

## **Appendix B**

### **Scope of Work and Project Requirements**

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# 1 Project Overview

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## 1.1 Background and Purpose

The State of Delaware Department of Health and Social Services (DHSS), Division of Public Health (DPH), seeks to procure professional services and a contractor-hosted Software as a Service (SaaS) product to manage single-year and multiple-year maintenance, hosting, and enhancement services for the Delaware Immunization Information System (IIS), DelVAX.

DHSS defines the “project” in Appendix B as the totality of contractor work and activities throughout the contract period, which is delineated by a set of project lifecycle phases. The purpose of Appendix B is to define the project lifecycle and phases; define the project team organization and roles; define the project deliverables; and define the project requirements (business, functional and technical requirements).

## 1.2 Project Lifecycle

The contractor shall organize and manage the project based on five distinct lifecycle phases: a Planning Phase, a Configuration and Customization Phase, a Testing and Deployment Phase, an Operations and Support Phase, and a Project Transition-Out Phase. Each phase is represented by a set of mandatory deliverables and activities required by the contractor.

### 1.2.1 Planning Phase

The Planning Phase includes all the mandatory deliverables and activities required by the contractor to proceed to the Configuration and Customization Phase:

- Schedule and conduct meetings with the project team to discuss the requirements; and finalize the format and content for each deliverable.
- Schedule and conduct meetings with the contractor regarding legacy data conversion planning.
- Finalize contractor and stakeholder staffing for all project phases.
- Finalize subcontractor and/or vendor contracts, if applicable.
- Provide deliverable: Project Schedule.
- Provide deliverable: Change Management Plan.
- Provide deliverable: Continuity of Operations Plan.
- Provide deliverable: Data Conversion Plan.
- Provide deliverable: Architecture Network Diagram.

### 1.2.2 Configuration and Customization Phase

The Configuration and Customization Phase includes all the mandatory deliverables and activities required by the contractor to proceed to the Testing and Deployment Phase:

- Schedule and conduct meetings with the project team to review the project status and schedule, and to discuss the deliverables and activities associated with this phase.
- Spin-up the cloud instance for the SaaS product.
- Configure the product.
- Customize the product, if applicable (e.g., interfaces, data conversion, etc.).
- Implement the Data Conversion Plan.
- Update the Project Schedule.
- Provide deliverable: Interface Control Document(s).
- Provide deliverable: Training Plan.
- Provide deliverable: Test Plan.

- Provide deliverable: Product Deployment Plan.

### **1.2.3 Testing and Deployment Phase**

The Testing and Deployment Phase includes all the mandatory deliverables and activities required by the contractor to proceed to the Operations and Support Phase:

- Schedule and conduct meetings with the project team to review the project status and schedule, and to discuss the deliverables and activities associated with this phase.
- Implement the Test Plan.
- Implement the Training Plan.
- Implement the Product Deployment Plan.
- Implement the Interface Control Document (s).
- Update the Project Schedule.
- Provide deliverable: User Guide.
- Provide deliverable: Data Element Dictionary.

### **1.2.4 Operations and Support Phase**

The Operations and Support Phase includes all the mandatory deliverables and activities required by the contractor:

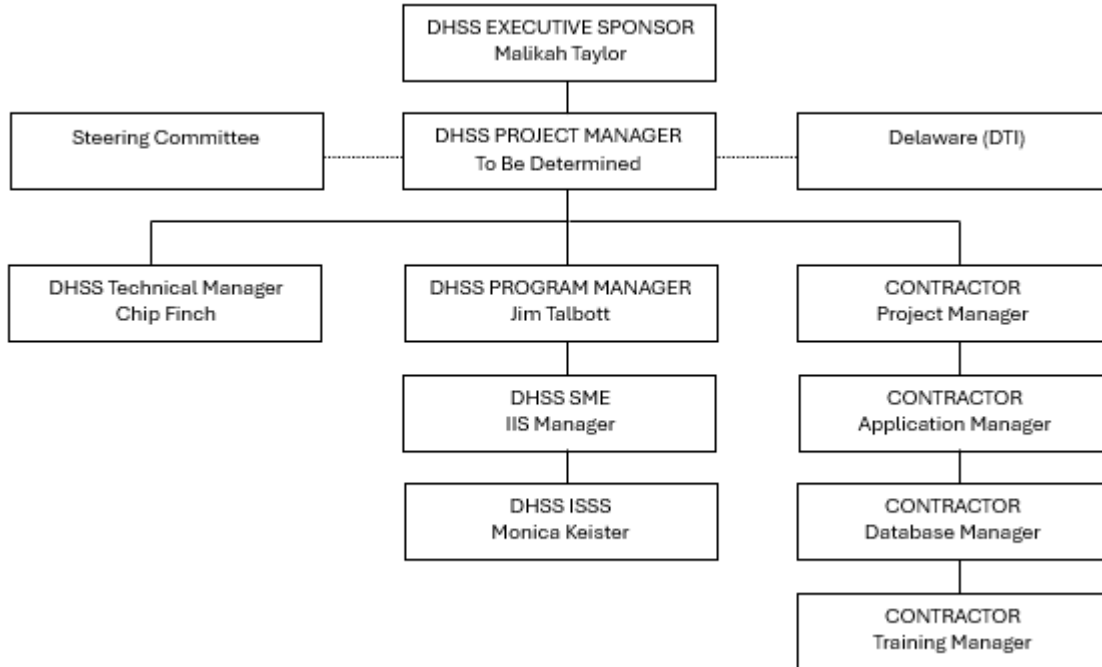
- Schedule and conduct meetings with the project team to review operations monitoring and quality control reports, issue tracking, and change control tracking.
- Implement the Continuity of Operations Plan.
- Implement Change Management Plan.
- Initiate Help Desk operations and incident management.
- Provide ongoing maintenance and support.
- Securely maintain all data and facilities.

### **1.2.5 Project Transition-Out Phase**

Upon termination of the contract, the contractor will provide a finalized copy of the Data Element Dictionary, and a copy of the database based on an agreed format and delivery method.

## 2 Project Team

### 2.1 Project Organization Chart



## 2.2 DHSS and Stakeholder Contact Information

### 2.2.1 DHSS

Name / Role	Organization / Email	Phone
Malika Taylor DHSS Executive Sponsor	Division of Public Health malikah.taylor@delaware.gov	302-744-4700
To Be Determined DHSS Project Manager		
Chip Finch DHSS Technical Manager	Information Resource Management alfred.finch@delaware.gov	302-255-9256
Jim Talbott DHSS Program Manager	Division of Public Health james.talbott@delaware.gov	302-744-4700
IIS Manager DHSS Subject Matter Expert	Division of Public Health To Be Determined	302-744-4700
Monica Keister DHSS IS Systems Support	Division of Public Health monica.keister1@delaware.gov	302-744-4700

## 2.3 DHSS Roles

### 2.3.1 Information Resource Management (IRM)

In support of the DHSS and Office of the Secretary - Administration, the mission of Information Resource Management (IRM) is to provide quality, efficient and cost-effective support in the management of technology resources. IRM provides DHSS divisions with information technology planning and management, information technology purchasing, network telecommunications, and help desk services. IRM is represented on the project team as the DHSS Project Manager, DHSS Technical Manager and MCI Coordinator.

### 2.3.2 Department of Technology and Information (DTI)

The Department of Technology and Information (DTI) is the state's central information technology (IT) organization. DTI establishes and enforces the State's IT policy and standards and provides enterprise technology services that enable other organizations to effectively fulfill their missions. DTI does not participate in the project directly but is available to the Project Manager as necessary.

### 2.3.3 DHSS Executive Sponsor

The DHSS Executive Sponsor represents DPH senior management and is responsible for the success of a project and provides sustainability, strategic planning, guidance and resources to the project team and DHSS Project Manager as necessary. The DHSS Executive Sponsor does not typically attend project meetings.

### 2.3.4 DHSS Project Manager

The DHSS Project Manager serves as primary coordinator for all project phases, attends all project meetings, works with the Contractor Project Manager to maintain the project plan and schedule, ensures all IRM, DPH and other stakeholder staff attend meetings as necessary, and manages work assignments as required (e.g., review deliverables, perform testing, etc.). The DHSS Project Manager will report to a Project Steering Committee made up of representative

managers from the DPH, IRM and DTI. This Committee will meet monthly to review project status, progress, and issues. The Project Steering Committee will report to an Executive Sponsors group. The Executive Sponsors group will be made up of representatives from DHSS, DTI, OMB, and the Division. They will meet quarterly to discuss overall project status, progress and issues, risks, project management, funding, staffing, sponsor issues, stakeholder participation and tasks planned for the upcoming quarter.

### **2.3.5 DHSS Program Manager**

The DHSS Program Manager serves as primary business lead for all project phases on behalf of DPH, attends all project meetings, works with the project team to maintain the project plan and schedule, disseminates program information to the contractor as needed (e.g., business requirements, processes, workflows, forms, reports, etc.), and manages work assignments of program staff as required (e.g., review deliverables, perform testing, etc.).

### **2.3.6 DHSS Subject Matter Expert (SME)**

The DHSS Subject Matter Expert (SME) contributes program knowledge and information in all project phases, attends project meetings as required, and reports to the DHSS Program Manager.

### **2.3.7 DHSS Information Systems Support Specialist (ISSS)**

The DHSS Information Systems Support Specialist (ISSS) serves as the DPH liaison between program staff and IRM, and between program staff and contractor IT staff. The ISSS participates in all project phases, attends all project meetings, and ensures the business requirements are properly communicated to the contractor and that program staff understand DTI policies and standards, and contractor information system processes and data. The ISSS reports to both the DHSS Technical Manager and DHSS Program Manager.

## **2.4 Contractor Roles**

### **2.4.1 Contractor Project Manager**

The Contract Project Manager serves as the chief liaison to the DHSS Project Manager for all project phases and has authority to make day-to-day decisions, facilitates all contractor activities (e.g., application, database, financial, legal, training, etc.), facilitates all deliverables, maintains the project schedule; schedules, hosts and leads all project meetings; authors and distributes agendas, meeting notes and weekly status reports; and ensures contractor staff attend project meetings as necessary. The Contractor Project Manager reports to the Contractor Project Director.

### **2.4.2 Contractor Application Manager**

The Contract Application Manager facilitates all SaaS product configuration, documents and communicates systems-related issues and downtime, coordinates with the contractor's Help Desk as necessary, attends all project meetings as required, and contributes knowledge and information to inform the authoring of deliverables (e.g., Project Plan and Schedule, Architecture Network Diagram, Test Plan, etc.). The Contractor Application Manager reports to the Contractor Project Manager.

**2.4.3 Contractor Database Manager**

The Contract Database Manager develops and maintains the contractor's databases, maintains data storage and retrieval systems, troubleshoots database issues, implements database recovery procedures and safety protocols, attends all project meetings as required, and contributes knowledge and information to inform the authoring of deliverables (e.g., Project Plan and Schedule, Data Conversion Plan, Interface Control Documents, Data Element Dictionary, etc.). The Contractor Database Manager reports to the Contractor Project Manager.

**2.4.4 Contractor Training Manager**

The Contractor Training Manager develops and maintains training materials; schedules and conducts training sessions; communicates with users; attends all project meetings as required; and contributes knowledge and information to inform the authoring of deliverables (e.g., Project Plan and Schedule, Training Plan, etc.). The Contractor Training Manager reports to the Contractor Project Manager.

### **3 Project Deliverables**

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The following subsections define the requirements and minimum data content for each deliverable. Section 1.0, Project Overview, stipulates which project phase the contractor will provide each deliverable. During the project phases, each deliverable is formalized and submitted to DHSS separately as a standalone document and is updated throughout the project per the contractor's Change Management Plan. The Project Schedule, and Test Plan, are submitted to DHSS in Microsoft Excel format. All other deliverables are submitted in Portable Document Format (PDF) format.

#### **3.1 Project Schedule**

The contractor shall provide the Project Schedule in Microsoft Excel format and include task number, task description, assigned staff, task dependencies, task start and end dates, task duration, percentage completed, task completion date, and a project calendar depicting all tasks. For the duration of the project, the contractor will deliver to DHSS weekly an updated Project Schedule. The contractor will define tasks at a sufficient level to track the work assignments of contractor, DHSS, and stakeholder staff, which at a minimum includes deliverables, configuration, customization, data conversion, training, testing and deployment. During the Operations and Support Phase, the Project Schedule will include issue resolution, change management, system downtime, or any other event or activity that requires tracking.

#### **3.2 Change Management Plan**

The contractor shall provide their Change Management Plan in PDF format and describe the change management process, both in terms of configuration and customization, define the method to request change, the process to rank and prioritize change requests (via a Configuration Control Board or equivalent), define the role of DPH, include a sample of any forms and artifacts used in the change management process (e.g., change request form, approval form, UAT, etc.), and list the project deliverables that will be updated (e.g., project schedule, test plan, approval form, user documentation, etc.).

#### **3.3 Continuity of Operations Plan**

The contractor shall provide their Continuity of Operations Plan in PDF format and describe their backup and recovery process of applications and data; and describe their methods to ensure all essential laboratory operations and follow-up services are continued following a natural disaster, power outage, or any other event that impacts facilities, staffing, systems, or data. The contractor shall identify any associated contractors, provide documentation of recovery procedures and testing, define the communication method for alerting DPH of a disaster or event requiring the execution of the Continuity of Operations Plan, and define the Service Level Agreement (SLA) time to return to operations following notification to DPH.

#### **3.4 Data Conversion Plan**

The contractor shall provide their Data Conversion Plan in PDF format and describe their method to transform and import legacy data from the current database hosted by the contractor. The contractor shall describe the approach to ensure data quality before and after the data conversion process, describe the manual and/or automated controls and methods to validate the conversion, and describe the process for data error detection and correction. The contractor shall include in their plan a data conversion specifications table that lists all source tables and fields, the target table and field for each source field, a data value mapping and/or rules for data transformation.

### **3.5 Architecture Network Diagram**

The contractor shall provide an Architectural Network Diagram in PDF format and depict the application and database servers, other contractor facilities if applicable, interfaces, DHSS users, and providers. The diagram will clearly document the location of all servers and contractor facilities; and the diagram will clearly document the IP and port specifications.

### **3.6 Training Plan**

The contractor shall provide a Training Plan in PDF format that describes their approach to training, includes a curriculum to demonstrate all core system functionality and a curriculum to summarize all business workflows and processes electronic reporting of immunization records, and consists of a copy of all training materials.

### **3.7 Test Plan**

The contractor shall provide a Test Plan in Excel format and document the test cases associated with the unit and integrated testing. The contractor must work with the DHSS project manager to identify the staff for testing, review the test packet before testing begins, and facilitate one or more meetings with staff to execute the test plan together. The contractor shall include test cases for all core system functionality associated with the baseline product in the test plan. The Test Plan shall include test cases for DPH-specific configuration, if applicable, and test cases for all customization work. The contractor shall include a narrative summary for each test case and a series of steps to execute each test case. Each test step shall consist of a narrative summary, user instructions for implementing the test step, the expected and actual outcomes, and testing notes.

### **3.8 Product Deployment Plan**

The contractor shall provide a Product Deployment Plan in PDF format and describe their approach to deployment, describe the method to communicate with DHSS and other stakeholders, include communication templates, and include a readiness checklist for facilities, environments, applications, databases, operations, and the Help Desk. The contractor shall describe their method of monitoring operations and quality control and include sample reports associated with operational monitoring and quality control.

### **3.9 User Guide**

The contractor shall provide a User Guide in PDF format that includes instructions and screen samples for navigating and using all core system functionality. The contractor will create a table of contents, organize and group the content according to core functionality, and provide instructions for contacting the Help Desk.

### **3.10 Data Element Dictionary (DED)**

The contractor shall provide a DED in PDF format and document all the table names, table descriptions, field names, field descriptions, field attributes, field positions, field sizes, valid values and primary keys associated with the application database and indicate whether each field is available in the Decision Support System. The contractor shall organize the DED with each table presented alphabetically as a separate section, order the fields for each table by position in the database, and depict the field information in a spreadsheet-like format.

### **3.11 Interface Control Document**

The contractor shall provide a separate Interface Control Document in PDF format for each required interface and include an overview and purpose of the interface, the technical requirements (e.g., interface method, ports, protocols), the data processing steps executed, the control report(s) for managing the interfaces, communication method, communication template, and communication SLA to advise DHSS staff and/or stakeholders regarding a processing outcome, and the message/file format and specifications. The specifications will include a listing of field names, field descriptions, field attributes, field sizes, and valid values.

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## 4 Project Requirements

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### 4.1 Contractor Knowledge and Experience

The contractors shall have the following knowledge and experience:

- Experience with operating a laboratory environment or subcontracting with a third party to operate a laboratory environment
- Experience with hosting systems as a SaaS solution for a state or equivalent jurisdiction or similar or larger size
- Experience hosting a provider and/or patient web portal for immunization records.
- Experience with hosting a decision support system for state staff to query and report on systems data
- Experience with converting and importing legacy systems data
- Experience configuring and processing Health Level Seven (HL7) messages for laboratory orders and results.
- Experience with interfacing other with systems, including state systems
- Experience with operating a Help Desk for state staff, providers, and/or patients
- Experience with providing comprehensive training to users

### 4.2 Offshore Prohibitions

Offshore is defined as not being within the United States or its territories. Offshore storage and transmission of DHSS data is prohibited. Onshore project data and project artifacts including backup and recovery files in any form shall not be accessed by offshore staff and shall not be copied, processed, transmitted, or moved offshore. The contractor is permitted to engage offshore resources including sub-contractors as specified in section 6.3.6 for development and lower level (unit & integration) testing only. The contractor is prohibited from using State data in any form even if masked or obfuscated for offshore testing. All aspects of User Acceptance Testing and production operations will take place onshore.

Associated Link:

[Offshore IT Staffing Policy](#)

### 4.3 Data Classification Policy

The contractor shall abide by the terms and conditions established the Delaware Data Classification Policy, which defines the roles and responsibilities of a Data Steward based on the data classification. The data classification for this procurement is **State of Delaware Secret**.

Associated Link:

[Data Classification Policy](#)

### 4.4 Terms and Conditions Governing Cloud Services and Data Usage

The contractor shall abide by the terms and conditions established in Terms and Conditions Governing Cloud Services and Data Usage Policy, which govern remote hosting/cloud systems and accessing/storing State data outside of the State network. The Terms and Conditions Governing Cloud Services and Data Usage Agreement has columns identifying which provisions are mandatory depending on whether the data is Public or Non-Public. The data classification for this procurement is **Non-Public**. The mandatory clauses are identified by the checkmark in the appropriate Public/Non-Public column in each agreement.

**Associated Links:**

[Terms and Conditions Governing Cloud Services and Data Usage Agreement](#)

[Terms and Conditions Governing Cloud Services and Data Usage Policy](#)

The contractor has the option to conditionally accept, or reject, any clause in the agreement. In such cases, the contractor will list the agreement clause number, state whether the clause is “accepted conditionally” or “rejected” and describe the reasoning and/or controls that are present to provide the same or similar compliance. Any exception identified by the contractor will be vetted by Delaware Department of Technology and Information (DTI) and the Delaware Deputy Attorney General (DAG). Individual clauses may be negotiated and updated by the DTI and DAG and the negotiated agreement version will be attached to the final contract.

During the Operations and Support Phase, the contractor will renew the Terms and Conditions Governing Cloud Services and Data Usage Agreement every 12 months.

**4.4.1 Criminal Background Check**

All contractor staff working on this project will be subject to a Criminal Background Check (CBC). The contractor will be solely responsible for the cost the CBC. DHSS will review the CBC results. DHSS at their sole discretion may request that a contractor staff be replaced if their CBC result is unsatisfactory.

**4.4.2 Cyber Liability Insurance**

All data in transit must be encrypted whether transmitted over a public or private network. If the contractor cannot comply with the requirement to encrypt data at rest, then the contractor must purchase adequate Cyber Liability Insurance to protect the contractor and the State from data breaches and other cyber security issues. The selected contractor will present a valid certificate of cyber liability insurance for attachment to the contract prior to contract signature.

**4.5 HIPAA Regulations and Standards**

The contractor shall certify compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations and requirements as described in Department of Health and Human Services, Office of the Secretary, 45 CFR Parts 160, 162 and 164 along with the updated ARRA and HITECH act provisions, as well as all HIPAA requirements related to privacy, security, transaction and code sets, and provider enumeration. The proposed solution must meet these cited requirements.

**4.6 Business Associate Agreement**

Because the data does not include Protected Health Information (PII), the requirement for a Business Associate Agreement (BAA) is waived.

**4.7 DHSS Data Rights**

All DHSS data (Public and Non-Public) related to services provided under this contract will remain the sole property of DHSS. De-identified or derived/aggregated DHSS data is not exempted from this requirement. This provision shall survive the life of the contract. The contractor does not acquire any right, title, or interest in DHSS data under this contract. Except as otherwise required by law or authorized by DHSS in writing, no DHSS data shall be retained by the contractor for more than 90 days following the date of contract termination. After the 90-day timeframe the following provisions will remain in effect: contractor will immediately delete or destroy this data in accordance with NIST standards and provide written confirmation to DHSS; the contractor is expressly prohibited from retaining, transferring, repurposing, or reselling DHSS data except as

otherwise authorized by DHSS in writing; the contractor retains no ongoing rights to this data except as expressly agreed to by DHSS in the contract.

#### **4.8 UAT and Training Environments**

The UAT and Training environments must be secured at a level equivalent to the security in place for the production environment. It must be sized and architected such that production-sized files can be copied over into UAT. The architecture must be equivalently configured so that performance and load testing will essentially produce the same results and expectations as testing in the production environment. Depending on the type of data (i.e., top secret/highly confidential, behavioral health) and specific security requirements around this data, there may or may not be an expectation to mask field values in the UAT and Training environments. Copying production data into lower environments may be prohibited especially for role-based training. Lower environments with production data that are secured in the same manner may be exempt from masking requirements as well however this may be subject to DHSS or Federal policies and regulations that override this potential exemption or explicitly disallow production data being copied into lower environments. The division Deputy Attorney General will be consulted on what is allowed/disallowed in non-production environments.

#### **4.9 Data Masking in Non-Production Environments**

While securing of production data is of critical importance, migration of that data to lower environments presents its own set of challenges as lower environments typically are not as secure as the production environment. Masking of production data in lower environments usually involves deletion or obfuscation of actual PII-related field values such that they have no meaning as plain text and there is no identifiable method of translation back to the original values. If there are plans to copy production data to a less secure environment, the contractor will describe in detail their proposed masking strategy. If there is no expectation that production data will be copied into less secure environments, the contractor will describe their proposed test data generation plans and state clearly in this section that masking of production data is not required under this proposal.

#### 4.11 Software as a Service (SaaS) Product Requirements

The system will include the following core functionality and processes:

1. Contains complete and timely demographic and immunization data for children, adolescents, and adults residing or immunized within its jurisdiction.
2. Promotes user access to immunization records is promoted for clinical decision-making.
3. Forecast pediatric, adolescent, and adult immunizations in a manner consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.
4. Manage patient status at the provider organization and jurisdiction levels.
5. Support vaccine product recall activities.
6. Support reporting and investigation of vaccine adverse events.
7. Support public health response during disease outbreaks.
8. Support immunization-related efforts in school settings.
9. Support immunization-related efforts in childcare settings.
10. Support immunization program activities during a public health emergency according to the jurisdiction's public health emergency plan.
11. Support inter-jurisdictional data exchange via the IZ Gateway (ie. VA, Oklahoma, etc).
12. Connections to all DPH and State systems must be maintained without interruption.
13. Maintain/monitors interface with state agency systems, including DELI, Vital Statistics and Records, Department of Education, WIC, and NCI Application.
14. Provide predefined and ad hoc assessment and coverage reports that users can generate without assistance from staff.
15. Generate reminder and recall activities.
16. Provide immunization records to individuals with appropriate authentication.
17. Ensure stakeholders have appropriate access to the data in the system for public and population health purposes.
18. Support vaccine management and quality assurance functions for VFC and state and local vaccine programs.
19. Provide data or produce reports for VFC and state and local immunization programs.
20. Identify, prevent, and resolve duplicated and fragmented patient records using an automated process.
21. Possess confidentiality policies that protect the privacy of individuals whose data are stored in the IIS system.
22. Implement comprehensive account management policies consistent with industry security standards.
23. Be physically and digitally secured by industry standards for protected health information, security, encryption, uptime, and disaster recovery.
24. Support system users who access and use the system functions and submit or access system data.
25. Exchange data with health information systems by current interoperability standards endorsed by the CDC for message content, format, and transport.
26. The electronic exchange of information with systems in other jurisdictions is consistent with the current CDC-endorsed HL7 Implementation Guide.
27. Support data exchange with the National Vaccine Tracking System (VTrckS).
28. Support provider site-level vaccine inventory management and reconciliation according to VFC and state and local immunization program requirements.
29. Maintain new database structures to support Immunization Quality Improvement Program (IQIP) Coverage Assessments, including the ability to persist the criteria, patients, immunization history, and UTD status by series for an assessment such that a coverage report could be generated from the persisted data at any time. The persistent

- data might also allow for a visit-over-visit comparison, missed opportunity report, patient listings, etc., that could be accomplished in a later phase.
30. Maintain a job that will process IZ Rates report requests that have not yet been processed.
  31. Maintain a new report that can calculate the missed Immunization opportunities (last visit only) for the patients included in the criteria. Maintain a second report to list the patients who missed an opportunity on their previous visit.
  32. Maintain a new report that lists the patients who were late to get up to date (i.e., after 24 months)
  33. Maintain a search screen allowing a user to find a prior AFIX persisted assessment or an assessment run by the batch job. The user could then generate a report or delimited extract containing the coverage assessment for one of the AFIX assessments found by the search.
  34. Maintain an extract file in the format specified by CDC that could then be imported into the AFIX online Tool, eliminating the need to enter data manually. NOTE—This applies only to the coverage assessments.
  35. Maintain new screens in the system to store all the AFIX assessment-related information. At the request of an IZ Rates report, the user could find an assessment created using the AFIX templates and then choose to add all the other information tracked during an assessment.
  36. Maintain a new report to show a breakdown of antigen doses by month of age.
  37. Maintain the existing invalid doses report to work with the persistent assessments. This report will show a list of patients with an invalid dose and why the dose was invalid.
  38. Maintain the existing clinic screen to show the history of saved assessments to use, in addition to the search screen, as another avenue for users to see assessment information and to allow the user to run all the same reports available from the assessment search screen.
  39. Maintain a new report to help administrators identify sites needing a visit or follow-up, possibly a six-month re-assessment visit. The provider may be recently enrolled and has never had a visit has not had a visit in x months, was a low performer, or has stopped sending data.
  40. To assist Type 3 providers with vaccine inventory management, maintain clear and previous criteria buttons for all HL7 screens' online training in WebIZ.
  41. Maintain annual updates of training material content.
  42. Maintain the ability to decrement inventory from HL7 messages for a clinic. The CDC will add more values to the HL7 LOINC code set for funding sources at the vaccine level.
  43. Maintain content management functionality and maintain clear and previous criteria buttons on all HL7 screens.
  44. Maintain the ability to provide links to existing training materials/environments.
  45. Maintain content Management Repository for Training Materials.
  46. Maintain reports to identify totals of HL7 doses marked as administered.
  47. Maintain Online Training for Type 3 Providers in WebIZ.
  48. Maintain a crosswalk table of HL7 doses administered that 'may' match the inventory.
  49. Revise Online Training for Type 3 Providers in WebIZ.
  50. Maintain automation of actual decrementing from the inventory in real-time.
  51. Vaccine Inventory On-Hand Screen:
    - Maintain clear and previous criteria buttons on all HL7 screens.
    - Maintain a new link called Pending VTrckS Shipments below the existing Pending Inventory Transfers link. Selecting this link will display the Receive Vaccine Inventory Shipments screen. Only clients utilizing the VTrckS interface will see this additional link.

52. Pending VTrckS Shipments Screen:
- Maintaining the Pending VTrckS Shipments screen will list all incoming shipments that have not been received for that specific clinic. To view, dismiss, and receive, a user must have their default provider/clinic set to the clinic under which the original vaccine order was placed.
53. The following fields will be displayed for each Shipment:
- Order ID
  - Order Line Number
  - Date Shipped
  - NDC
  - Lot Number
  - Quantity Shipped
54. The following buttons will be available on the Pending VTrckS Shipments screen:
- Details: View the Vaccine Shipment Details screen.
  - Receive: Mark the inventory as received and display the Add New Vaccine Inventory screen with all applicable fields pre-populated from the Shipment. The resulting Inventory Transaction ID will be stored with the Shipment for future cross-reference.
  - Dismiss: If the user does not want to receive the indicated Shipment in their inventory, selecting this button will cause the Shipment to no longer be displayed.
  - Cancel: Selecting this button will return the user to the Pending VTrckS Shipments screen.
  - Maintain clear and previous criteria buttons on all HL7 screens.
55. The Inventory by Doses grid will be updated and maintained to behave differently based on the value of the Allow Aggregate-Level Vaccine Administered Reporting checkbox on the Add/Edit Inventory Reconciliation screen.
- Vaccine Shipment Details Screen (through the 'Details' button):
  - The Vaccine Shipment Details screen displays a read-only view of all the details associated with the Pending Inventory Shipment, including:
    - Registry Information ties directly back to the original vaccine order placed in WebIZ.
    - Order Date
    - Order ID
    - Line No
56. VTrckS Information (This is derived from the CDC VTrckS system):
- Order Create Date
  - Order Id
  - Line No
  - Date Shipped
  - Delivery Number
  - Deliver Line No
  - Carrier(s)
  - Tracking Number(s)
  - Expedited Shipment
57. Vaccine Information (This is derived from the vaccine distributor and should match what is being delivered to the clinic):
- Quantity Requested
  - Quantity Shipped
  - Order Line Fulfilled
  - Partial Shipment
  - Manufacturer

- NDC
  - Lot Number
  - Lot Expiration Date
58. The following button will be available on the Vaccine Shipment Details screen:
- Cancel: Selecting this button will return the user to the Pending VTrckS Shipments screen.
59. Vaccine Inventory Screen (through the Receive button):
- On the Add Vaccine Inventory screen, clinics will see the information supplied by the auto-filled shipment file. However, the funding source for each line item needs to be selected to add the pending inventory shipment into the inventory. Any changes from the physical shipment can also be made so that the inventory is a true representation of what the clinic has physically (i.e. lot number, number of doses delivered, etc.).
  - The following items are additional validations done on the screen receiving the inventory:
    - Not allowing a lot number that contains anything other than a standard character, number, or dash. (No other special characters, spaces, etc. will be allowed.)
    - If the user selects a Funding Source where the “Report to VTrckS” is set to YES, the system will not allow the “Vaccine|Mfg|NDC|Brand” to contain an entry without an NDC.
    - If the user selects a Funding Source with “Report to VTrckS” set to YES, a warning is displayed if the user enters a lot number over 10 characters in length. (They may choose to continue and enter the value, but only the first 10 characters will be reported to VTrckS.)
60. Vaccine Inventory Reconciliation Screen:
- On the Vaccine Inventory Reconciliation screen, the output of all PDF reports that list inventory information was updated to rename the field from “VFC PIN” to “VFC/VTrckS PIN.”
  - Maintain the ability to change with the CDC and Meaningful Use standards.
  - Maintain the ability to upload and download files in specified formats and have the files processed as currently defined.
  - Maintain HL7 Errors/Warnings/Info and message type to the database.
  - Maintain Traffic Analysis DataMart and dashboard.
  - Maintain tree view log analyzer.
  - Maintain Onboarding portal.
  - Maintain all meta-data currently associated with the ERR segment (segment name, field position, error code, error description, etc.).
  - Maintain expansion warnings to include informational data that helps explain the issues with the AA and AEs.
  - Maintain the message stats (for example, create three vaccinations in the update).
  - Maintain a scoring mechanism to support more robust reporting on information provided by the AA and AEs.
  - Maintain message analyzer leverage of data pulled from the database with errors, warnings, and information.
  - Maintain Updated onboarding tool for 2.5.1 Release 1.5
  - Maintain additional tutorial documentation to the tool.
  - Maintain health checks.
  - Maintain new reports to the tool.

- Maintain message analyzer functionality in the onboarding tool to assist providers with debugging their messages.
  - Maintain contextual analysis of the messages to scrutinize the provided messages further.
  - Maintain web service testing code snippets.
  - Maintain the new setup of the WSDL for testing and adopt the WCF version of the WSDL.
  - Maintain additional tutorial documentation to the tool.
  - Maintain clipboard functionality for error messages.
  - Maintain the ability to change the default colors used in the analyzer.
  - Maintain the export functions of the HL7 tables to Excel.
  - Maintain extract option for HL7 reports.
  - Maintain facility codes/EHRs relationship to clinics.
  - Maintain message analyzer for 2.5.1 Release 1.5.
  - Maintain new reports to the message analyzer.
  - Maintain the security function allowing users to access their messages - HL7 message analyzer and Traffic DB.
  - Maintain Metric based alerts.
  - Maintain the following metrics:
    - Rejection reasons
    - Number of immunizations (not VXU count per se, but number of immunizations received)
    - Trends/Indicators - find things like providers with sudden drops in volume, find sudden spike in errors.
  - Maintain reports of:
    - X number of commonly reported problems
    - Maintain s/vxu messages received, but no vaccinations received
    - Most common errors/warnings in a time period
    - Most common errors/warnings on a facility report card view
    - Summarize HL7 messages by facility code (Example: a facility has 10 errors, show error types (PID, RXA)
    - Monthly error/warning report
    - Specific errors for follow-up
    - Report card for the SYSTEM
    - Wall of shame
    - Charts have export capability
  - Maintain expansion of the Onboarding HL7 tool to include reports, training, and tutorial materials.
  - Improve ability to relate facility codes and EHRs to clinics.
  - Maintain clear and previous criteria buttons on all HL7 screens.
  - Maintain file import capability to consume the HP Claims file information.
  - Maintain HEDIS file functionality.
  - Maintain Flat File functionality.
  - Maintain Billing functionality.
61. Edit Vaccine Inventory Reconciliation Screen:
- The Inventory by Doses grid will be updated to behave differently based on the value of the Allow Aggregate-Level Vaccine Administered Reporting checkbox on the Add/Edit Inventory Reconciliation screen.
62. Hosting Requirements:
- The Subscription will include the configuration of multiple environments.

- The Subscription must support the following environments, applications, and databases and conform to all State architectural standards.
  - Cloud will host the DelVAX system
  - Production Hosting Requirements:
    - The immunization registry system of record for Delaware.
    - Available 24/7 except for scheduled maintenance and upgrades.
  - Testing Hosting Requirements:
    - Delaware utilized the environment to test full and patch set releases.
    - In the test environment, the end-user functional testing is performed to ensure that new releases function as expected before production deployment.
    - Environment will be available on weekdays from 8:00 am to 6:00 pm ET.
  - Training Hosting Requirements:
    - The environment used by Delaware for training providers on how to use the system.
    - Available 24/7 apart from scheduled maintenance and upgrades.
  - Quality Assurance (QA) Hosting Requirements:
    - The environment must verify HL7 data quality before a provider can send HL7 messages to the production environment.
    - Available 24/7 except for scheduled maintenance and upgrades. The contractor will be required to develop any enhancements deemed necessary for DelVAX. Enhancements will be determined by the Center for Disease Control's mandates, the Immunization program's wish list, and if special funds become available for an enhancement project.
63. Interface with the Delaware Master Client Index (MCI) using web services; store the MCI in the product database as an alternate patient identifier; and, when necessary, issue a web service to create a new MCI.
64. Integrate with the Delaware OKTA single sign-on platform.

#### **4.11.1 Quality Assurance (QA) Requirements**

- The environment must verify HL7 data quality before a provider can send HL7 messages to the production environment.
- It must be available 24/7 except for scheduled maintenance and upgrades.
- The contractor will implement and operate an ongoing quality management program at no additional cost to DHSS for measuring and reporting performance.
- Under the contractor's initiative or when requested by DHSS, corrective action plans will be documented and implemented.
- The contractor will implement a Performance Monitoring System at no additional cost to provide DHSS with a manual or automated method and other tools to report the quality and performance measurements agreed upon by DHSS and the contractor.
- The contractor must document and publish desk-level procedures and report quality analysis results. DHSS will specify standard performance measurement reports to be prepared by the contractor's Quality Management Program (QMP) and Performance Monitoring System, including an online dashboard displaying metrics defined by DHSS. The reports must be posted in a central location specified by DHSS with alerts as they are updated or posted.
- DHSS must have access to the data repository to run queries and produce independent audit reports.
- IIF (Impact Incidence Form) will be delivered and uploaded to SharePoint by the Contractor to the State within five business days of the incident. The State's review will

begin after delivering an IIF in this status for non-SLA-impacting events. IIF containing a (Corrective Action Plan) to be delivered and uploaded to SharePoint (Sys Aid) by the contractor to the State within 10 business days of the incident. If CAP details are not available by the 10th business day from the incident date, the Contractor is to formally request a CAP delivery extension that includes a proposed delivery date for a CAP. Delivery extension must be documented in CAP and emailed to the State. The State's review will begin after delivering an IIF with this status for SLA-impacting events.

#### **4.11.2 Core Functionality Summary**

The contractor shall provide an itemized a list of the SaaS product core functionalities (e.g. essential infrastructure, support health care providers in delivering age- and risk-appropriate immunization services, support the control and management of vaccine-preventable disease outbreaks, support and inform stakeholder efforts to improve immunization rates, and support health care providers in meeting the requirements of the Vaccines for Children (VFC) program and state and local vaccine programs) and for each functionality provide a description and include user interface screen samples. The contractor has the option to provide the equivalent information in the form of a User Guide.

#### **4.11.3 Core Reports Summary**

The contractor shall provide an itemized list of core reports that are deemed critical to health care providers that deliver immunization services and to meet the requirements of the Vaccines for Children (VFC) program and state and local vaccine programs, the control and management of vaccine-preventable disease outbreaks, and the stakeholder's efforts to improve immunization rates. For each report, describe the purpose and include a sample report using test data.

#### **4.11.4 Data Element Dictionary (DED)**

The contractor shall provide a DED and document all the table names, table descriptions, field names, field descriptions, field attributes, field positions, field sizes, valid values and primary keys associated with the application database and indicate whether each field is available in the Decision Support System. The contractor shall organize the DED with each table presented alphabetically as a separate section, order the fields for each table by position in the database, and depict the field information in a spreadsheet-like format.

### **4.12 Professional Service Requirements**

The contractor will perform the following professional services:

#### **4.12.1 Help Desk**

The contractor shall provide help desk services to DHSS staff, providers, and/or patients by phone and email and optionally through the Internet using a secured online chat session. The help desk will field questions and issues on all aspects of the contract.

The contractor shall operate the Help Desk from 9:00 am to 5:00 pm EST, Monday through Friday. The contractor will acknowledge receipt of all help desk inquiries submitted by email within 5 minutes of receipt and resolve emailed inquiries within two hours. All help desk inquiries initiated by phone or online chat will be determined during the exchange with the user, with the option to follow-up by phone or email if the exchange exceeds 10 minutes.

#### **4.12.2 Data Conversion Summary**

The contractor shall describe its approach and methodology for transforming and importing legacy data from the current database it hosts. The contractor shall also describe its approach to ensuring data quality before and after the data conversion process, the manual and/or automated controls and methods for validating the conversion, and the process for data error detection and correction.

#### **4.12.3 Change Management Summary**

The contractor shall describe their approach and methodology to change management. The contractor shall summarize their change management process, both in terms of configuration and customization, summarize the method to request change, summarize the process to rank and prioritize change requests (via a Configuration Control Board or equivalent), summarize the associated artifacts (e.g., change request form, approval form, UAT, etc.) and deliverables (e.g., project schedule, test plan, approval form, user documentation, etc.), and summarize the role of DHSS.

#### **4.12.4 Continuity of Operations Summary**

The contractor shall describe their approach and methodology to ensure all systems and data are securely and routinely backed up; and recovered timely following a natural disaster, power outage, cyber security attack, or any other event that impacts systems or data. The contractor shall identify any associated vendors, summarize backup and recovery procedures, summarize the testing and certification process, summarize the communication method for alerting DHSS of a disaster or event requiring the execution of the Continuity of Operations Plan, and reference the Service Level Agreement (SLA) time to return to operations following notification to DHSS.

##### **4.12.4.1 Backup, Recovery, & Retention**

- A top priority is a backup of the organization's data files and the ability to recover such data. Organizations' local management should assess the business process using the supported data and/or systems and assign a Recovery Point Objective (RPO) and Recovery Time Objective (RTO). The backup of the associated media should correlate to the RPO/RTO. In addition to RPO and RTO, recovery objects must account for the time to restore or make the backup system. If multiple systems have the same or similar RPO, then recovery should be prioritized. In addition, the backup methods must support the RPO and RTO.
- Data backups must be encrypted for the State of Delaware's confidential, secret, and top-secret data. Furthermore, the data must only reside at rest on state-owned or DTI-approved systems or devices.
- The contractor (s) providing offsite backup storage for State data should have appropriate clearances for the highest level of data classification stored. Physical access controls implemented at offsite backup storage locations should meet or exceed the physical access controls of the source systems. Additionally, backup media is protected by the highest State sensitivity levels for information stored.
- Storage media protection and authentication controls at the storage system and media levels should be implemented to provide substantial barriers against unauthorized stored data disclosure, theft, and corruption.
- Backup media should be stored in a locked, fireproof container (UL-rated for media protection) during transport and retained at a pre-determined offsite location unless an approved offsite vaulting service is used (e.g., Iron Mountain, VRI, etc.). Backup media must be stored according to the application's Disaster Recovery Criticality and Level, as specified in the Delaware Information Security Policy unless other DTI-approved mitigating factors are implemented to protect the State's data.

- IT management should ensure that safeguards are in place to protect the integrity of data files during the recovery and restoration of data files, especially where such files may replace more recent files.
- A process should be implemented by the contractor to verify the success of the electronic information backup. Backups are periodically tested to ensure recovery within the expected timeframe.
- Testing helps to identify if:
  - Backups are incomplete.
  - The backup software was wrongly configured.
  - Encryption has caused a lockout (unknown password).
  - Backup is only readable by an earlier version of your software.
  - Backup cannot perform the restore from backup media, which is several months old.
  - Dormant backup software bugs now plague your newly upgraded operating system.
  - The tape breaks during the backup process.
  - Unexplained reboots could have caused a system crash and tape rewind during the backup process.
- Signing Authorities held by the offsite backup storage contractor(s) for access to State backup media are reviewed annually or when an authorized individual leaves or changes job responsibilities.
- Procedures between the organization and the offsite backup storage contractor(s) are reviewed at least annually.
- Backup tapes and/or containers should be identified by labels and/or a bar-coding system.
- The retention of electronic data files should reflect the business needs of an agency, as well as any legal and regulatory requirements for records retention, such as Delaware Public Records Law (29 Delaware Code §501-526) and the Delaware Freedom of Information Act (29 Delaware Code Ch. 100 et seq.). The storage media used for archiving information should be appropriate to its expected longevity. The format in which the data is stored is carefully considered, especially where proprietary formats are involved.
- The archiving of electronic data is to be retained in a manner consistent with the Delaware Public Records Law requirements as provided in the Agency's Specific Retention Schedules and the State General Retention Schedules and by using the procedures of the Delaware Public Archives (DPA) for authorizing records disposition:
  - For Model Guidelines for Electronic Records, go to the link: <https://archives.delaware.gov/government-services/records-policies/>.
  - Click on the following link to locate State of Delaware retention schedules: <https://archives.delaware.gov/government-services/retention/general-records-retention-schedules/>.
- Regulations often include the retention period required for certain types of data.
- To maximize efficiency, reduce costs, and minimize risks, agencies should manage data and information effectively to lower their storage footprint. Through active storage management, storing key information in shared repositories appropriate to its classification, avoiding storing duplicates, utilizing deduplication, and routinely reviewing retention schedules, agencies should be able to contain and lower storage growth.
- General Maintenance tasks include the best practices adopted by the Department of Technology and Information (DTI), through the Technology and Architecture Standards Committee (TASC). The contractor will develop solutions using architecture, software, and hardware deemed to be in a Standard or Acceptable category by DTI. When an architecture, software, or hardware is moved to a category of discontinue the contractor must develop a plan to move to a solution considered Standard. DHSS expects

contractors to monitor the applicable sections of DTI Enterprise Standards and Policies website and maintain these standards throughout the life of the contract. These standards are applicable to all Information Technology use throughout the State of Delaware.

#### **4.12.5 Quality Management**

- The contractor will implement and operate an on-going quality management program at no additional cost to DHSS for measuring and reporting performance. Under the contractor's initiative or when requested by DHSS, corrective action plans will be documented and implemented.
- The contractor will implement a Performance Monitoring System at no additional cost to provide DHSS a manual or automated method and other tools used to provide reporting of the quality and performance measurements agreed upon by DHSS and the contractor. The contractor must document and publish desk level procedures and report results of quality analysis.
- DHSS will specify standard performance measurement reports to be prepared by the contractor's Quality Management Program (QMP) and Performance Monitoring System including an online dashboard displaying metrics as defined by DHSS. The reports must be posted in a central location specified by DHSS with alerts as reports are updated or posted. DHSS must have access to the data repository to run queries and produce independent audit reports.
- IIF (Impact Incidence Form) to be delivered and uploaded to SharePoint by the contractor to the State within 5 business days of incident. For non-SLA-impacting events, the State's review will begin after delivery of an IIF in this status.
- IIF containing a (Corrective Action Plan) to be delivered and uploaded to SharePoint (Sys Aid) by the contractor to the State within 10 business days of incident. If CAP details are not available by the 10th business day from incident date, the contractor will formally request a CAP delivery extension that includes a proposed delivery date for a CAP. Delivery extension must be documented in CAP as well as emailed to the State. For SLA-impacting events, the State's review will begin after delivery of an IIF in this status.