

Stage 1 Business Analysis

California Department of Technology, SIMM 19A.3 (Ver. 3.0.8, 02/01/2022)

1.1 General Information

1. Agency or State entity Name: 4260 - Health Care Services, Department of

If Agency/State entity is not in the list, enter here with the organization code.

Click or tap here to enter text.

- 2. Proposal Name and Acronym: Interoperability Project
- 3. Proposal Description: (Provide a brief description of your proposal in 500 characters or less.)

The purpose of the proposed project is for the Department of Health Care Services (DHCS), as the State Medicaid Agency (SMA), to implement Application Programming Interfaces (APIs) for Patient Access, Provider Directory, and Drug Formulary to comply with the Centers for Medicare and Medicaid Services (CMS) Interoperability and Patient Access Final Rule. The APIs will enable beneficiaries to access personal health information, list of providers, and outpatient prescription drugs via Third Party Applications. The implementation of APIs will empower beneficiaries to coordinate their own health care, provide opportunity for providers and beneficiaries to make informed health care decisions, and reduce the burden to payers and providers that can lead to better health outcomes for beneficiaries.

Proposed Project Execution Start Date: 7/1/2022

4. S1BA Version Number: Version 2

1.2 Submittal Information

1. Contact Information

Contact Name: Gloria Hart

Contact Email: Gloria.Hart@dhcs.ca.gov

Contact Phone: (279) 599-2828

2. Submission Type: Updated Submission (Post-Approval)

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If Withdraw, select Reason: Choose an item.

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

Sections Changed, if this is a Submission Update: (List all sections changed.)

- 1.1 General Information
- 1.3 Business Sponsorship
- 1.4 Stakeholder Assessment
- 1.5 Business Program
- 1.7 Business Outcomes Desired
- 1.8 Project Management
- 1.9 Initial Complexity Assessment
- 1.10 Funding

Summary of Changes: (Summarize updates made.)

- 1.1 General Information Updated the proposal description
- 1.3 Business Sponsorship Updated the business owner.
- 1.4 Stakeholder Assessment Clarified Federal stakeholder as CMS.
- 1.5 Business Program Minor updates to describe business need for the DHCS organization in relation to data exchange activities.
- 1.7 Business Outcomes Desired Updated to describe the scope as limited to the technical components of the CMS Final Rule.
- 1.8 Project Management Updated to reflect the business process impacts.
- 1.9 Initial Complexity Assessment Updated to reflect a reduced complexity score due to no impact to existing DHCS systems.
- 1.10 Funding Updated to reflect the estimated cost for this effort.
- 3. Attach Project Approval Executive Transmittal to your email submission.
- 4. Attach Stage 1 Project Reportability Assessment to your email submission.

1.3 Business Sponsorship

1. Executive Champion (Sponsor)

Title: Deputy Director, Chief Data Officer

Name: Linette Scott, M.D.

Business Program Area: Enterprise Data and Information Management

Title: Deputy Director

Name: Susan Philip

Business Program Area: Health Care Delivery Systems

2. Business Owner

Title: Assistant Deputy Director

Name: Phil Heinrich

Business Program Area: Enterprise Data and Information Management

Enter any content that you want to repeat, including other content controls. You can also insert this control around table rows in order to repeat parts of a table.

3. Product Owner

Title: Chief, Health Information Management Division

Name: Mike Bhatt

Business Program Area: Health Information Management

TIP: Copy and paste or click the + button in the lower right corner on any section to add additional Executive Champions, Business Owners, or Product Owners with their related Business Program Areas as needed.

1.4 Stakeholder Assessment

The Stakeholder Assessment is designed to give the project team an overview of communication channels that the state entity needs to manage throughout the project. More stakeholders may result in increased complexity to a project.

1. Indicate which of the following are interested in this proposal and/or the outcome of the project. (Select 'Yes' or 'No' for each.)

State Entity Only: No

Other Departments/State Entities: No

Public: No

Federal Entities: Yes

Governor's Office: No

Legislature: No

Media: No

Local Entities: No

Special Interest Groups: No

Other: No

2. Describe how each group marked 'Yes' will be involved in the planning process.

Federal Entities (CMS) – DHCS will engage with the CMS throughout the planning process to coordinate requests for Federal Financial Participation and to ensure that DHCS changes are consistent with federal requirements for interoperability.

1.5 Business Program

- Business Program Name: DHCS Interoperability
- **2. Program Background and Context:** (Provide a brief overview of the entity's business program(s) current operations.)

DHCS is the single state agency responsible for administering the Medi-Cal Program. As such, DHCS has been responsible for implementing interoperability programs such as the Promoting Interoperability Program (PIP). PIP, formerly the Medi-Cal Electronic Health Record (EHR) Incentive Program, was authorized under the federal Health Information Technology for Economic and Clinical Health Act (HITECH) in 2009. The HITECH Programs, including PIP, ended in Fall 2021. However, CMS continues to advance interoperability requirements through new regulations. In May 2020, CMS issued the Interoperability and Patient Access Final Rule. This rule places specific requirements on SMAs, Medicaid managed care plans, Children's Health Insurance Program (CHIP) agencies, and CHIP managed care entities. DHCS has responsibility to comply with the required provisions of the CMS Interoperability and Patient Access Final Rule. DHCS understands that CMS does not require nor intend for any business value to be generated by SMAs to meet the interoperability requirements. Rather, the Interoperability Final Rule requires SMAs to make patient, provider, and formulary data available through an API to third-party applications. The APIs will enable third-party application developers to serve beneficiaries their personal health information, list of providers, and outpatient prescription drugs. The implementation of APIs will empower beneficiaries to coordinate their own health care, provide opportunity for providers and beneficiaries to make informed health care decisions, and reduce the burden to payers and providers that can lead to better health outcomes for beneficiaries. Thus, the responsibility for developing the business-value laden business applications to access the Medicaid data lies wholly with the third-party application developers and is not within the scope for DHCS. As a result, the Medi-Cal Interoperability effort has been refined to be limited to the investment in creating the APIs to make the required data available to third-party applications to meet the technical component of the Final Rule.

3. How will this proposed project impact the product or services supported by the state entity?

The required APIs will provide the basis for future enterprise interoperability. This effort will allow us to share data with third party applications, thus allowing the public more streamlined access to their health data. DHCS is not developing third-party applications for this effort, just opening the gateway to share data.

TIP: Copy and paste or click the + button in the lower right corner to add Business Programs, with background and context and impact descriptions as needed.

1.6 Project Justification

1. Strategic Business Alignment

Enterprise Architect

Title: Enterprise Strategy & Services Branch / Senior Enterprise Architect

Name: Ioana Alcouffe

Strategic Plan Last Updated? 9/14/2015

Strategic Business Goal: Comply with Federal Regulations

Alignment: CMS requires compliant data sharing practices, to include those that require interoperability with third party applications. Federal regulatory compliance is a condition for enhanced Federal Financial Participation (FFP) and may be necessary to avoid potential loss in enhanced CMS funding.

TIP: Copy and paste or click the + button in the lower right corner to add Strategic Business Goals and Alignments as needed.

Mandate(s): Federal

Bill Number/Code, if applicable: 21st Century Cures Act (Public Law 114-255)

Add the Bill language that includes system-relevant requirements:

Under the authority of the 21st Century Cures Act, the CMS has required in administrative rule the SMAs share patient, provider, and formulary data in required, interoperable standards. (https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and)

TIP: Copy and paste or click the + button in the lower right corner to add Bill Numbers/Codes and relevant language as needed.

2. Business Driver(s)

Financial Benefit: No

Increased Revenue: No

Cost Savings: No

Cost Avoidance: Yes

Cost Recovery: No

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

If the answer to the above question is "Yes," please explain:

Federal regulatory compliance is necessary to avoid potential loss in enhanced CMS funding.

Improvement

Better Services to the People of California: Yes

Efficiencies to Program Operations: No

Improved Equity, Diversity, and/or Inclusivity: No

Improved Health and/or Human Safety: No

Improved Information Security: No

Improved Business Continuity: No

Improved Technology Recovery: No

Technology Refresh: No

Technology End of Life: No

1.7 Business Outcomes Desired

Executive Summary of the Business Problem or Opportunity:

The CMS Interoperability and Patient Access Final Rule, published May 2020, requires SMAs to establish the Patient Access, Provider, and Formulary APIs to make available a variety of data available to third-party applications, at a beneficiary's request.

DHCS understands that CMS does not require nor intend for any business value to be generated by SMAs in order to meet the interoperability requirements. Rather, the Final Rule requires SMAs make patient, provider, and formulary data available through APIs to third-party applications. Thus, the responsibility for developing the business-value laden business applications to access the Medicaid data lies wholly with the third-party application developers and is not within the scope for DHCS. As a result, the Medi-Cal Interoperability effort has been refined to be limited to the investment in creating the APIs to make the required data available to third-party applications to meet the technical component of the Final Rule.

DHCS' primary goal is to comply with CMS' Final Rule to avoid penalties resulting from non-compliance and to comply with the required Fast Healthcare Interoperability Resources (FHIR) standard that defines how healthcare information can be exchanged between different systems regardless of how it is stored in those systems.

Objective ID: 1

Objective: DHCS will support appropriate access to data required under the CMS Interoperability and Patient Access Final Rule (Final Rule), that is maintained by DHCS, via FHIR APIs ensuring beneficiaries have the information to make informed care decisions using an authorized Third-Party Application (TPA) of their choice.

Metric 1: Upon implementation of the FHIR API solution, DHCS shall demonstrate that the documented capabilities for each FHIR API and the requirements necessary for TPA organizations to gain production API access, are publicly accessible in accordance with the Final Rule.

Baseline: Zero percent of TPA organizations can access these datasets via a FHIR API today. DHCS has a manual data collection process for an individual recipient request. Documentation/guidance on production API access is not currently publicly accessible to TPA organizations.

Target Result: 100% percent of TPA organizations will have access to the FHIR API documentation as well as the necessary steps they must take to gain production API access, in accordance with the Final Rule.

Objective ID: 2

Objective: DHCS will avoid a loss in enhanced federal funding due to noncompliance with the Final Rule by achieving compliance.

Metric 1: Loss of enhanced federal funding avoided by complying with the Final Rule.

Baseline: DHCS is not currently compliant with the federally mandated dates outlined in the Final Rule. DHCS has lost \$0 dollars to date, in related federal funding, due to non-compliance with the Final Rule.

Target Result: DHCS will lose \$0 dollars in related federal funding, by complying with the Final Rule in accordance with the agreed upon dates approved by CMS as part of the Advanced Planning Document process.

TIP: Copy and paste or click the + button in the lower right corner to add Objectives as needed. Please number for reference.

TIP: Objectives should identify WHAT needs to be achieved or solved. Each objective should identify HOW the problem statement can be solved and must have a target result that is specific, measurable, attainable, realistic, and time-bound. Objective must cover the specific. Metric and Baseline must detail how the objective is measurable. Target Result needs to support the attainable, realistic, and time-bound requirements.

1.8 Project Management

1. Project Management Risk Score: 0.3

(Attach a completed <u>Statewide Information Management Manual (SIMM) Section 45 Appendix A Project Management Risk Assessment Template</u> to the email submission.)

2. Project Approval Lifecycle Completion and Project Execution Capacity Assessment

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

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): No

1.9 Initial Complexity Assessment

1. Business Complexity Score: 1.3

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

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

Programmatic regulations: Yes

HIPAA/CIIS/FTI/PII/PCI: No

Security: No

ADA: No

Other: No

Not Applicable: No

Noncompliance Description:

This effort will support DHCS compliance with the CMS Interoperability and Patient Access Final Rule (CMS-9115-F) and ONC 21st Century Cures Act Final Rule (RIN 0955-AA01). DHCS as an SMA is specifically named as an entity that is required to comply.

References to the specifics rules in question are listed below:

https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and

https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification.

3. Additional Assessment Criteria

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

How many locations and total users is the project anticipated to affect?

Number of locations: N/A

Estimated Number of Transactions/Business Events (per cycle): N/A

Approximate number of internal end-users: N/A

Approximate number of external end-users: N/A.

1.10 Funding

Planning

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

If Yes, when will a budget action be submitted to your Agency/DOF for planning dollars?

Budget Request Name: 4260-168-BCP-2021-A1 - FY 2021-22 - 4/1/2021

Budget Request Name: 4260-193-BCP-2022-A1 - FY 2022-23 - 4/1/2022

Budget Request Name: 4260-203-BCP-2023-A1 - FY 2023-24- 4/1/202

2. Please provide the Funding Source(s) and dates funds for planning will be made available:

Federal

CA-2021-06-03-MMIS-PAPD - 6/30/2021

CA-2022-05-20-MMIS-PAPD-IAPDU - 5/20/2022

CA-2022-12-22-MMIS-PAPDU - 12/22/2022

General Fund - 7/1/2021

Project Implementation Funding

1. Has the funding source(s) been identified for project implementation? Yes

If known, please provide the Funding Source(s) and dates funds for implementation will be made available:

DHCS will seek 90/10 FFP through an Implementation Advance Planning Document (APD) with CMS.

DHCS has a state BCP to request state general fund associated with this effort.

Will a budget action be submitted to your Agency/DOF? Yes

If "Yes" is selected, specify when this BCP will be submitted: 2/1/2023

2. Please provide a rough order of magnitude (ROM) estimate as to the total cost of the project: Estimated budget is \$2.5 to \$5 million. Less than \$10 Million

End of agency/state entity document.

Please ensure ADA compliance before submitting this document to CDT.

When ready, submit Stage 1 and all attachments in an email to ProjectOversight@state.ca.gov.

Department of Technology Use Only

Original "New Submission" Date: 9/16/2024

Form Received Date: 9/16/2024
Form Accepted Date: 9/16/2024

Form Status: Completed

Form Status Date: 9/16/2024

Form Disposition: Approved

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

Form Disposition Date: 9/16/2024

Department of Technology Project Number (0000-000): 4260-247