Stage 1 Business Analysis

California Department of Technology, SIMM 19A.2 (Rev. 2.2, 5/31/2020)

1.1   General Information

Agency or State Entity Name: Department of Public Health

   If Agency/State entity not in list, then enter here. Click or tap here to enter text.

Organization Code: 4265

Proposal Name: California Immunization Registry 3 (CAIR3)

Proposal Description: CDPH proposes the replacement of the current state immunization information system (IIS), CAIR2 (California Immunization Registry 2). The COVID-19 pandemic has highlighted the significant weaknesses and limitations with the CAIR2 system in handling large-scale vaccination events. This effort will improve California immunization data quality and the Department's ability to address large-scale disasters such as the COVID-19 pandemic moving forward.

When do you want to start the project? 7/1/2022

Department of Technology Project Number (0000-000): 4265-080

1.2   Submittal Information

Contact Information

   Contact First Name: Tina

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Submission Date: 12/8/2021

Version Number: 0.2

Project Approval Executive Transmittal – (Attach Transmittal to the email submission.)

1.3   Business Sponsorship

Add additional Executive Sponsors or Business Owners as needed.

Executive Sponsors

Title: CDPH Center for Infectious Disease (CID), Division of Communicable Disease Control (DCDC), Chief

First Name: James

Last Name: Watt, MD, MPH

Business Program Area: (Name of the business program area represented by the Executive Sponsor(s))

CDPH Center for Infectious Disease (CID) Division of Communicable Disease Control (DCDC)

Business Owners

Title: Assistant Chief

First Name: Maria

Last Name: Volk

Business Program Area: CDPH CID DCDC Immunization Branch (IZB)

Title: Information Systems Supervisor 2, Acting Chief

First Name: Michael

Last Name: Powell

Business Program Area: CDPH CID DCDC IZB Registry and Immunization Rate Assessment Section

TIP: Copy and paste a row to add a Sponsor or Business Owner as needed.

Program Background and Context

The California Department of Public Health (CDPH), which resides in the California Health and Human Services Agency (CHHS), is organized into five centers dedicated to different aspects of public health policy and programs. One of those centers, the Center for Infectious Diseases (CID), protects the people in California from the threat of preventable infectious diseases and assists those living with an infectious disease in securing prompt and appropriate access to health care, medications, and associated support services. The Center for Infectious Diseases operates programs

through four divisions and offices: Division of Communicable Disease Control (DCDC), Office of Binational Border Health (OBBH), Office of Refugee Health, and Office of Aids (OA).

The Division of Communicable Disease Control (DCDC) works to promptly identify, prevent and control infectious diseases that pose a threat to public health, including emerging and re-emerging infectious diseases, vaccine-preventable agents, bacterial toxins, bioterrorism, and pandemics. DCDC encompasses six programs and branches: Immunization Branch (IZB), Communicable Disease Emergency Response Program, Infectious Disease Branch, Infectious Diseases Laboratory Branch, Sexually Transmitted Diseases Control Branch, and Tuberculosis Control Branch.

The mission of the Immunization Branch (IZB) is to provide leadership and support to public and private sector efforts to protect the population against vaccine-preventable diseases. The CDPH IZB 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 uses immunization data for epidemiological assessments and mandatory reporting.[1]

IZB includes the Registry and Assessments Section, which is responsible for, and provides oversight for, CAIR2, California's statewide Immunization Information System (IIS). Immunization information systems or IIS are an effective tool in helping the IZB achieve its mission. 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. 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.[2]

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.[3]

The original CAIR system (CAIR1) was a collaboration of registries throughout the state of California. The vast majority of Californian counties used the CAIR1 Software Application and were called CAIR Software Regions.[4] At that time, the remaining 10 counties used other software products. These included San Diego County which operated the San Diego Immunization Registry (SDIR), Imperial County which utilized its own software), and then eight counties in the central part of the state that used the RIDE/Healthy Futures software (San Joaquin County, Amador County, Calaveras County, Alpine County, Stanislaus County, Tuolumne County, Merced County, and Mariposa County).

The CAIR2 system was launched in three phases and formally accepted as complete on April 30, 2017. As a result of CAIR2, patient records and vaccine doses containing Health Leven Seven (HL7)

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[1] State of California. Department of Public Health. *Statewide Immunization Information (SIIS) Project Feasibility Study Report (FSR) Version 1.0*. July 23, 2008.
[2] State of California. Department of Public Health. *CAIR 2.0 Feasibility Study Report (FSR) Version 3.0*. July 14, 2011.
[3] State of California. Department of Public Health. *CAIR 2.0 Feasibility Study Report (FSR) Version 3.0*. July 14, 2011.
[4] State of California. Department of Public Health. *CAIR 2.0 Feasibility Study Report (FSR) Version 3.0*. July 14, 2011.

messages could be directly incorporated and there was a reduction in the time to produce cross-regional or statewide Healthcare Effectiveness Data and Information Sets (HEDIS) patient match reports.[5] By the end of the project, eight of the original 10 regions had joined CAIR2 and there were only two independent regions remaining.

Key attributes of CAIR2 include:

- CAIR2 is internet accessible.

- 49 of 58 CA counties participate counties accounting for 88 percent of California's population.

- Has secure, user interface allowing users to add/edit patients and vaccine doses, manage vaccine inventory, schedule patient immunizations according to the Advisory Committee on Immunization Practices (ACIP) recommendations, and run a variety of reports, including on aggregate and individual patients.

- Both independent regional registries agreed in 2019 to send patient and vaccine doses updates to CAIR2 so that all state immunization data will reside in the CAIR2 'hub' though this had not yet been implemented because of the COVID-10 pandemic. In June 2021, SD county made the decision to move to CAIR2 with a target date of March 2022.

- Supports electronic messaging in the standard HL7 format, including both vaccine updates (VXU message type) and query/responses (QBP message type) between providers and the IIS. Currently, about nearly 10,000 locations submitting electronic data, and >3,000 submitting electronic queries.

CAIR2, currently maintained by CDPH's Immunization Branch and a third-party vendor, is recognized and funded by CDC as the official state IIS.

In early 2020, the COVID-19 pandemic began, and the Department shifted priorities to address COVID-related efforts.

Over the course of the last year, the COVID-19 pandemic has highlighted the significant weaknesses and limitations with the CAIR2 system in handling large-scale vaccination events. Among the limitations are:

- Inability to support high volumes of incoming HL7 VXU and QBP messages.

- Suboptimal patient matching leading to excessive generation of duplicate patients, resulting in incomplete upload of patient COVD-19 vaccine doses.

- Insufficiently robust reporting capacity for system users, including counties and health plans.

- Poorly performing dose replacement (historical vs. administered doses) and record update logic.

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[5] State of California. Department of Public Health. *CAIR 2.0 Post Implementation Evaluation Report (PIER) Version 1.0*. June 15, 2018.

- Unmanageable vaccine scheduler.

- Inability to un-merge mistakenly merged patients.

As a result of the significant weaknesses with the current CAIR2 system, IZB is in need of a new and more robust process for handling large-scale vaccination events.

1.4   Stakeholders

Key Stakeholders

(Stakeholder" are individuals or groups impacted by the business processes addressed by the proposed project)

Organization Name: CDPH, Center for Infectious Diseases (CID), Division of Communicable Disease Control (DCDC)

Stakeholder Name: James Watt, MD, MPH (CDPH DCDC Chief)

Stakeholder Internal or External? Internal

When is the Stakeholder Impacted?

  Input to Business Process: Yes

  During Business Process: Yes

  Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

The Division of Communicable Disease Control (DCDC) encompasses six programs and branches: Immunization Branch (IZB), Communicable Disease Emergency Response Program (CDER), Infectious Disease Branch, Infectious Diseases Laboratory Branch, Sexually Transmitted Diseases Control Branch, and Tuberculosis Control Branch. The mission of Immunization Branch (IZB) is to provide leadership and support to public and private sector efforts to protect the population against vaccine-preventable diseases. The Registry and Assessments Section within CDPH's DCDC IZB is responsible for the current CAIR2 system. DCDC uses CAIR2 to capture, store, track, and consolidate vaccination data from multiple sources.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

The Division of Communicable Disease Control (DCDC) Chief is the project's Executive Sponsor, who will advocate for the project's success with internal and external stakeholders, resolve project issues elevated to the sponsor-level, and communicate about the project outside CDPH as needed. The DCDC Chief will provide ongoing strategic direction to maintain the project's alignment with Agency, Department, and division-level strategic goals.

The project team will identify the subject matter expertise needed for the project and will work with the IZB business units to identify IZB Subject Matter Experts (SMEs). IZB will allocate and assign staff to

the project accordingly. The IZB SMEs will identify, validate, and prioritize business requirements; participate in testing prior to solution implementation; and receive training on the "to-be" solution.

The project team will engage IZB stakeholders early and will communicate with them often. The project team will prepare and implement plans for structured communication that extends throughout the life of the project. The project's stakeholder management plan will describe the approach for interacting with stakeholders, setting and managing expectations, and ensuring stakeholders are effectively and appropriately involved throughout the project lifecycle.

Designated IZB staff will work to anticipate and manage the impacts of transitioning to a new system. The project's organizational change management effort will smooth the transition to the "to-be" solution by establishing an understanding of readiness, setting expectations, and cultivating acceptance.

DCDC branch and section management will advocate for the success of the project and will resolve project issues elevated for their attention. DCDC management will receive reports on the progress and status of the project at regular intervals and will ensure project information is disseminated appropriately.

DCDC will be responsible for post-implementation support using State and/or vendor resources.

Organization Name: CDPH, Information Technology Services Division (ITSD)

Stakeholder Name: Yasser Lahham (CDPH ITSD CIO)

Stakeholder Internal or External? Internal

When is the Stakeholder Impacted?

> Input to Business Process: No

> During Business Process: Yes

> Output of Business Process: No

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

The Information Technology Services Division (ITSD) is responsible for providing information resources and technology to DCDC and other business units within CDPH. ITSD assesses and works collaboratively with DCDC staff to identify the most appropriate technological platforms and necessary hardware investments, identifies and estimates major costs, and determines network readiness. ITSD monitors, and adjusts when needed, resources to support operations (e.g., increasing memory, adding servers). ITSD works with developers to deploy code to external environments (i.e., staging and production), uses its discretion to review code, and identifies any issues.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

The CIO will work in partnership with the Executive Sponsor, and as a member of project Steering Committee, to promote successful project outcomes.

ITSD will allocate technical and project management resources to plan and execute the project. The CDPH Information Security Office (ISO) and the CDPH Enterprise Architecture (EA) Team will be engaged early for guidance and support. The CDPH ISO will engage the CHHS ISO. Designated ITSD staff will identify, clarify, and validate technical requirements, receive technical knowledge transfer and/or training, and participate in testing prior to solution implementation. The full scope of project participation for this stakeholder depends on the solution that is ultimately selected.

Organization Name: San Joaquin County Regional Immunization Data Exchange (RIDE)

Stakeholder Name: Justin Labadie, Department Applications Analyst IV

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

Input to Business Process: Yes

During Business Process: Yes

Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

The RIDE regional registry is used by eight counties in the Central Valley as an immunization information system (IIS). RIDE has a current data sharing agreement with CDPH to supply all RIDE historical and ongoing data to CAIR2. Therefore, the change to new CAIR3 software may impact the way data is shared between CAIR2 and RIDE.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

Participation of the RIDE technical team in aspects of the project will be necessary to assure smooth transition of the data sharing component. RIDE will also be involved in the requirements gathering portion of the project.

Organization Name: CDPH Center for the Family Health (CFH) Woman Infants and Children (WIC) Program

Stakeholder Name: Christine Nelson, WIC Division Chief

Stakeholder Internal or External? Internal

When is the Stakeholder Impacted?

Input to Business Process: No

During Business Process: Yes

Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

The Women, Infants and Children Division helps families get healthy food by providing nutrition education, breastfeeding support, vouchers for healthy foods, and referrals to healthcare and other community services. As a result of a federal mandate, CDPH WIC has recently implemented a new management information system known as WIC WISE, transitioned from paper vouchers to the WIC EBT card, and implemented a new WIC App that provides service to WIC families through their smart phones (e.g., finding WIC-eligible foods, local agency offices, authorized vendors, etc.). The use of these new systems has provided important usable data with which WIC can improve WIC family services as well as WIC operations, including preventing, detecting, and responding to potentially fraudulent activities. There is an interface (immunization lookup) that exists between WIC WISE and CAIR2. Any changes to CAIR2 will impact the interface with the WIC WISE system.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

Since there is data exchange between the WIC WISE system and the CAIR2 system, any replacement to CAIR2 will require testing from the WIC Program to ensure that the interface is functioning.

Organization Name: Clinical Organizations / Sites

Stakeholder Name: Various

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

Input to Business Process: Yes

During Business Process: Yes

Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

Adoption of a new CAIR system by California will require concerted effort on many fronts. Organizations representing the user community will be used to gather input on functionality but will also be critical in getting the word out about coming changes to CAIR. They are the primary users of the CAIR2 system and promote Interoperability compliance (Centers for Medicare & Medicaid - CMS) They participate in COVID Vaccine Program (CoVP). They play a key role in the ease of access to and completeness of patient records. They also help improve efficiency overall with respect to ordering vaccines, reporting doses administered, and improving patient care via accurate vaccine forecasting at the point of care. They generate coverage assessment, Immunization Quality Improvement for Providers (IQIP).

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

They will be engaged as needed by leveraging periodic newsletters and ad hoc communications, IIS communications, webinars, and IIS trainings. Engaging this key stakeholder group will enable CAIR3 to expand its use as a lifelong registry. This group could be engaged through various existing forums (affiliated organizations and CA chapters) to include the American Academy of Pediatrics (AAP), American Academy of Family Practitioners (AAFP), hospital association, CA Primary Care Association, FQHC Association, CA Medical Association to provide insight/requirements into new CAIR3 functionality, as well as be kept informed of project deliverables and timelines.

Clinical sites that are not currently reporting to CAIR may be contacted to determine challenges and/or training related to using CAIR.

Organization Name: Centers for Disease Control and Prevention (CDC)

Stakeholder Name: Jan Hicks Thomson (CDC Public Health Analyst, Immunization Information Systems Support Branch, Immunization Services Division, National Center for Immunization and Respiratory Diseases)

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

> Input to Business Process: Yes

> During Business Process: Yes

> Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

A champion of ensuring accurate and current vaccination information for all Californians, the CDC is a critical funding partner of this project, as well as a subject matter expert in terms of required functionality and capability of an IIS and data quality. CDC sponsored the Immunization Gateway (IZ Gateway) Project that facilitates data exchange between IIS, large federal agencies, and multi-jurisdictional providers.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

Frequent meetings are held with IIS SME (Jan Hicks Thomson) to provide guidance and direction in terms of national policy and oversight of the project progress and spending. CDC leverages California's experience in planning and identifying a viable replacement of its CAIR system to share with other jurisdictions and partners. Since there are limitations on data sharing, CDPH will evaluate its participation in the IZ Gateway project (a CDC-sponsored initiative) by working with the Legal team.

Organization Name: Department of Healthcare Services (DHCS)

Stakeholder Name: Linette Scott

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

Input to Business Process: No

During Business Process: No

Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

The mission of DHCS is to provide Californians with access to affordable, integrated, high-quality health care, including medical, dental, mental health, substance use treatment services and long-term care. Their vision is to preserve and improve the overall health and well-being of all Californians. DHCS funds health care services for about 14 million Medi-Cal beneficiaries. About one-third of Californians receive health care services financed or organized by DHCS, making the Department the largest health care purchaser in California. Changes to California's current IIS would impact DHCS since it touches cross-departmental data sharing and engagement. In support of the State's ongoing COVID response, there is a need to promote and drive statewide efforts in management of associated data for all California citizens including improved data sharing among state agencies for expanded outreach to clients. DHCS receives IIS data that supports Medi-Cal.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

The stakeholder will be involved in periodic briefings and kept informed throughout the project.

Organization Name: Local Health Departments (LHDs)

Stakeholder Name: Various

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

Input to Business Process: Yes

During Business Process: Yes

Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

California's local health departments play a vital role in preparing for and responding to public health emergencies. CAIR2 is a key tool that LHDs use to access immunization data for reporting. The CDPH informs, coordinates, and assists local health services and offices in the matters of public health. As such, LHDs are impacted by this project since they have access to immunization data and aggregate reporting.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

The stakeholders will be included in local health calls and periodic regional meetings for collection of requirements and barriers to adoption.

Organization Name: Californians

Stakeholder Name: Various

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

      Input to Business Process: No

      During Business Process: No

      Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

Californians access to immunization records via a portal for school, camp, and vaccine credentialing. A variety of consumer access vendors, products and strategies are developing in the marketplace. They are direct recipients of the CAIR2 data.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

The stakeholder will be engaged through primary care providers. Primary care providers can provide printed materials available in their offices or could also use social media.

Organization Name: American Immunization Registry Association (AIRA)

Stakeholder Name: Rebecca Coyle, AIRA Executive Director

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

      Input to Business Process: Yes

      During Business Process: Yes

      Output of Business Process: No

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

AIRA exists to support and promote the use of immunization information to ensure healthy communities through the development and implementation of immunization information systems (IIS)

as a crucial tool in preventing vaccine-preventable diseases. California is an active member of AIRA, who convenes the Immunization Information System (IIS) community to drive policy. As a large state, AIRA looks to California to refine its strategies. Through AIRA, California policy can be instrumental for the rest of the country.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

California will actively participate in regional and national meetings to review and collect feedback on project direction and focus. AIRA and its members are a receptive audience for what California plans and does. AIRA will be involved in the requirements gathering for the new system.

Organization Name: CDPH Office of Legal Services (OLS) and CA Legislators

Stakeholder Name: Will Maguire (CDPH OLS)

Stakeholder Internal or External? Internal

When is the Stakeholder Impacted?

    Input to Business Process: Yes

    During Business Process: Yes

    Output of Business Process: No

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

California legislators and the CDPH Office of Legal Services Advocacy based on understanding of State need and benefits to constituents.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

Provide guidance and direction on statutes and legislation related to the CAIR system.

Organization Name: CA Advisory Councils (Childhood/adult) (CAIR User Group)

Stakeholder Name: Michele Barkus (CDPH CID Public Health Advisor)

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

    Input to Business Process: No

    During Business Process: No

    Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

They are advocates of the CAIR system and encourage adoption and utilization of the system.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

The stakeholder will be informed via periodic meetings, emails, and other communications.

Organization Name: CA Immunization Coalition (CIC)

Stakeholder Name: Catherine Martin

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

      Input to Business Process: Yes

      During Business Process: Yes

      Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

CIC in collaboration with partners throughout California encourage families to keep up with check-ups and routine immunizations. Immunization registry began has a childhood registry and has since expanded to lifespan registry. CIC is a potential advisory group to promote lifespan registry for the individual.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

The stakeholder will be informed via periodic meetings and email or other communications.

Organization Name: CDPH Vaccine for Children (VFC) Program

Stakeholder Name: Claudia Aguiluz (CDPH VFC Program Manager)

Stakeholder Internal or External? Internal

When is the Stakeholder Impacted?

      Input to Business Process: Yes

      During Business Process: Yes

      Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

The Vaccines for Children (VFC) Program is a federally-funded, state-operated vaccine supply program. This national program is intended to help raise childhood immunization levels, especially

among infants and young children throughout the U.S. Since its start on October 1, 1994, California's VFC Program has annually supplied vaccine, at no cost, to participating public and private sector providers. Any changes to the CAIR2 system will provide an opportunity to assess the degree to which VFC systems and processes should be tightly or loosely coupled with the new CAIR system.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

Stakeholders will be included in periodic meetings/discussions to determine the approach for maintaining and sharing data between the two systems or to consider how the new system might serve the Program's needs.

Organization Name: Other Statewide Programs (Department of State Hospitals and Department of Correction and Rehabilitation)

Stakeholder Name: Scott Davidson (CDCR)

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

  Input to Business Process: No

  During Business Process: No

  Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

CDCR uses CAIR to submit immunization data for inmates. Since there are special sensitivities for inmate information, CAIR2 handles their data differently. CDCR is essential to capturing requirements specific to the handling of inmate immunization data.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

CDCR will be involved in testing to ensure their systems interface with the new CAIR system.

Organization Name: Health Plan Payers and Insurers

Stakeholder Name: Various

Stakeholder Internal or External? External

When is the Stakeholder Impacted?

  Input to Business Process: No

  During Business Process: No

Output of Business Process: Yes

How are Stakeholders impacted? (Describe how the stakeholder is involved in the process)

Health Plan Payers and Insurers use the data in CAIR via the Healthcare Effectiveness Data and Information Set (HEDIS). There is one HEDIS process for all vaccines and one that is COVID-specific. HEDIS is a tool used by more than 90 percent of U.S. health plans to measure performance in healthcare by accessing areas such as effective of care, access and availability of care, and utilization.

How will the Stakeholder participate in the project? (Describe how the stakeholder will be involved in the project)

Health Plan Payers and Insurers will be Informed of the updates to the CAIR system.

TIP: Copy and paste to add Stakeholders as needed.

1.5   Business Program

1.5.1. Organization Name: California Department of Public Health (CDPH)

Business Program Name: Division of Communicable Disease Control (DCDC), Immunization Branch (IZB)

When is the unit impacted?

Input to the Business Process: Yes

During the Business Process: Yes

Output of the Business Process: Yes

How is the business program unit impacted? (Describe how the business program unit will be involved in the project)

The Division of Communicable Disease Control (DCDC) encompasses six programs and branches, including the Immunization Branch (IZB). The mission of Immunization Branch (IZB) is to provide leadership and support to public and private sector efforts to protect the population against vaccine-preventable diseases. The Registry and Assessments Section within CDPH's DCDC IZB is responsible for the current CAIR2 system. DCDC uses CAIR2 to capture, store, track, and consolidate vaccination data from multiple sources.

How will the business program unit participate in the project?

The DCDC will allocate and assign staff to the project as Subject Matter Experts (SMEs). The SMEs will identify, validate, and prioritize business requirements; receive training on the "to-be" solution; and participate in testing prior to solution implementation. Designated IZB staff will work to anticipate and manage the impacts of transitioning to a new system on staff and business processes. The project's organizational change management effort will smooth the transition to the "to-be" solution for IZB staff by establishing an understanding of readiness, setting expectations, and cultivating acceptance. DCDC management will advocate for the success of the project and will resolve project issues elevated to their level. DCDC management will receive reports on the progress and status of the project at regular intervals and will ensure project information is disseminated timey and appropriately.

TIP: Copy and paste to add Business Programs as needed.

1.6   Business Alignment

Business Driver(s)

Financial Benefit: No

    Increased Revenue: No

    Cost Savings: No

    Cost Avoidance: No

    Cost Recovery: No

Mandate(s): Choose an item.

Improvement

    Better Services to Citizens: Yes

    Efficiencies to Program Operations: Yes

    Improved Health and/or Human Safety: Yes

    Technology Refresh: No

Security

    Improved Information Security: No

    Improved Business Continuity: Yes

    Improved Technology Recovery: No

    Technology End of Life: No

Strategic Business Alignment

Strategic Plan Last Updated? 3/28/2019

1. Strategic Business Goal: Protect the Public's Health

Alignment: This effort will enhance California's resilience to current and emerging health threats by allowing the CDPH Immunization Branch to better handle vaccination events of both small and large scale.

2. Strategic Business Goal: Promote Health and Wellness

Alignment: This effort will help promote health and wellness by providing a more reliable platform to support immunization data and share pertinent data with external partners such as the CDC.

3. Strategic Business Goal: Optimize Data and Technology

Alignment: This effort will optimize data and technology improve the capturing, storing, tracking, and consolidation of vaccination data for better evidence-based decision making.

4. Strategic Business Goal: Enhance Services through Agile Operations

Alignment: This effort will involve key stakeholders during relevant project phases to ensure that that the outputs are customer-focused, transparent, and efficient.

TIP: Copy and paste to add Strategic Business Goals and Alignments as needed.

Executive Summary of the Business Problem or Opportunity:

The COVID-19 pandemic has highlighted the inadequacies of CAIR2, the current state immunization information system (IIS). Since the beginning of the pandemic, the application was unable to process vaccination data reliably and consistently.

During February and March of 2021, a significant increase in electronic data traffic produced a huge backlog of unprocessed doses and unanswered vaccine history queries. Because of the system issues, submissions were being held through the gateway and provisional acknowledgements had to be issued, resulting in many doses falling through the cracks without provider awareness.

Over a six-week period, a significant number of State and Vendor resources were engaged in almost daily incident rooms and parallel remediation efforts. Those efforts ranged from application and database finetuning to hardware configuration changes in attempts to stabilize the system.

In addition to failures to properly support increased data traffic, the pandemic revealed additional weaknesses that must be addressed in selection and deployment of a new CAIR system.

California has the opportunity to re-examine its strategy for CAIR2 and is proposing a new approach to better serve the needs of Californians. Key objectives of the new strategy for CAIR include the following:

1. The solution must be capable of managing a large volume of incoming submissions and responding to system queries from its approximately 10,000 submitting partners.
2. An improved/optimized patient matching algorithm is needed to support accurate and rapid processing of a high volume of electronic data being submitted around the clock.
3. Easily configurable parameters are needed to accommodate changing business rules such as changes needed to the vaccine scheduler.
4. System and hosting stability are essential during high traffic periods such as during a pandemic.
5. Better internal and external reporting functionality is needed to support all IIS users, including health care providers, health plans, and the CDC.

Providers need a trusted source for reliable vaccination data to serve their patient population. During a pandemic, providers rely on access to data to target underrepresented populations and ensure equitable access to vaccines. The State cannot perform its responsibility to monitor and report vaccination rates without a stable and reliable system to capture and house the data accurately.

Business Problem/Opportunity ID: 1

Business Problem/Opportunity Description:

Improve Data Processing and Data Quality:

During February and March of 2021, the significant increase in electronic data traffic produced a huge backlog of unprocessed doses and unanswered vaccine history queries in CAIR2. Increasing the number of messages processed per day will result in more timely data so that the Immunization Branch can better support participating health care providers and other authorized users. More timely information will assist doctors in making more informed clinical decisions. Due to the COVID-19 pandemic, there has been an increase in consumer requests for more immediate access to their vaccination data. Minimizing the lag between data entering CAIR and when that data is available to the customer or for reporting purposes to CDC will improve health and human safety as well as improve business continuity.

In addition, the current patient matching algorithm in the CAIR2 system is inadequate. The Immunization Branch receives on average 6,000 patients daily that placed in a "pending" status, meaning they require manual corrections (merging duplicate patient records or unmerging incorrect matches). Since the help desk staff (Data Exchange Team) can only dedicate so much time for the manual corrections, the backlog of corrections has accumulated to approximately 1.4 million pending records as of November 2021. This would also improve efficiencies to program operations by allowing the Data Exchange Team to provide support in other areas as needed. By addressing the data quality issues, the Immunization Branch can better improve health and human safety by reporting data more accurately and timely to external partners.

Objective ID: 1.1

Objective:

Within one year of implementation, improve services to providers by increasing the Department's ability to handle incoming immunization submissions to 2.5 million per day. By increasing the volume of data, the Immunization Branch can better support users such as health care providers that rely on this data for decision making.

Metric: The number of messages processed per day by the system.

Baseline: 1.5 million messages per day.

Target: 2.5 million messages per day.

Measurement Method: Program will run a daily report on the number of messages successfully processed per day and apply system monitoring utilizing existing CDPH tools. Program can also run simulations to ensure that the system can handle 2.5 million messages per day.

Objective ID: 1.2

Objective:

Within one year of implementation, improve data quality by decreasing the number of patient records held in suspension per day by 1.7%. Records held in suspension are unable to be processed into the database because they have more than one possible match in the database. Corrections of those pending records require manual intervention and are prone to human error. A reduction in pending records will prevent a large backlog of accumulating corrections and improve services to the public.

Metric: Percentage of patient records that are held in suspension per day and require manual corrections.

Baseline: 2.1% of new incoming records are held in suspension on average per day.

Target: 0.4% of new incoming records are held in suspension on average per day.

Measurement Method: Program will monitor dashboards daily that show the percentage of patient records requiring manual corrections to ensure that the pending rate is at 0.4% or below.

Business Problem/Opportunity ID: 2

Business Problem/Opportunity Description:

Reduce Workload Related to Vaccine Updates:

Currently under the CAIR2 system, the vaccine scheduler determines when doses are due. The scheduler pulls data from medical providers that submit messages via data exchange or by entering manually through the user interface. However, this system is not adaptable to changes. Whenever a rule change occurs (e.g., due to new regulations), all vaccines in the system must be regression

tested. The ability to incorporate automated regression testing would reduce the workload to regression test the vaccine scheduler after rule changes are published.

Objective ID: 2.1

Objective:

Within one year of implementation, reduce the timeframe necessary to address updates to the vaccination scheduler by 50% so that the Immunization Branch can respond to vaccine updates and implement in a timelier manner. When the scheduler is inaccurate due to delays in updating it, the clinical recommendations are also less accurate as a result. This impacts health and/or human safety. Improvements to this schedule change process will reduce missed opportunities for people to obtain vaccinations by allowing new rules to be implemented in a timelier manner.

Metric: Time (in weeks) to implement schedule change.

Baseline: Two weeks on average.

Target: 1 week on average.

Measurement Method: Program will measure vaccine scheduler implementation duration: starting from the time they receive the changes until the change is available to the user. Program will compare the new scheduler implementation durations to the benchmarks established in the previous system for equivalent vaccine types.

Business Problem/Opportunity ID: 3

Business Problem/Opportunity Description:

Improve System Stability:

During February and March of 2021, the significant increase in electronic data traffic to CAIR2 produced a huge backlog of unprocessed doses and unanswered vaccine history queries. Extraordinary utilization of human and hardware resources over a period of about six weeks were necessary to stabilize the system.

Objective ID: 3.1

Objective:

Within one year of implementation, support the approximately 10,000 data submitting partners with 24hr /7day application up-time. When the system is down, providers cannot access the database to make clinical decisions based on immunization data. This results in missed opportunities to vaccinate Californians. Improving the availability of the platform to providers and other submitting partners will strengthen service to the public and improve health and safety.

Metric: Scheduled uptime (percentage) for the application.

Baseline: 99.5% application uptime.

Target: 99.9% application uptime.

Measurement Method: ITSD will use telemetry tools/automated monitoring and reporting with immediate alerts to ensure business uptime is constantly maintained. Program will generate monthly reports to leadership on the application uptime for visibility.

Business Problem/Opportunity ID: 4

Business Problem/Opportunity Description:

Improve Reporting and Data Sharing Capabilities:

Under the current CAIR2 system, there are limitations to the reporting capabilities. The Immunization Branch is required to provide reports to external partners, such as daily COVID doses administered reports to CDC, a variety of county-wide reports, and health plans HEDIS (Healthcare Effectiveness Data and Information Set) reports. One of the main reports is a yearly IIS report to CDC, the Immunization Information System Annual Report (IISAR), which includes aggregated, statewide, and current immunization data from California to meet requirements of the Comprehensive Child Immunization Act of 1993. Under the CAIR2 system, it takes on average a month to pull together the data required to submit the IISAR. IZB needs the ability to pull the required data within a matter of days, rather than a month.

The second reporting issue relates to the user experience. Reports must be detailed and customizable to improve user experience and allow them to make informed decisions as it relates to administering vaccines. Currently in the CAIR2 system, external partners are able to run 'canned' as well as ad hoc reports. However, the system often times out, resulting in calls to the CAIR help desk. This presents an opportunity to produce a variety of patient-specific and aggregate patient reports, both 'canned' and ad hoc reports, without timing out.

Objective ID: 4.1

Objective:

Within one year of implementation, reduce the timeframe necessary to provide data to CDC's mandatory annual Immunization Information System Annual Report (IISAR) by 93%. The IISAR data is used as an evaluation tool for CDC and partners to measure immunization progress, identify areas for improvement, and policy-level decision making.

Metric: Days to provide data to CDC for IISAR.

Baseline: 30 days (one month).

Target: Two days.

Measurement Method: Within one year of implementation and then annually in conjunction with report submission, program will document the IISAR duration, starting with when the report is initiated to when it is completed and compare to baseline.

TIP: Copy and paste to add Problem/Opportunities and/or related Objectives as needed.

TIP: Each Problem/Opportunity statement must have at least one Objective.

Project Approval Lifecycle Completion and Project Execution Capacity Assessment

1. Does the proposal development or project execution anticipate sharing resources (state staff, vendors, consultants or financial) with other priorities within the Agency/state entity (projects, PALs, or programmatic/technology workload)?

   Answer (yes or no): Yes

2. Does the Agency/ state entity anticipate this proposal will result in the creation of new business processes or changes to existing business processes?

   Answer (No, New, Existing, or Both):   Both New and Existing Processes

1.7   Project Management

Project Management Risk Score: 0.4

(Attach a completed Statewide Information Management Manual (SIMM) Section 45 Appendix A to the email submission.)

Existing Data Governance and Data

1. Does the Agency/state entity have an established data governance body with well-defined roles and responsibilities to support data governance activities?

   Answer (Unknown, Yes, No, Clear): Yes

   If Yes, include the data governance organization chart as an attachment to your email submission.

2. Does the Agency/state entity have data governance policies (data policies, data standards, etc.) formally defined, documented, and implemented?

   Answer (Unknown, Yes, No, Clear): Yes

   If Yes, include the data governance policies as an attachment to your email submission.

   For security and confidentiality reasons, we have not attached our work in progress draft data governance framework to this proposal.

3. Does the Agency/state entity have data security policies, standards, controls, and procedures formally defined, documented, and implemented?

Answer (Unknown, Yes, No, Clear): Yes

If Yes, attach the existing documented security policies, standards, and controls used to your email submission.

(1) The CDPH Information System Security Requirements for Projects provides 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 minimum security requirements it contains. The CDPH Information Systems Security Requirements for Projects document explains 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 will also be used in conjunction with the CDPH ISO compliance review program of its information system services customers. These security requirements serve as a universal set of requirements which must be met regardless of physical hosting location or entities providing operations and maintenance responsibility. For security and confidentiality reasons, we have not attached the CDPH Information System Security Requirements for Projects to this proposal.
(2) All state departments are required to have implemented an information privacy program (Government Code Section 11019.9), including rules of conduct regarding personal information (Civil Code Section 1798.20), a designated employee in charge of ensuring program compliance (Civil Code Section 1798.22), and other guidelines, procedures, training, and compliance as outlined in the Information Practices Act (IPA) (Civil Code Section 1798 et seq.) and the State Administrative Manual (Sections 5100 and 5300 through 5399).
(3) CDPH follows the privacy policies contained in the Information Privacy Program documented in Chapter 11 of the Public Health Administrative Manual. For security and confidentiality reasons, we have not attached the Public Health Administrative Manual to this proposal.

4. Does the Agency/state entity have user accessibility policies, standards, controls, and procedures formally defined, documented, and implemented?

Answer (Unknown, Yes, No, Clear): Yes

If Yes, attach the existing documented policies, accessibility governance plan, and standards used to the email submission.

CDPH understands the importance of ensuring that its Internet-facing websites are accessible by the intended audiences and that its internal electronic and information technology systems are accessible by authorized state employees, including persons with disabilities. CDPH IT projects incorporate requirements to address these needs by complying with accessibility requirements such as the requirements set out in Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. Section 794d), and regulations implementing that act as set forth in Part 1194 of Title 36 of the Code of Federal Regulations. CDPH accessibility practices align with the guidance provided by the following sources.

(1) California Department of Technology, IT Accessibility Resource Guide, SIMM Section 25, October 2017. Link: https://cdt.ca.gov/wp-content/uploads/2017/10/SIMM-25-October-2017.pdf
(2) State Administrative Manual Section 4833, Information Technology Accessibility Policy. Link: http://sam.dgs.ca.gov/TOC/4800.aspx
(3) Office of the State CIO, IT Policy Letter (ITPL): Information Technology Accessibility (ITPL 10-10). Link: https://cdt.ca.gov/technology-letters/ Section 4-1065 of the Public Health Administrative Manual, which addresses Web Site and Information Technology Accessibility. For security and confidentiality reasons, we have not attached the Public Health Administrative Manual to this proposal.

5. Do you have existing data that you are going to want to access in your new solution?

    Answer (Unknown, Yes, No, Clear): Yes

    If Yes, include the data migration plan as an attachment to your email submission.

    During the project, IZB will work with a data migration vendor to develop a plan for data migration.

6. If data migration is required, please rate the quality of the data.
    Select data quality rating: Some issues identified with the existing data.

1.8   Criticality Assessment

Business Criticality

Legislative Mandates: Choose an item.

Bill Number(s)/Code(s): Click or tap here to enter text.

Language that includes system relevant requirements: Click or tap here to enter text.

TIP: Copy and paste to add Bill Numbers/Codes and relevant language.

Business Complexity Score: 2.5

(Attach a completed SIMM Section 45 Appendix C to the email submission.)

Noncompliance Issues: Indicate if your current operations include noncompliance issues and provide a narrative explaining how the business process is noncompliant.

Programmatic regulations: Choose an item.

HIPAA/CIIS/FTI/PII/PCI: Choose an item.

Security: Choose an item.

ADA: Choose an item.

Other: Choose an item.

        N/A: Yes

   Noncompliance Description: Click or tap here to enter text.

Additional Assessment Criteria

1. What is the proposed project Implementation start date? Click or tap to enter a date.

2. Is this proposal anticipated to have high public visibility?   Choose an item.
   If "Yes", then please identify the dynamics of the anticipated high visibility below:
   As a result of the COVID-19 pandemic, there has been an increased need for an immunization information system (IIS) that can handle large-scale vaccination events. Since the COVID-19 vaccine has such high visibility to the public and all Californians, the new proposed system for handling vaccination records will also be highly visible.

3. If there is an existing Privacy Threshold Assessment/Privacy Information Assessment, then include as an attachment to your email submission.

4. Does this proposal affect business program staff located in multiple geographic locations? Yes

   If Yes, provide an overview of the geographic dynamics below and enter the specific information in the space provided.

   City Richmond   State: CA

   Number of locations: 1

   Approximate number of Staff: 21

   City Los Angeles   State: CA

   Number of locations: 1

   Approximate number of Staff: 5

   City Fresno   State: CA

   Number of locations: 1

   Approximate number of Staff: 4

   City Orange   State: CA

   Number of locations: 1

   Approximate number of Staff: 3

   City Redding   State: CA

   Number of locations: 1

   Approximate number of Staff: 1

City Riverside   State: CA

Number of locations: 1

Approximate number of Staff: 1

City Rocklin   State: CA

Number of locations: 1

Approximate number of Staff: 1

City San Bernardino   State: CA

Number of locations: 1

Approximate number of Staff: 1

City San Diego   State: CA

Number of locations: 1

Approximate number of Staff: 1

TIP: Copy and paste to add Locations as needed.

1.9   Funding

1. Does the Agency/state entity anticipate requesting additional resources through a budget action to complete the project approval lifecycle?

   Answer (Yes, No, Clear): No

2. Will the state possibly incur a financial sanction or penalty if this proposal is not implemented?

   Answer (Yes, No, Clear): No

   If yes, please identify the financial impact to the state:

   Click or tap here to enter text.

FUNDING SOURCE	FUND AVAILABILTY DATE
General Fund: Choose an item.	Click or tap to enter a date.
Special Fund: Choose an item.	Click or tap to enter a date.
Federal Fund: Yes	9/1/2021
Reimbursement: Choose an item.	Click or tap to enter a date.
Bond Fund: Choose an item.	Click or tap to enter a date.
Other Fund: Choose an item.	Click or tap to enter a date.

   If "Other Fund" is selected, specify the funding source: Click or tap here to enter text.

1.10 Reportability Assessment

1. Does the Agency/state entity's IT activity meet the definition of an IT Project found in the State Administrative Manual (SAM) Section 4819.2?

   Answer (Yes, No, Clear): Yes

   If No" this initiative is not an IT project and is not required to complete the Project Approval Lifecycle. (Reportable Project Decision Tree (RPDT) Reference Guide, Reference R1.)

2. Does the activity meet the definition of Maintenance or Operations found in SAM Section 4819.2?

Answer (Yes, No, Clear): No

If Yes, this initiative is not required to complete the Project Approval Lifecycle. Please report this workload on the Agency Portfolio Report and provide an explanation below:

Click or tap here to enter text.

3. Has the project/effort been previously approved and considered an ongoing IT activity identified in SAM Section 4819.2, 4819.40? **NOTE**: Requires a Post Implementation Evaluation Report (PIER) submitted to the CDT.

   Answer (Yes, No, Clear): No

   If Yes, this initiative is not required to complete the Project Approval Lifecycle. Please report this workload on the Agency Portfolio Report.

4. Is the project directly associated with any of the following as defined by SAM Section 4812.32? Includes single-function process-control systems; analog data collection devices, or telemetry systems; telecommunications equipment used exclusively for voice communications; Voice Over Internal Protocol (VOIP) phone systems; acquisition of printers, scanners and copiers.

   Answer (Yes, No, Clear): No

   If Yes, this initiative is not required to complete the Project Approval Lifecycle. Please report this workload on the Agency Portfolio Report.

5. Is the primary objective of the project to acquire desktop and mobile computing commodities as defined by SAM Section 4819.34, 4989 (RPDT Reference Guide, References R8)?

   Answer (Yes, No, Clear): No

   If Yes, this initiative is a non-reportable project. Approval of the Project Approval Lifecycle is delegated to the head of the state entity. Submit a copy of the completed, approved Stage 1 Business Analysis to the CDT and track the initiative on the Agency Portfolio Report.

6. Does the Project meet all of the criteria for Commercial-off-the-Shelf (COTS) Software and Cloud Software-as-a-Service (SaaS) delegation as defined in SAM Section 4819.34, 4989.2, and SIMM Section 22? (RPDT Reference Guide, Reference R9.)

   Answer (Yes, No, Clear): No

   If Yes, this initiative is a non-reportable project. Approval of the Project Approval Lifecycle is delegated to the head of the state entity; however, submit an approved SIMM Section 22 COTS/SaaS Acquisition Information Form to the CDT.

7. Will the project require a Budget Action to be completed?

Answer (Yes, No, Clear): No

8. Is it anticipated that the project will exceed the delegated cost threshold assigned by CDT as identified in SIMM Section 15 Departmental Delegated Cost Thresholds?

Answer (Yes, No, Clear): Yes

9. Are there any previously imposed conditions place on the state entity or this project by the CDT (e.g. Corrective Action Plan)?

Answer (Yes, No, Clear): No

If Yes, provide the details regarding the conditions below: Click or tap here to enter text.

10. Is the system specifically mandated by legislation?

Answer (Yes, No, Clear): No

Department of Technology Use Only

Original "New Submission" Date: 6/21/2022

Form Received Date: 6/21/2022

Form Accepted Date: 6/21/2022

Form Status: Completed

Form Status Date: 6/21/2022

Form Disposition: Approved

     If Other, specify: Click or tap here to enter text.

Form Disposition Date: 6/21/2022