidates to the attention of the Risk Manager (PM). Project team members and the POIS may also communicate risk candidates to the Risk Manager by email, telephone, or ad hoc meetings. Potentially serious risk candidates should be communicated as soon as practical rather than waiting for the next meeting.

The project team will use the CA-PMM toolkit (SIMM17C\_Toolkit\_v2009 11-10-09.xls) and Appendix C of the Information Technology Project Oversight Framework to identify project categories and risks.

## 7.3 Sources of Risk

Project risks can come from various sources. Project team members must be vigilant in recognizing and documenting potential risks so that they can be properly evaluated for project impact. Some common risk sources include:

- The technology used on the project.
- The legal, financial, and/or regulatory environment in which the project is executed.
- Relationships among the organizations involved in the project.
- Sufficiency and allocation of project resources.
- Unrealistic or conflicting stakeholder expectations.
- Mandated or unrealistic implementation date.

## 7.4 Risk Escalation

The PM escalates risks to the POIS, the Steering Committee, and the Technology Agency depending on the risk severity, as indicated in the risk escalation matrix below:

**Table 7-2: Risk Escalation Matrix**

		Risk Severity		
		High	Medium	Low
Escalation	Technology Agency	X		
	Steering Committee; POIS	X	X	
	Project Manager	X	X	X

The method of risk escalation is as follows:

- High, medium, and low severity risks are reported to the Project Manager in regular project status reports and meetings.
- High and medium severity risks are reported to the Steering Committee during Steering Committee meetings.
- High and medium severity risks are reported to the POIS in monthly Project Management Reports.
- High severity risks are reported to the Technology Agency by the POIS in monthly IPO Reports.

## 7.5 Risk Analysis

Risk analysis is the process of assessing the probability of occurrence of the risk and the impact it will have on the project objectives. The result is further measured against the urgency with which management activities must be undertaken.

### 7.5.1 Probability

Risks are assigned a probability rating based on the estimated likelihood of a risk event occurring.

**Table 7-3: Probability Ratings**

Likelihood of Risk Event	Probability Rating
<20%	1
21-40%	2
41-60%	3
61-80%	4
>80%	5

## 7.5.2 Potential Impact

Risks are assigned an impact rating based on the estimated negative impact on project schedule, scope, budget or quality.

**Table 7-4: Impact Ratings**

Criteria	Impact Rating
Less than a 5% change to schedule, scope, budget, or quality	1
5 – 10% change to schedule, scope, budget, or quality	2
11 – 15% change to schedule, scope, budget, or quality	3
16 – 24% change to schedule, scope, budget, or quality	4
25% or greater change to schedule, scope, budget, or quality	5

## 7.5.3 Timing

Risks are assigned a numerical timing based on the time period within which action must be taken to successfully respond to the risk. The timing scale is used to assess the impact of the urgency with which risk management activities must be undertaken. The following Timing Scale is based on the need to begin risk management work. It varies based on the duration of the project.

**Table 7-5: Timing Scale**

Project Duration	Risk Factor
Within the next six months	1
Six months to a year from now	0.66
Over a year from now	0.33

## 7.5.4 Risk Level

The Risk Level is the amount of project risk exposure based on the probability of occurring, the impact of the risk, and its timing.

**Risk Level = Probability x Impact x Timing**

**Table 7-6: Risk Levels**

Risk Level	Classification	Color
9 and Below	Low	Green
10 to 15	Medium	Yellow
16 to 25	High	Red

## 7.6 Risk Register

The Risk Register serves as the repository of all the risks identified and contains the analysis and action plan addressing each, and assessment of the results. The register also serves as a useful input to lessons learned and helps the PM continuously improve the Risk Management Plan and activities.

Below are examples of risks identified as part of prior efforts. As the CAIR 2.0 Strategy project is approved and initiated, a comprehensive Risk Management Plan will be developed to update and monitor the Risk Register.

**Table 7-7: Risk Registry – Note: The following table is included for illustrative purposes only and will be completed by the Risk Manager once the project is approved and initiated.**

#	Risk	Probability (1 – 5)	Potential Impact (1 – 5)	Time Frame	Risk Level* (1 – 25)	Consequences	Brief Description of Risk Response
1	Lack of availability of key staff due to program workload and competing priorities.	3	4	Within the next six months	12 Yellow	Increase project schedule	The project will require guarantee from the project sponsor to supply sufficient subject matter experts (SME) to the project team. The sponsor will be required to sign the charter thereby committing these crucial resources. If the SMEs become unavailable or are determined to be inadequate by the project manager and team, the risk will be escalated to the sponsor with a request for additional SME.
2	Lack of availability of funding or spending authority.	5	5	Over a year from now	8.25 Green	Increase project schedule	CDPH will collaborate with Department of Health Services to obtain Federal approval IAPD funding and establish an interagency agreement with them to solidify project funding.
3	Delays in control agency approvals may cause CDPH to miss one-time Federal funding opportunities for CAIR 2.					Delay project start	Will work closely with control agencies and be available to answer all their questions promptly.
4	Lengthy state procurement processes may cause CDPH to miss Federal funding spending deadlines for CAIR 2.	3	4		12 Yellow	Increase project schedule or project cancellation	Will work closely with DGS and CDPH acquisition specialists. The PM will respond to their requests for information promptly.

#	Risk	Probability (1 – 5)	Potential Impact (1 – 5)	Time Frame	Risk Level* (1 – 25)	Consequences	Brief Description of Risk Response
5	California public health crises could require the focus of the project sponsor and other high-level department management.	3	4	Within the next six months	12 Yellow	Decrease in project decision-making and control	As described in the agreed upon project charter, the project manager will work with the sponsor, steering committee, and project team to assess and propose a revised plan to accommodate the situation. If the delay is significant, this may require a SPR with a new schedule and budget.
6	The use of technology unfamiliar to the project team could adversely affect project cost and schedule.			Over a year from now	0	Increase project schedule and cost	The vendor contract will contain provisions that detail their area of responsibility and CDPH expectations/requirement. The PM ultimately has the primary responsibility to mitigate this risk and will work closely with the acquisition specialists and steering committee to ensure the vendor hires staff skilled in the technology being implemented.
7	Delays in availability of hosting facilities could delay production implementation.			Over a year from now	0	Increase project schedule.	The chosen technical solution will be within CDPH (OTECH) standards and the PM will work closely with the OTech team throughout the project, including requirements, design, procurement, testing and implementation.

#	Risk	Probability (1 – 5)	Potential Impact (1 – 5)	Time Frame	Risk Level* (1 – 25)	Consequences	Brief Description of Risk Response
8	Changes in state or federal regulations could adversely affect project cost and schedule.			Over a year from now	0	Increase project scope, schedule, and cost.	The project sponsor will keep the PM abreast of Federal program changes that may impact the CAIR project. The program sponsor participates in regular Federal and State immunizations meetings and conferences. Any required changes will be managed by the change management plan and processes. This may require a SPR.

#	Risk	Probability (1 – 5)	Potential Impact (1 – 5)	Time Frame	Risk Level* (1 – 25)	Consequences	Brief Description of Risk Response
9	External stakeholders (CAIR regional managers) may resist accepting the new CAIR 2 system and processes.			Over a year from now		Increase project schedule and cost.	The CDPH Immunization Branch (IZ) worked with the external stakeholders to gather system requirements during development of this FSR. They obtained stakeholder feedback via three stakeholder webinars and a follow-on survey tool. They also included the external stakeholders in market research activities and alternative analysis. Stakeholder resistance at this point looks very unlikely, but the PM will monitor this closely. The PM will assess stakeholders in terms of their awareness of the project, the influence they can exert, determination of any resistance or concerns they may have, identification of optimum communication, and a summary of actions to be taken.

## 7.7 Risk Response Planning

### 7.7.1 Risks Response Action Plan

The Risk Owner is responsible for developing an appropriate risk response action and for tracking the status of the risk and the response activity. The Risk Owner reports any changes in risk status at the monthly project team meeting. The Risk Response Action Plan includes the following elements:

- **Cause:** The triggers that create the conditions for the risk to occur.
- **Consequence:** Describes the results of the realization of a risk.
- **Avoidance Plan:** Attempts that are made to overcome the risk by eliminating its cause. This may require a change to the project plan so that the risk will not occur, possibly resulting in reducing scope, obtaining additional information, adding resources, or acquiring additional expertise.
- **Mitigation Plan:** The probability of the risk and impact to the project is reduced, but not fully avoided. For example, selecting a known technology lessens the risk as compared to using new technology. If a new technology cannot be avoided, then selecting a contractor experienced in the technology could mitigate or lessen the risk.

### 7.7.2 Risk Response Strategy

The Risk Owner, with the approval of the Risk Manager (PM), determines the appropriate risk response strategy from the options below:

- **Transference:** The ability to have another entity absorb some of the risk, such as an insurance company or late fees for vendors.
- **Acceptance:** Understanding the risk and its potential impact and choosing to take no action.
- **Contingency Plan:** The steps and procedures to follow should a known potential risk occur.

Other elements of the Risk Response Strategy include:

- **Trigger Events:** Trigger events are occurrences or activities that indicate that a given risk will occur or is already occurring. A trigger event can be internal to the project, meaning that at the conclusion of a particular activity or deliverable, the risk either will or will not happen. Trigger events can also be external to the project, such as a change in the political landscape or economic environment.
- **Owner:** The individual on the project team who has been assigned the responsibility of monitoring the risk and letting the team know if the Risk Management Plan needs to be activated.

## 7.8 Risk Response Assessment

The Risk Owner, with the approval of the Risk Manager (PM), conducts an evaluation of the results based on the course of action taken for each of the risks using the following methodology:

- **Response Plan Effectiveness:** An assessment of the degree to which the risk management activities were effective in dealing with the risk.
- **Residual Risks:** Risks that remain even though risk management activities took place as planned.
- **Secondary Risks:** Risks that are actually created through the implementation of the planned risk management activities.
- **Risk Status:** A statement of the current condition of the risk.
- **Closure Date:** The date the risk was determined to be no longer possible or threatening to the project.

## 8.0 Economic Analysis Workbook (EAW)

The worksheets included in this section provide a comprehensive analysis of the costs and associated funding for implementing the project. This section presents the assumptions and calculations made to prepare the EAW pursuant to the Technology Agency instructions (SIMM section 20C).

The purpose of the EAW is to document and compare the costs and financial benefits of the current CAIR operation (“existing system”) with those of each feasible alternative that was considered. From the five alternatives (see section 5.3) initially presented and discussed with the project team and stakeholders, two were deemed most feasible and practical in meeting California’s needs.

The estimated costs of the two alternatives are documented in the EAW worksheets, while the specific state and contracted resources and associated costs to support the proposed alternative are provided below. The funding necessary for implementing and maintaining the proposed alternative over the projected life of the project are also described in the EAW worksheets and below.

### 8.1 Existing System/Baseline Cost Worksheet

The Existing System/Baseline Cost worksheet documents the existing and forecasted costs of the current CAIR operating environment, including IT and program costs to be impacted directly by the proposed system. As noted in the Technology Agency instructions and by the project team, existing staff costs reflect actual staffing allocations and dollars budgeted for annual program operations should the proposed alternative *not* be undertaken.

#### 8.1.1 Continuing Information Technology Costs

Continuing IT Costs are the estimated resources needed to operate and maintain the existing systems. Existing IT costs will decrease when the project is implemented as staff transition from maintaining and operating the current systems to supporting the new system.

#### 8.1.2 Continuing Existing Program Costs

Existing Program Costs reflect the personnel services and other costs associated with program work to be affected directly by the proposed system. The proposed system will improve operational efficiencies, which will increase staff availability to resolve backlogs and address under-resourced program responsibilities. It is not expected that the program will experience a reduction in total Personnel Years (PYs) as a result of the proposed system, but rather will be more effective in accomplishing its mission as resources are redirected to other business critical responsibilities.

### 8.2 Proposed Alternative

The Proposed Alternative worksheet documents estimated one-time and continuing costs for implementing the proposed solution. A detailed description of the proposed alternative is provided in section 5 of this FSR document. The total project cost is the sum of one-time and continuing IT project costs through the first full FY of M&O. Based on the EAW estimates, the total project cost of implementing the proposed alternative is approximately \$6.2 million over four years.

The proposed alternative reflected in the EAW – ALT (P) tab, corresponds to Alternative # 2/Option B described in section 5.3.2 of this document and reflects the estimated costs of implementing a partial

consolidation of the seven (7) CAIR Software Regions utilizing new registry software. This alternative brings CAIR closest to a full consolidation without mandating regional participation, and consolidates the data from the seven (7) CAIR Software Regions with the other three (3) regions continuing to use their existing software or migrating to the consolidated system if they so choose. Interoperability is enabled via HL7 amongst the consolidated region, remaining regions, and providers.

The option of implementing new registry software as a key component of the proposed alternative is available through the acquisition of COTS software or a public domain or public health developed product such as the Wisconsin Immunization Registry (WIR). It should be noted that other acquisition options exist such as leveraging the San Diego Regional Immunization Registry (SDIR) software which is available to the State with no purchase or licensing fees based on a contractual agreement between San Diego and the software vendor (Software Partners, LLC). Therefore, this option would also meet the State's objective to minimize software acquisition costs.

In completing the FSR, informal interviews were scheduled with public health staff in several states to speak of their experience in transitioning from a regionalized immunization registry model to a centralized registry. The ability to identify best practices and lessons learned helped inform the alternatives, estimates, and projections contained within the FSR and EAWs.

There are a number of assumptions that apply to all the alternatives, and to some degree, existing system estimates. These include:

- The project schedule assumes the PM will start full-time work on CAIR 2.0 on July 1, 2012.
- Public domain software is preferred in lieu of paying software licensing and continuing software maintenance fees.
- The costs for ALT (P) and ALT (1) are identical with an additional year being added to ALT (1) that accounts for the development of modifications to the existing CAIR software.
  - Notes:
    - ALT (P) corresponds to Alternative #2/Option B (see section 5.3.2).
    - ALT (1) corresponds to Alternative #2/Option A (see section 5.3.2).
    - ALT (2) corresponds to Alternative #3/Option B (see section 5.3.3).
- The projections for ALT (2) include increased costs to account for the customization, interfaces, and data migration for a full consolidation to include the CAIR Software Regions and independent regions.
- California will leverage the model, best practices, and lessons learned by New York State's transition from a regionalized to a centralized immunization registry.
- The project schedule for the proposed alternative (see section 6.5.8), is based on the following:
  - First FY (2012/2013) will initiate the Procurement phase with the development of an RFP. It is estimated that the RFP process will take approximately a year to complete.
  - Third FY (2014/2015) will constitute the first full year of the project execution of the proposed alternative.
  - A full year of M&O follows in FY (2015/2016).

## 8.2.1 One-Time IT Project Costs

One-time IT project costs are the estimated costs to implement the proposed solution and include the resources, hardware, software, and data center charges in support of the new system.

### 8.2.1.1 One-Time Project Staff Costs

One-time project staff costs represent the estimated cost of *state* personnel required to implement the project. The current CAIR Software Region Technical Team, comprised of fourteen resources (see section 4.1.10), is

contracted through the Public Health Foundation Enterprises (PHFE) and therefore considered “other contractor services” rather than state staff.

For the proposed alternative, it is envisioned that the first FY will require a small team (1.3 PYs) to draft the RFP and begin the Procurement phase. Additional IT resources will be added to the team in the second and third fiscal years as the project is initiated and executed.

Table 8-1 below reflects the number and costs of one-time state staff to support the project throughout each fiscal year.

**Table 8-1: One-Time Staff Costs**

Classification	Annual Salary Benefits	FTE	PYs by FY				Cost by FY			
			2012/13 (7 M)	2013/14 (12 M)	2014/15 (12 M)	2015/16 (5 M)	2012/13	2013/14	2014/15	2015/16
Data Processing Manager (DPM) Level III Project Manager	\$131,382	1	0.58	1	1	0.42	\$76,640	\$131,382	\$131,382	\$54,743
Project Oversight (PO) Senior Information Systems Analyst (ISA)	\$113,362	0.33	0.19	0.33	0.33	0.14	\$21,822	\$37,409	\$37,409	\$15,587
Information Technology Services Department (ITSD) DPM Level III Technical	\$131,382	0.25	0	0.15	0.25	0.10	\$0	\$19,160	\$32,846	\$13,686
Information Technology Services Department (ITSD) System Software Specialist I (SSSI) Data Center Support	\$103,093	0.5	0	0.29	0.5	0.21	\$0	\$30,069	\$51,547	\$21,478
Information Technology Services Department (ITSD) Staff Information Systems Analyst (SISA) Technical Support	\$103,109	0.25	0	0.15	0.25	0.10	\$0	\$15,037	\$25,777	\$10,741
Division of Communicable Disease Control (DCDC) Health Program Manager (HPM) Level II Contract Management	\$97,703	0.1	0	0.06	0.1	0.04	\$0	\$5,699	\$9,770	\$4,071
<b>Overhead (\$16,800 per PY)</b>							\$13,287	\$33,558	\$41,258	\$17,190
<b>TOTAL</b>		2.43	0.78	1.97	2.43	1.01	\$111,749	\$272,314	\$329,989	\$137,495

### 8.2.1.2 Hardware Purchase

When implemented, the proposed alternative will be maintained in the State data center facility and supported by CDPH in CTA's Tenant Managed Services – Premium environment. Therefore, the one-time purchase and installation estimates of the hardware for the proposed alternative are reflected as Data Center Services costs in Table 8-3 below.

### 8.2.1.3 Software Purchase

Working in conjunction with OTech, CDPH will purchase the necessary software in support of the proposed alternative. The software typically required for this type of project includes Windows Server operating system, SQL Server database, .NET for the application environment and business logic environment, and Enterprise Message Broker to support incoming and outgoing message translation, consumption, and extraction.

It should be noted that the software requirements will be finalized following the selection of the Project Implementation Vendor and solution at the conclusion of the Procurement phase.

Similar to the hardware estimates, the one-time software costs have been combined and submitted under the Data Center Services costs in Table 8-3 below.

#### 8.2.1.4 Contract Services Costs

Leveraging New York State’s immunization registry operational model, CDPH will contract a Project Implementation Vendor as the solution integrator. Responsibilities of the Project Implementation Vendor will include managing the software customization, data migration, verification and validation, training and rollout activities once the project is approved and initiated. These one-time Contract Services costs are estimated at approximately \$2.52 million and reflected in Table 8-2 below.

In addition to the Project Implementation Vendor resources, it is estimated that four resources from the existing CAIR Software Region Technical Team will be allocated to support the RFP efforts and project activities at an estimated cost of \$1.22 million. Again, it should be noted that the current CAIR Software Region Technical Team is considered contracted resources and not State staff within the EAW forecast.

**Table 8-2: Estimated One-Time Contract Service Costs**

Contract Service	FY 2012/13	FY 2013/14	FY 2014/15	FY 2015/16	Total Cost
Software Customization, Data Migration, Training, Rollout Activities	0	\$360,000	\$1,440,000	\$600,000	\$2,400,000
IV&V	0	\$17,500	\$70,000	\$29,167	\$116,667
Other Contract Services*	\$148,750	\$256,250	\$600,000	\$250,000	\$1,255,000
<b>TOTAL</b>	\$148,750	\$633,750	\$2,110,000	\$879,167	\$3,771,667

\*Estimate for the first 12 months (7 months in 12/13, 5 months in 13/14) includes 1.5 FTEs from the existing CAIR Software Regions’ Technical Team in addition to \$30,000 in DGS costs. Estimate for the remaining months includes four FTEs from existing CAIR Software Region Technical Team.

#### 8.2.1.5 Data Center Services

Support of the proposed alternative, once implemented, will be maintained in the State data center Tenant Managed Services – Premium environment and supported by CDPH. The one-time cost of this support, as indicated in Table 8-3 below, is forecasted for FY 2014/15 when the hosting environment is established and includes the initial setup of the operating systems, installation of the servers and proposed system, and any associated hardware and licensing fees.

**Table 8-3: Estimated One-Time Data Center Service Costs**

Data Center Service	Cost
One-time install of active directory servers, application servers, database servers, and web servers	\$26,180
<b>TOTAL</b>	<b>\$26,180</b>

## 8.2.2 Continuing IT Project Costs

Continuing IT Project Costs are the estimated resources needed to maintain and operate the proposed alternative once it is implemented. For the proposed alternative, these projections include annual and monthly data center charges, IT resources needed to support the ongoing maintenance of the system as it transitions from project-based to operations, and the current CAIR Software Region Technical Team that will work in collaboration with the Project Implementation Vendor in providing recruitment, provider support, and day-to-day operations of the new system. A significant amount of these continuing IT project costs are allocated to the M&O phase of the project in FY 2015/16 and 2016/17.

### 8.2.2.1 Continuing Project Staff Costs

The estimated annual cost for staff needed to support the proposed solution following implementation is shown in Table 8-4.

**Table 8-4: Continuing IT Staff Costs**

Classification	Annual Salary and Benefits (thou)	FTE	PYs by FY		Cost by FY (thou)	
			2015/16 (7 M)	2016/17 (12 M)	2015/16 (7 M)	2016/17 (12 M)
ITSD DPM III Technical	\$131,382	.25	.15	.25	\$19,160	\$32,845
ITSD SSSI Data Center Support	\$103,093	.50	.29	.50	\$30,069	\$51,546
ITSD Staff ISA Technical Support	\$103,109	.25	.15	.25	\$15,037	\$25,777
DCDC HPM II Contract Management	\$97,703	.10	.06	.10	\$5,699	\$9,770
Overhead					\$10,780	\$18,480
<b>TOTAL</b>		<b>1.1</b>	<b>.64</b>	<b>1.1</b>	<b>\$80,744</b>	<b>\$138,418</b>

### 8.2.2.2 Continuing Project Staff Workload Justification

Workload justifications for continuing IT staff are included in the tables below.

**Table 8-5: Systems Software Specialist I (0.5 py)**

<b>Activity –Data Center Support-CAIR System</b>		<b>Average Hours per Item</b>	<b># of Items</b>	<b>Total Annual Hours</b>
Server Administration	This position is responsible for the administration of the virtual server environments for CAIR enterprise technology systems. Regular duties will include: creation and configuration of virtual servers running on VMWare ESX host servers; testing hardware, software and security patches prior to production release and implement as needed; implement best practice configurations for High Availability and Distributed Resource Scheduling for virtual clusters; work with EMC Fiber Channel SAN storage connections and LUN configurations; and configure virtual networking services for secure data transmission between hosting environments.	320	1	320
Software Installation	This position requires the installation, configuration and maintenance of the following services: backup and recovery services, applications and patches deployment management system, antivirus systems, encryption solutions, Microsoft Active Directory services, and other enterprise applications. The position will resolve CAIR system issues that CDPH Help Desk staff is unable to correct.	320	1	320
Technical Consulting	Performs technical consulting, investigating and researching for CAIR and providing performance trend analysis reports and recommendations to the technical leads. Contributes technical expertise to project management teams on CAIR system solutions and server. Liaison with other CAIR system personnel and vendors in the area of network support, equipment acquisition and product evaluation with respect to electronic information processing.	260	1	260
<b>Total hours for workload projected for this classification</b>				<b>900</b>
<b>1,800 Hours = 1 PYNumber of PY's requested</b>				<b>0.5</b>

**Table 8-6: Health Program Manager II (0.1 PY)**

<b>ACTIVITY – Program Coordination</b>		<b>Average Hours per Item</b>	<b># of Items</b>	<b>Total Annual Hours</b>
CAIR Program Coordination	Develops policies for the Immunization Branch related to CAIR; interprets policy to subordinate staff; analyses of ongoing and new CAIR issues and keeps the Branch Chief informed of current activities; reviews and approves recommendations and proposed solution to CAIR issues. Prepares, reviews, and edits CAIR reports, issue memoranda, position papers, and controlled correspondence. Prepares and gives presentations and/or training at conferences and meetings.	180	1	180
<b>Total hours for workload projected for this classification</b>				<b>180</b>
<b>1,800 Hours = 1 PY</b>				
<b>Number of PY's requested</b>				<b>0.1</b>

**Table 8-7: Data Processing Manager III (0.25 py)**

<b>ACTIVITY – CAIR System Manager</b>		<b>Average Hours per Item</b>	<b># of Items</b>	<b>Total Annual Hours</b>
Supervision and Administration	Oversee the CARE maintenance and operations  (M & O) plan, schedule, procurement and budget. Assign resources; tasks; establish and monitor quality assurance and control activities; ensure business and technical requirements are met; conduct project communications; other  M & O tasks as needed.	180	1	180
Procurement and Contract Management	Identify needed products and services; conduct procurements; manage contractors and suppliers; review and obtain approval for deliverables and products.	135	1	135
System Quality	Implement system controls and tracking mechanisms; monitor system performance; manage and evaluate change requests; evaluate project deliverables and products.	90	1	90
Meeting Management	Conduct CAIR system team meetings; prepare for and conduct regular change-control committee meetings.	45	1	45
<b>Total hours for workload projected for this classification</b>				<b>450</b>
<b>1,800 Hours = 1 PY</b>				
<b>Number of PY's requested</b>				<b>0.25</b>

**Table 8-8: Staff Information Systems Analyst (0.25 py)**

<b>ACTIVITY – CAIR Application Technical Support</b>		<b>Average Hours per Item</b>	<b># of Items</b>	<b>Total Annual Hours</b>
Technical Support	Complete CAIR maintenance and operation tasks as assigned by the CAIR System Manager. assess system performance.	180	1	180
Procurement and Deliverable Analysis	Research needed products and services; prepare procurements documents; review contractors and supplier's products and services; advise CAIR System Manager on approval or denial of system deliverables and products.	135	1	135
Change Management	Track and analyze change request documents and make recommendations to CAIR System Manager based on your analysis.	90	1	90
Meeting Preparation	Help prepare for CAIR system team and change-control committee meetings.	45	1	45
<b>Total hours for workload projected for this classification</b>				<b>450</b>
<b>1,800 Hours = 1 PY</b>				
<b>Number of PY's requested</b>				<b>0.25</b>

### 8.2.2.3 Hardware Lease/Maintenance

These estimates have been combined with software maintenance/licensing charges as part of the Continuing IT Project Costs and submitted under Data Center Services in Table 8-10 below.

### 8.2.2.4 Software Maintenance/Licensing

These costs have been combined with hardware lease/maintenance estimates as part of the Continuing IT Project Costs and submitted under Data Center Services in Table 8-10 below.

### 8.2.2.5 Contract Services Costs

As the proposed alternative is implemented, resources from the current CAIR Software Region Technical Team will be redirected to work in conjunction with the Project Implementation Vendor to fully operationalize the new system.

The estimated annual cost of contract services for ongoing system maintenance and operations of the proposed solution are shown in Table 8-9.

**Table 8-9: Estimated Continuing Contract Service Costs**

<b>Contract Service</b>	<b>FY 2015/2016 (7 M)</b>	<b>FY 2016/17 (12 M)</b>
Contract Services (Project Implementation Vendor resources and current CAIR Software Region Technical Team)	\$641,667	\$1,100,000
	\$641,667	\$1,100,000

### 8.2.2.6 Data Center Services

The estimated annual cost of services provided by the State data center for ongoing system operations/maintenance of the proposed solution are shown in Table 8-10. These estimates are inclusive of the annual and monthly hardware and software charges incurred once the hosting environment is established, and continuing and during the M&O phase.

**Table 8-10: Estimated Continuing Data Center Service Costs**

<b>Data Center Service</b>	<b>FY 2014/2015 (6 Months)</b>	<b>FY 2015/2016 (Annual Cost)</b>	<b>FY 2016/2017 (Annual Cost)</b>
Data Center Services	\$77,295	\$154,590	\$154,590
TOTAL	\$77,295	\$154,590	\$154,590

### 8.2.2.7 Other Continuing Costs

No other continuing costs have been estimated for the proposed alternative.

## 8.3 Economic Analysis Summary

This worksheet displays summary financial data for the alternative solutions. It also provides calculations to help determine whether the proposed system is economically justified, and which alternative offers the most cost-effective solution.

## 8.4 Project Funding Plan

The Project Funding Plan shows the funding needs for both one-time and continuing costs of the proposed solution on an annual, non-cumulative basis. The purpose of this worksheet is to show how each year of the proposed alternative will be funded, including redirections from existing system baselines, redirections from other sources, and new budget actions.

The primary funding source for CAIR 2 is Federal Medicaid/Medicare (CMS) obtained from the California Department of Health Services (DHS) via an interagency agreement. DHS is currently working with CMS to get the implementation advance planning document (IAPD) approved for this effort. The secondary source is the redirection of current operational funds provided by

Federal Centers for Disease Control (CDC). The CDPH Immunization Branch has been in regular communication with the CDC regarding the CAIR project. The CDC has approved this one-time re-direction that supports the implementation of CDC operational standards. An IAPD to the CDC is not required in this case.

**EXISTING SYSTEM/BASELINE COST WORKSHEET**

All costs to be shown in whole (unrounded) dollars.

	FY 2012/2013		FY 2013/2014		FY 2014/2015		FY 2015/2016		FY 2016/2017		TOTAL	
	PYs	Amts	PYs	Amts								
<b>Continuing Information</b>												
<b>Technology Costs</b>												
Staff (salaries & benefits)	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
Hardware Lease/Maintenance		100,000		100,000		100,000		100,000		100,000		500,000
Software Maintenance/Licenses		100,000		100,000		100,000		100,000		100,000		500,000
Contract Services		1,400,000		1,400,000		1,400,000		1,400,000		1,400,000		7,000,000
Data Center Services		100,000		100,000		100,000		100,000		100,000		500,000
Agency Facilities		100,000		100,000		100,000		100,000		100,000		500,000
Other		0		0		0		0		0		0
<b>Total IT Costs</b>	<b>0.0</b>	<b>1,800,000</b>	<b>0.0</b>	<b>9,000,000</b>								
<b>Continuing Program Costs:</b>												
Staff	0.1	9,770	0.1	9,770	0.1	9,770	0.1	9,770	0.1	9,770	0.5	48,850
Other		1,000,000		1,000,000		1,000,000		1,000,000		1,000,000		5,000,000
<b>Total Program Costs</b>	<b>0.1</b>	<b>1,009,770</b>	<b>0.5</b>	<b>5,048,850</b>								
<b>TOTAL EXISTING SYSTEM COSTS</b>	<b>0.1</b>	<b>2,809,770</b>	<b>0.5</b>	<b>14,048,850</b>								







**ECONOMIC ANALYSIS SUMMARY**  
 All costs to be shown in whole (unrounded) dollars.

	FY 2012/2013		FY 2013/2014		FY 2014/2015		FY 2015/2016		FY 2016/2017		TOTAL	
	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts
<b>EXISTING SYSTEM</b>												
Total IT Costs	0.0	1,800,000	0.0	1,800,000	0.0	1,800,000	0.0	1,800,000	0.0	1,800,000	0.0	9,000,000
Total Program Costs	0.1	1,009,770	0.1	1,009,770	0.1	1,009,770	0.1	1,009,770	0.1	1,009,770	0.5	5,048,850
Total Existing System Costs	0.1	2,809,770	0.1	2,809,770	0.1	2,809,770	0.1	2,809,770	0.1	2,809,770	0.5	14,048,850
<b>PROPOSED ALTERNATIVE</b>	<b>Corresponds to Alternative #2B - Partial Consolidation w/New Registry Software</b>											
Total Project Costs	0.8	260,499	1.9	906,064	2.4	2,543,464	1.6	1,893,663	1.1	1,393,009	7.8	6,996,699
Total Cont. Exist. Costs	0.1	2,661,020	0.0	2,543,750	0.0	2,200,000	0.0	1,733,333	0.0	1,400,000	0.1	10,538,103
Total Alternative Costs	0.9	2,921,519	1.9	3,449,814	2.4	4,743,464	1.6	3,626,997	1.1	2,793,009	7.9	17,534,802
COST SAVINGS/AVOIDANCES	(0.8)	(111,749)	(1.8)	(640,044)	(2.3)	(1,933,694)	(1.5)	(817,227)	(1.0)	16,761	(7.4)	(3,485,952)
Increased Revenues		0		0		0		0		0		0
Net (Cost) or Benefit	(0.8)	(111,749)	(1.8)	(640,044)	(2.3)	(1,933,694)	(1.5)	(817,227)	(1.0)	16,761	(7.4)	(3,485,952)
Cum. Net (Cost) or Benefit	(0.8)	(111,749)	(2.6)	(751,793)	(4.9)	(2,685,487)	(6.4)	(3,502,713)	(7.4)	(3,485,952)		
<b>ALTERNATIVE #1</b>	<b>Corresponds to ALTERNATIVE #2A - Partial Consolidation w/Modified CAIR Software</b>											
Total Project Costs	0.8	261,665	1.9	768,569	2.3	2,097,345	2.3	2,173,445	1.3	1,749,210	9.0	8,496,419
Total Cont. Exist. Costs	0.0	2,651,250	0.0	2,543,750	0.0	2,200,000	0.0	2,200,000	0.0	1,733,333	0.0	12,728,333
Total Alternative Costs	0.8	2,912,915	1.9	3,312,319	2.3	4,297,345	2.3	4,373,445	1.3	3,482,543	9.0	21,224,752
COST SAVINGS/AVOIDANCES	(0.7)	(103,145)	(1.8)	(502,549)	(2.2)	(1,487,575)	(2.2)	(1,563,675)	(1.2)	(672,773)	(8.5)	(7,175,902)
Increased Revenues		0		0		0		0		0		0
Net (Cost) or Benefit	(0.7)	(103,145)	(1.8)	(502,549)	(2.2)	(1,487,575)	(2.2)	(1,563,675)	(1.2)	(672,773)	(8.5)	(7,175,902)
Cum. Net (Cost) or Benefit	(0.7)	(103,145)	(2.4)	(605,694)	(4.6)	(2,093,269)	(6.8)	(3,656,944)	(8.0)	(4,329,717)		
<b>ALTERNATIVE #2</b>	<b>Corresponds to ALTERNATIVE #3B - Full Consolidation w/New Registry Software</b>											
Total Project Costs	0.8	261,665	1.9	963,569	2.3	2,877,345	1.3	2,074,210	0.5	1,446,185	6.7	7,622,974
Total Cont. Exist. Costs	0.0	2,651,250	0.0	2,543,750	0.0	2,200,000	0.0	1,733,333	0.0	1,400,000	0.0	10,528,333
Total Alternative Costs	0.8	2,912,915	1.9	3,507,319	2.3	5,077,345	1.3	3,807,543	0.5	2,846,185	6.7	18,151,307
COST SAVINGS/AVOIDANCES	(0.7)	(103,145)	(1.8)	(697,549)	(2.2)	(2,267,575)	(1.2)	(997,773)	(0.4)	(36,415)	(6.2)	(4,102,457)
Increased Revenues		0		0		0		0		0		0
Net (Cost) or Benefit	(0.7)	(103,145)	(1.8)	(697,549)	(2.2)	(2,267,575)	(1.2)	(997,773)	(0.4)	(36,415)	(6.2)	(4,102,457)
Cum. Net (Cost) or Benefit	(0.7)	(103,145)	(2.4)	(800,694)	(4.6)	(3,068,269)	(5.8)	(4,066,042)	(6.2)	(4,102,457)		

**PROJECT FUNDING PLAN**

All Costs to be in whole (unrounded) dollars

	FY 2012/2013		FY 2013/2014		FY 2014/2015		FY 2015/2016		FY 2016/2017		TOTALS	
	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts	PYs	Amts
<b>TOTAL PROJECT COSTS</b>	<b>0.8</b>	<b>260,499</b>	<b>1.9</b>	<b>906,064</b>	<b>2.4</b>	<b>2,543,464</b>	<b>1.6</b>	<b>1,893,663</b>	<b>1.1</b>	<b>1,393,009</b>	<b>7.8</b>	<b>6,996,699</b>
RESOURCES TO BE REDIRECTED												
Staff	0.8	111,749	1.9	272,314	2.4	329,989	1.6	218,240	1.1	138,419	7.8	1,070,710
Funds:												
Existing System		148,750		633,750		2,213,475		1,675,423		1,254,590		5,925,988
Other Fund Sources		0		0				0		0		0
<b>TOTAL REDIRECTED RESOURCES</b>	<b>0.8</b>	<b>260,499</b>	<b>1.9</b>	<b>906,064</b>	<b>2.4</b>	<b>2,543,464</b>	<b>1.6</b>	<b>1,893,663</b>	<b>1.1</b>	<b>1,393,009</b>	<b>7.8</b>	<b>6,996,699</b>
ADDITIONAL PROJECT FUNDING NEEDED												
One-Time Project Costs	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
Continuing Project Costs	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
<b>TOTAL ADDITIONAL PROJECT FUNDS NEEDED BY FISCAL YEAR</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>
<b>TOTAL PROJECT FUNDING</b>	<b>0.8</b>	<b>260,499</b>	<b>1.9</b>	<b>906,064</b>	<b>2.4</b>	<b>2,543,464</b>	<b>1.6</b>	<b>1,893,663</b>	<b>1.1</b>	<b>1,393,009</b>	<b>7.8</b>	<b>6,996,699</b>
Difference: Funding - Costs	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
Total Estimated Cost Savings	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
<b>FUNDING SOURCE*</b>												
General Fund	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0
Federal Fund	30%	78,150	30%	271,819	32%	817,146	62%	1,182,000	100%	1,393,009	53%	3,742,123
Special Fund	7%	18,235	7%	63,424	7%	172,632	4%	71,166	0%	0	5%	325,458
Reimbursement	63%	164,114	63%	570,820	61%	1,553,686	34%	640,497	0%	0	42%	2,929,118
<b>TOTAL FUNDING</b>	<b>100%</b>	<b>260,499</b>	<b>100%</b>	<b>906,064</b>	<b>100%</b>	<b>2,543,464</b>	<b>100%</b>	<b>1,893,663</b>	<b>100%</b>	<b>1,393,009</b>	<b>100%</b>	<b>6,996,699</b>

\*Type: If applicable, for each funding source, beginning on row 29, describe what type of funding is included, such as local assistance or grant funding, the date the funding is to become available, and the duration of the funding.

**Federal Fund - Immunization Registry Funds- Available - Ongoing**

**Special Fund - Health Statistics Special Fund - Available - Through Implementation of Project**

**Reimbursement - Federal CMS through DHCS - Available at IAPD and IAA approval - Through Implementation of Project**

### ADJUSTMENTS, SAVINGS AND REVENUES WORKSHEET

Annual Project Adjustments	FY 2012/2013		FY 2013/2014		FY 2014/2015		FY 2015/2016		FY 2016/2017		Net Adjustments	
	PYs	Amts	PYs	Amts								
<b>One-time Costs</b>												
Previous Year's Baseline	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0		
<b>(A)</b> Annual Augmentation /(Reduction)	<b>0.0</b>	<b>0</b>										
<b>(B)</b> Total One-Time Budget Actions	<b>0.0</b>	<b>0</b>										
<b>Continuing Costs</b>												
Previous Year's Baseline	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0		
<b>(C)</b> Annual Augmentation /(Reduction)	<b>0.0</b>	<b>0</b>										
<b>(D)</b> Total Continuing Budget Actions	<b>0.0</b>	<b>0</b>										
<b>Total Annual Project Budget Augmentation /(Reduction) [A + C]</b>	<b>0.0</b>	<b>0</b>										

[A, C] Excludes Redirected Resources

**Total Additional Project Funds Needed [B + D]**

<b>0.0</b>	<b>0</b>
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**Annual Savings/Revenue Adjustments**

Cost Savings	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0		
Increased Program Revenues		0		0		0		0		0		

## Appendix A: Abbreviations and Acronyms

Acronym or Abbreviation	Definition
#	number
ACIP	Advisory Committee of Immunization Practices
AES	Advanced Encryption Standard
AIMS	Agency Information Management Strategy
aka	also known as
ARRA	American Recovery and Reinvestment Act
ASP	Active Server Pages
Bay	Bay Area
BCP	Budget Change Proposal
BMI	Body Mass Index
CA	California
CAH	Critical Access Hospital
CAIR	California Immunization Registry
CaIOHII	California Office of Health Information Integrity
CaIWORKs	California Work Opportunities and Responsibility to Kids
CA-PMM	California Project Management Methodology
CC	Central Coast
CCB	Change Control Board
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CHHS	California Health and Human Services
CID	Center for Infectious Diseases
CIO	Chief Information Officer
CIR	California Immunization Record
CMAS	California Multiple Award Schedule
CMS	Centers for Medicare and Medicaid Services
CoCASA	Comprehensive Clinic Assessment Software Application
COTS	commercial-off-the-shelf
CSV	Comma Separated Values
CV	Central Valley
DCDC	Division of Communicable Disease Control
DD&I	design, development and implementation
Dept.	department

Acronym or Abbreviation	Definition
DGS	Department of General Services
DHCS	Department of Health Care Services
DNS	Domain Name System
.doc	Microsoft Word document
DPM	Data Processing Manager
DRP	Disaster Recovery Plan
DSL	Digital Subscriber Line
DTaP	diphtheria, tetanus toxoids, and acellular pertussis
EAW	Economic Analysis Workbook
e.g.	exempli gratia, a Latin expression meaning "for example"
EHR	Electronic Health Record
ELPD	Entity Level Provider Directory
Email	Electronic Mail
EO	Executive Order
EPSDT	Early Periodic Screening, Diagnosis and Treatment
Etc.	et cetera, a Latin expression meaning "and other things" or "and so on"
Ext.	extension
FERPA	Family Educational Rights and Privacy Act
FFP	Federal Financial Participation
FIPS	Federal Information Processing Standard
FSR	Feasibility Study Report
FTE	full time equivalent
FY	fiscal year
GB	Gigabyte
GHz	Gigahertz
H&SC	Health and Safety Code
HCFA	Healthcare Financing Administration
HEDIS	Healthcare Effectiveness Data and Information Set
Hib	Haemophilus influenzae type b
HIE	Health Information Exchange
HIPAA	Health Information Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health Act
HHS	U.S. Department of Health and Human Services
HL7	Health-Level Seven
HTML	Hypertext Markup Language

Acronym or Abbreviation	Definition
http	hypertext transfer protocol
IAPD	Implementation Advanced Planning Document
IDS	intrusion detection system
i.e.	id est, a Latin expression meaning "that is"
IEEE	Institute of Electrical and Electronic Engineers
IHS	Indian Health Service
IIS	Immunization Information System
ILPD	Individual Level Provider Directory
Imperial	Imperial County
In Emp	Inland Empire
IPO	Independent Project Oversight
IPOM	Immunization Program Operations Manual
IPS	intrusion prevention system
ISA	Information Systems Analyst
ISO	Information Security Office
IT	information technology
ITAP	Information Technology Acquisition Planning
ITPL	IT Policy Letters
ITPP	Information Technology Procurement Plan
ITSD	Information Technology Services Division
IV&V	Independent Verification and Validation
IZB	Immunization Branch
La-Or	Los Angeles-Orange
M	months
MAC	Macintosh
MB	Megabyte
MD	Medicinae Doctor, a Latin expression meaning "Doctor of Medicine"
MI	Michigan
MMIS	Medicaid Management Information System
M&O	maintenance and operations
MPI	Master Patient Index
MN	Minnesota
MSA	Multiple Service Award
MU	Meaningful Use
NIS	National Immunization Survey

Acronym or Abbreviation	Definition
NVAC	National Vaccine Advisory Committee
NwHIN	Nationwide Health Information Network
NC	Northern California
NY	New York
ORP	Operational Recovery Plan
OTech	Office of Technology Services
PCI	Personal and Confidential Information
PDF	Portable Document Format (PDF)
PHAM	Public Health Administrative Manual
PHFE	Public Health Foundation Enterprises
PHI	protected health information or personal health information
PIER	Post Implementation Evaluation Report
PM	Project Manager
PMBOK	Project Management Body of Knowledge
PMI	Project Management Institute
PMM	Project Management Methodology
PMO	Project Management Office
PMP	Project Management Plan
PO	Project Oversight
POIS	Project Oversight and Initiation Section
PPMB	Planning and Project Management Branch
PSP	Project Summary Package
PY	Personnel Year
RAM	Random Access Memory
RFP	Request for Proposal
RFO	Request for Offer
Sac	Greater Sacramento Area
SACWIS	Statewide Automated Child Welfare Information System
San J	San Joaquin Valley
SAM	Statewide Administrative Manual
S-CHIP	State Children's Health Insurance Program
SD	San Diego
SDLC	Software Development Life Cycle
SDIR	San Diego Regional Immunization Registry
sFTP	secure File Transfer Protocol

Acronym or Abbreviation	Definition
SIIS	Statewide Immunization Information System
SIMM	Statewide Information Management Manual
SISA	Senior Information Systems Analyst
SME	Subject Matter Expert
SP	Service Pack
SPR	Special Project Report
SR1	Security Requirements for Projects
SQL	Structured Query Language
SVGA	Super Video Graphics Array
TB	Tuberculosis
TCP/IP	Transmission Control Protocol / Internet Protocol
thou	thousands
TXT	Text
UAT	User Acceptance Test
U.C.	University of California
U.S.	United States
VACMAN	Vaccine Management System
VB	Visual Basic
VFC	Vaccines for Children
VPN	Virtual Private Network
VTrckS	Vaccine Tracking System
WBS	work breakdown structure
WIC	Women Infants and Children
WIR	Wisconsin Immunization Registry
www	world wide web
XML	Extensible Markup Language

## Appendix B: Questionnaire for Information Security and Privacy Components

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**State of California**

**California Technology Agency**

**Questionnaire for Information Security  
and Privacy Components  
in Feasibility Study Reports  
and Project-Related Documents**

**SIMM 20D**

**April 2011**

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## REVISION HISTORY

REVISION	DATE OF RELEASE	OWNER	SUMMARY OF CHANGES
Initial Release	July 2008	Office of Information Security & Privacy Protection	
Update	March 2011	Technology Agency - Office of Information Security	Formatting, name and logo change.
Update	April 2011	Technology Agency - Office of Information Security	Formatting and SIMM Numbering

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2.0 INFORMATION SECURITY OFFICER (ISO) ROLE AND RESPONSIBILITIES .....	3
3.0 PROPOSED SYSTEM.....	4

## Questionnaire for Information Security and Privacy Components in Feasibility Study Reports and Project-Related Documents

### 1.0 INTRODUCTION

The following Questionnaire assists state agencies with describing the information security and privacy components associated with an IT project in its Feasibility Study Reports and other project-related documents. The Office of Information Security reviews these documents to ensure information security and privacy components are addressed by the state agency and provide its recommendations to the California Technology Agency.

If any of the answers could be considered sensitive in nature, the agency should address them in a separate addendum marked “Confidential” and included as an attachment to the document.

### 2.0 INFORMATION SECURITY OFFICER (ISO) ROLE AND RESPONSIBILITIES

1. What is the role and responsibilities of the Agency ISO in relationship to this project?

As directed by the State Administrative Manual (SAM), the Information Security Office (ISO) is “required to oversee agency compliance with policies and procedures regarding the security of information assets.” Additionally, SAM states “Oversight responsibility at the agency level for ensuring the integrity and security of automated files, databases, and computer systems must be vested in the agency Information Security Officer”.

A key way that the California Department of Public Health (CDPH) Information Security Office (ISO) supports risk management and compliance responsibilities is by reviewing the technical requirements for Projects. While ensuring that they support State and agency security policies, they also must securely align with the business requirements defined by the Project.

For this purpose, the CDPH ISO developed the Security Requirements for Projects (SR1) document. This document provides the minimum security requirements mandated by the CDPH ISO for projects governed and/or subject to the policies and standards of CDPH. Projects that intend to deploy systems/applications into the CDPH system infrastructure, or will utilize CDPH information system services, are also subject to these minimum security requirements.

In addition, the SR1 is intended to assist CDPH and its service customers in understanding the criteria CDPH will use when evaluating and certifying the system design, security features and protocols used by project solutions utilizing CDPH services. These security requirements are also used in conjunction with the CDPH ISO compliance review program for its information system services customers.

Finally, the SR1 serves as a universal set of requirements which must be met regardless of physical hosting location or entities providing operations and maintenance responsibility. These requirements do not serve any specific project, nor do they prescribe any specific implementation technology.

2. Will the ISO be involved in developing and reviewing the security requirements?

Yes.

3. Will the ISO be involved in developing and reviewing the security testing efforts?

Yes.

4. Has the ISO participated in the response to these questions and signed off on the project-related document(s)?

Yes.

### 3.0 PROPOSED SYSTEM

1. Who will be the designated owner of the proposed system (system)?

CDPH.

2. Who will be the custodians and users of the system?

The custodians will be the CDPH CAIR Technical Team and OTech. Users of the system are described in section 3.1.1.5 of this FSR.

3. Has the data for the system been classified by the owner? Explain.

Yes

4. Does the project require development of new application code or modification of existing code? Explain.

The project will require obtaining new registry software which will be customized to meet CDPH's requirements.

5. Will your agency share the data for the system with other entities? If so, who?

- a. Federal partners – Yes
- b. Local city/county partners – Yes
- c. State agency partners – Yes
- d. Judicial branch – No
- e. Universities – Yes
- f. Researchers – Yes
- g. Others – Yes (provider EHR-S, health plans, HIEs)

6. If data for the system is to be shared with other entities, will your agency implement data exchange agreements with the entities? Explain.

Yes.

7. Are there checkpoints throughout the software development life cycle (SDLC) verifying and certifying that the security requirements are being met?

Yes.

8. At what points will risk assessments be performed throughout the SDLC?

Risk assessments will be performed at each phase of the SDLC.

9. At what point will vulnerability assessments be performed once the system is put into production (e.g., ongoing risk management after implementation)?

Vulnerability assessments will be performed periodically after the system is in production.

10. Will this system collect federal data? If so, have you yet determined the National Institute for Standards and Technology 800-53 rating (i.e., high / medium / low)?

No.

11. Does your state agency's Five Year IT Capital Plan address information security and privacy as related to this system?

Information security policies as applicable are provided in section 5.1.3 of this FSR.

## Appendix C: Complexity Assessment

Project Name: CAIR 2.0 Strategy Project  
 OCIO Project #:  
 Department:  
 Revision Date: 5/5/11

## Complexity Assessment

### Business Complexity

**Instructions:** On a scale of .5 - low to 4-high (0 = N/A), rate each applicable attribute and compute the Business Complexity by dividing the total by the number of items rated above zero. [Notes: Business and technical complexity will be computed automatically in this worksheet, using the ratings you enter. Move your pointer over each attribute cell, marked with a red triangle, to see a definition of the attribute.]

Low Complexity	Business Attribute	High Complexity	Rating
0	1	2	3
Static	Business rules	Changing	3.5
Static	Current Business Systems	Changing	3
Known and Followed	Decision Making Process	Not Known	4
Low	Financial Risk to State	High	0.5
Local	Geography	State Wide	4
Clear and Stable	High Level Requirements	Vague	1
Few & Routine	Interaction with Other Departments and Entities	Many and New	4
None	Impact to Business Process	High	4
Few & Straight Forward	Issues	Multiple & Contentious	2.5
High	Level of Authority	Low	3
Clear	Objectives	Vague	1
Established	Policies	Non-existent	2
Minimal	Politics	High	3.5
Familiar	Target Users	Unfamiliar	0.5
Experienced	Project Manager's Experience	Inexperienced	1
Experienced	Team	Inexperienced	1
Loose	Time Scale	Tight	1
Low	Visibility	High	4
Total:			43.5
Complexity:			2.4

Project Name: CAIR 2.0 Strategy Project  
 OCIO Project #:  
 Department:  
 Revision Date: 5/5/11

# Complexity Assessment

## Technical Complexity

**Instructions:** On a scale of 0-low to 4-high, rate each applicable attribute and compute the Technical Complexity by dividing the total by the number of items rated above zero. Use the definitions in the student notebook for clarity.

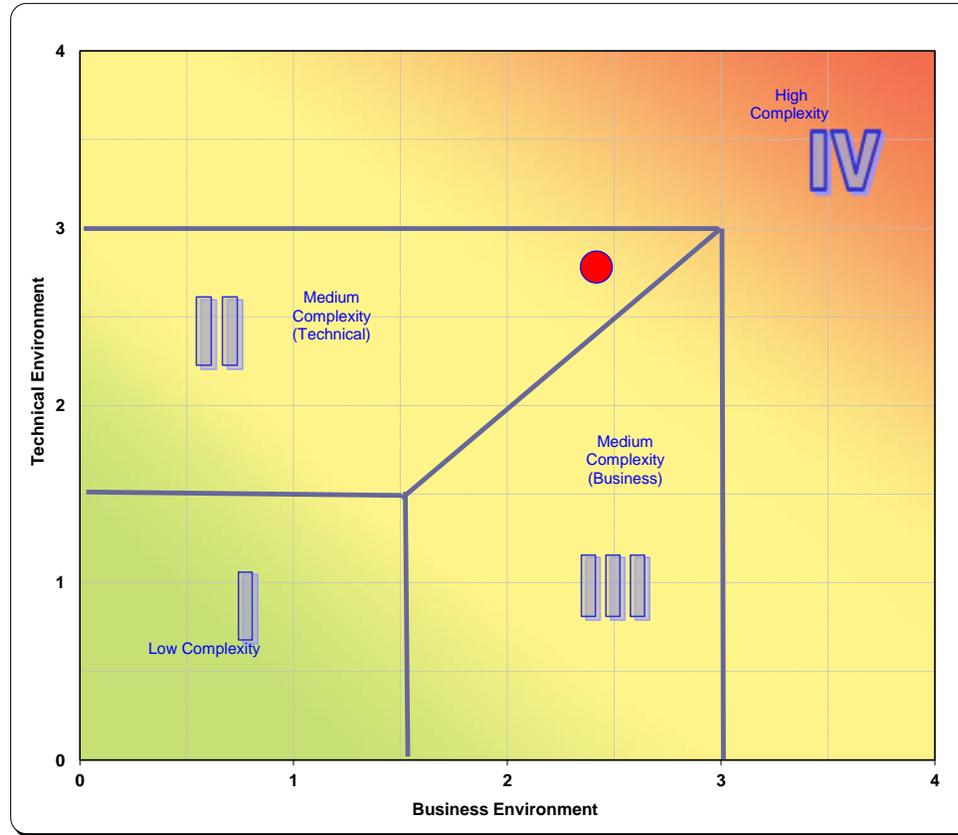
Low Complexity	Technical Attribute	High Complexity	Rating
0			
1	2	3	4
Local	Communications	State wide	4
Established	Delivery Mechanism	New	1.5
Local	Geography	State wide	4
Proven	Hardware	New	3.5
Stand-alone	Level Of Integration	Tightly Integrated	3.5
Proven/Stable	Networks (L/W)	New	1
In place	New Technology Architecture	Not in place	3
9-5, Mon-Fri	Operations	24-hour, 7-day	4
Expert	PM Technical Experience	Novice	2
Established and in use	Scope Management Process	None	1
Light	Security	Tight	4
Proven	Software	New	2.5
Established and In Use	Standards And Methods	None	2
Experienced	Team	Inexperienced	1
High	Tolerance To Fault	Low	4
Low	Transaction Volume	High	3.5
Total:			44.5
Complexity:			2.8

Project Name: CAIR 2.0 Strategy Project  
 OCIO Project #:  
 Department:  
 Revision Date: 5/5/11

# Complexity Assessment

## Complexity Diagram

**Instructions:** Plot your project in the appropriate complexity zone.  
 [Note: Your project will be plotted automatically in this worksheet, using the values computed in the previous tables.]



Scores	Business Complexity	<input type="text" value="2.4"/>
	Technical Complexity	<input type="text" value="2.8"/>

Project Name: CAIR 2.0 Strategy Project  
 OCIO Project #:  
 Department:  
 Revision Date: 5/5/11

## Complexity Assessment

### Suggested Project Manager Skill Set Guidelines

Complexity		Duration		Budget		Resources	
<input type="radio"/>	Zone 1	<input type="radio"/>	< 6 months	<input type="radio"/>	<\$500K	<input type="radio"/>	< 5
<input type="radio"/>	Zone II, Medium Zone III, Medium	<input type="radio"/>	< 1 year	<input type="radio"/>	<\$1M	<input type="radio"/>	<10
<input checked="" type="radio"/>	Zone II, High Zone III, High	<input checked="" type="radio"/>	>1 year; < 3 years	<input checked="" type="radio"/>	>\$1M; <\$5M	<input checked="" type="radio"/>	11 – 20
<input type="radio"/>	Zone IV	<input type="radio"/>	>3 years; <10 years	<input type="radio"/>	>\$5M; <\$100M	<input type="radio"/>	21 – 40
		<input type="radio"/>	>10 years	<input type="radio"/>	>\$100M	<input type="radio"/>	40+

PM Level: 2

Experience: 3 – 5 years as a key team member on a medium or large IT project or as a Project Manager on small or medium IT project. Technical experience commensurate with the proposed technology.

Professional Knowledge: Strong working knowledge of the CA-PMM, department's methodology, Software Development Life Cycle. Familiar with CA Budgeting, Procurement and Contracting processes.

<b>For Oversight Purposes:</b>
Zone I = Low Criticality/Risk
Zones II and III = Medium Criticality/Risk
Zone IV = High Criticality/Risk

**Assess the complexity of the project periodically: every two - three months and/or at the conclusion of each phase**

## Appendix D: CAIR Software Application version 3.30 Entity Relationship Diagram



## Appendix E: CAIR Software Application Import Entity Relationship Diagram



## Appendix F: Procurement Phase High Level Schedule



