VIRGINIA'S NEWBORN SCREENING DATA EXCHANGE ONBOARDING GUIDE

For Participants and Participant Vendors

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Introduction

Virginia's Newborn Screening Program

Virginia's Newborn Screening (NBS) Program consists of coordinated and comprehensive educational activities, dried-blood spot screening, follow-up by the Virginia Department of Health and referrals to specialists for diagnosis, medical and dietary management, and long-term treatment. By state statute, every newborn in Virginia should be tested for 33 genetic and/or metabolic disorders within days of birth, unless a parent or guardian objects on the grounds that the test conflicts with their religious practices.

The Division of Consolidated Laboratory Services (DCLS) within the Virginia Department of General Services (DGS) conducts the newborn dried blood spot screening tests in collaboration with the Virginia Department of Health (VDH). The Follow-up team at VDH has nurses who coordinate follow-up activities until the infant is diagnosed, screened negative, or reaches 6 months of age. Babies who are diagnosed with certain heritable disorders or genetic diseases through newborn blood-spot screening are referred to the VDH's Care Connection for Children network for care coordination services.

Electronic Data Exchange

Virginia Health Information (VHI), along with their technology vendor CRISP Shared Services (CRISP), provide support for the state's public health reporting pathway (PHRP) to allow secure transport of public health reportable data between hospitals and providers and state agencies like VDH and DCLS. Some reportable data types that are transported using the PHRP include immunization (VIIS), cancer registry, syndromic surveillance, electronic lab reporting (ELR) data, and NBS dried blood spot data.

VHI/CRISP and DCLS work in partnership to support the bi-directional secure and standards-based exchange of NBS lab orders and results between hospitals/birthing facilities and DCLS. The NBS data is formatted using nationally adopted health vocabularies, such as LOINC and SNOMED, and HL7 2.5.1 message specifications based on the Public Health Informatics Institute (PHII) Newborn Dried Blood Spot (NDBS) Screening Implementation Guide for Laboratory Orders and the HL7 Lab Results Interface (LRI) Implementation Guide for Laboratory Results.

Although dried-spot cards will still be used for specimen collection and physically delivered to DCLS, hospitals/birthing facilities are encouraged to begin transmitting their electronic orders via VHI's PHRP.

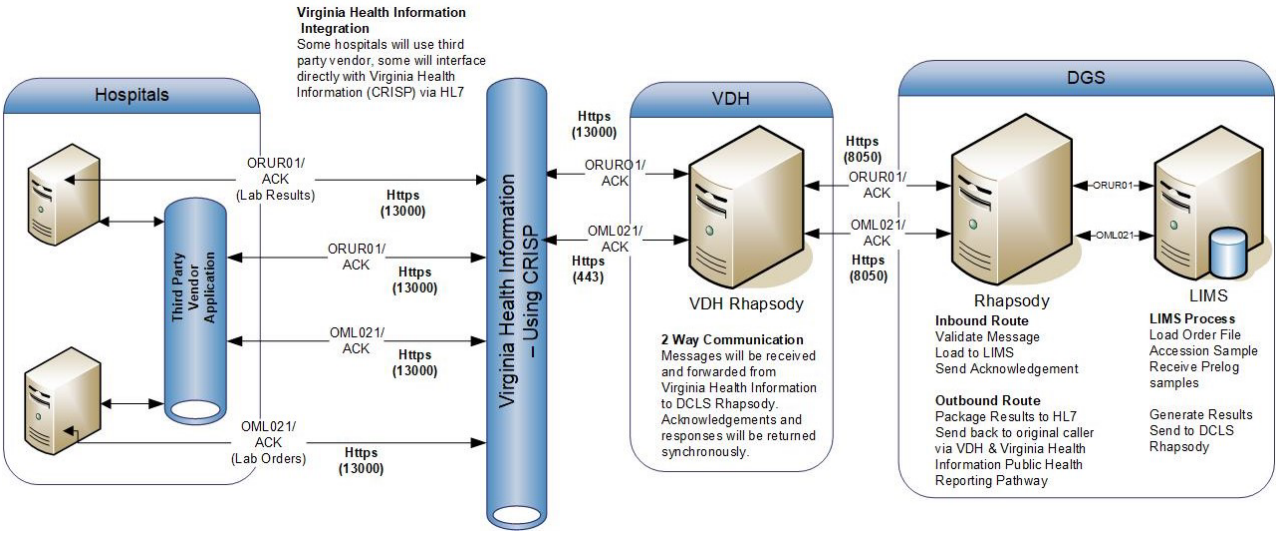
Prospective electronic messaging participants must go through an onboarding and validation process and obtain approval from DCLS prior to participating in Virginia's NBS Data Exchange program. More information can be found on DCLS's webpage at:

http://www.dgs.virginia.gov/division-of-consolidated-laboratory-services/resources/nbs-data-exchange/

Questions should be emailed to **DCLS Messaging Support** at: DCLS_MSG_SPPT@dgs.virginia.gov.

Diagram of NBS Data Exchange

This diagram below depicts an overview of NBS data exchange architecture and integration with VHI/CRISP, VDH, and DCLS. Bi-directional data flows of NBS lab orders and NBS lab results are included.



Onboarding & Connectivity Set-up

To participate in Virginia's NBS Data Exchange program, Participants and Participant Vendors must first complete the steps in this section. All onboarding documents can be found on DCLS's webpage. VHI, along with their technology vendor, CRISP, will assist Participants with establishing connectivity.

Step 1 – Complete the Onboarding Documents

1. Obtain an OID to identify your Facility and Sending Application. An OID is a globally unique identifier that is assigned to an entity (for example: 2.16.840.1.113883.3.9). To obtain an OID, go to: http://www.hl7.org/oid/index.cfm and follow the on-screen instructions. If an OID has already been assigned to your Facility and Sending Application, this step may be skipped.
2. Locate the "Participant Form" on DCLS's webpage. Complete the form and email to DCLS Messaging Support.
3. Locate the "Data Exchange Agreement" on DCLS's webpage. Read, sign, and email the agreement to DCLS Messaging Support. Please note, if the Participant is partnering with a third-party vendor, a Data Exchange Agreement is NOT required by the Participant, and this step may be skipped.
4. DCLS Messaging Support will review the onboarding documents. Once approved, an executed copy of the Newborn Screening Data Exchange Agreement will be returned to the Participant (if applicable) and forwarded to VHI for processing.
5. Once the Onboarding documents have been approved, the Participant is ready for Step 2.

Step 2 – Establish Message Transport (HTTPS)

1. VHI will create an HTTPS account for the Participant using the information provided on the "Participant Form." This includes:
    a. A signed VHI Newborn Screening Data Exchange Agreement
    b. Your organization's OID (vendor hubs should have their own OID)
    c. Your organization's physical address
    d. Client generated certificate signing request (CSR)
    e. Peer IP address(es) from which your organization will send data
    f. Contact information – Name, email and phone number, for the appropriate technical resource(s)
2. Via secure email, VHI will provide the Participant with the TEST and PROD endpoints for exchanging NBS lab orders, credentials that will enable connection to the TEST and PROD endpoints by the Participant and client specific public cert to be used. Estimated timeline for creating public cert after

receipt of CSR is 3- 5 days. The Participant will confirm connectivity with VHI and follow up via email if troubleshooting help is needed.

3. Once the Participant has a test message with the custom headers ready, please notify DCLS_MSG_SPPT and include VHI at phrsupport@vhi.org that you are ready to begin testing.
4. Participants must include the following custom headers with their message to ensure proper routing and delivery:
    - **Css-custom-oid**: OID identifying the sending organization. This OID must be acquired by the participant or participant's vendor and provided to VHI during the application process.
    - **Css-transaction-id**: Unique identifier provided by the submitting entity to identify the transaction for audit and response purposes. Each request provided to VHI must contain a unique identifier within the scope of the organization making the request.
    - **Css-phr-type**: Indicates the type of newborn screening message being submitted. Valid Report Types for the Css-*phr-type* header are:
        - ✓ **NBSORDERS_ENCRYPT** – Newborn Screening Orders
        - ✓ **NBSResults** – Newborn Screening Results
5. Participants need to ensure their firewall allows a connection to the Public Health Reporting Pathway which uses port 443.
6. For NBS orders, VHI forwards ACKS and NACKS from DCLS indicating successful (or unsuccessful) HL7 message processing.
    a. If you receive an ACK, this indicates you have connected successfully with a properly formatted HL7 message.
    b. If you receive a NACK, this indicates you have connected successfully, but your HL7 message is not formatted correctly per the DCLS specs.
    c. If you do not receive an ACK or NACK, this indicates that the connection was unsuccessful. If this happens, check the err directory for any other errors.

Step 3 – End-to-End Connectivity Testing

1. After HTTPS connectivity has been established, the Participant will send an email to DCLS Messaging Support and request a date/time to perform a basic connectivity end-to-end test.
2. DCLS Messaging Support will coordinate a testing window with VHI/CRISP and the Participant.
3. The Participant will send a .txt file (Hello World) through the interface to the DCLS'S TEST endpoint.
4. Upon successful completion of Connectivity Testing, the Participant will move on to the next phase of Implementation.

Lab Orders Implementation

This section provides an overview of the project steps associated with implementing electronic data exchange of NBS Lab Orders from the Participant to DCLS.

Step 1 – Obtain Implementation Guide and Test Case Documentation

1. Obtain the current version of DCLS's NBS Lab Orders Implementation Guide. This can be found on DCLS's webpage. This guide is the main resource provided by DCLS for HL7 development and contains the requirements and specifications that are needed to build and develop the Lab Order message payload.
2. Also available on DCLS's webpage are the Test Scenarios for NBS Lab orders. Sample HL7 messages & corresponding dried blood spot (DBS) card labels are provided and can serve as a good reference throughout the Participant's development phase.

Step 2 – Establish a Project Timeline and Meeting Schedule

1. Establish a project plan and project timeline.
2. Identify project resources, roles, and contact information.
3. Establish a meeting schedule (this is typically weekly or bi-weekly). Meetings are used throughout the project to share updates and address any questions or challenges that may come up. Additional meetings can be held to go over more in-depth questions regarding specs or anything else. Questions can also be emailed to DCLS Messaging Support at any time.

Step 3 – Develop Required Components

1. Develop the HL7 Lab Order message. This message should be built based on the specifications outlined in the DCLS Implementation guide.
2. Develop the DBS card electronic label. This label should contain all the data elements that are sent in the HL7 order and should be generated and printed once the HL7 order is submitted. The data on the label should be identical to the data submitted in the HL7 order. The label and order will be cross-checked by DCLS to verify data is a match as part of their data entry verification process of each order.
3. Develop all other necessary components that will be needed for the end user on the Participant side to enter and submit all required data to DCLS. This generally includes an electronic form where ask-at-collection data (i.e., collection date, feeding type, etc.) can be entered. It is helpful to build in validations that align with the requirements to help reduce the frequency of NACKed orders.

4. Set up print capability to print the DBS card labels. This may include purchasing new label printers. Some label printer models that are recommended by DCLS are included in the Implementation Guide.
5. Develop a plan for tracking ACK & NACK messages that are sent back from DCLS. If a NACK is sent back, this indicates that there was an issue with the HL7 format and/or content and DCLS is requesting a corrected order. It is good to have a mechanism in place, such as an automated email, to notify end users on the Participant side when NACKs are received, and corrections need to be made.
6. Develop capability for end users to submit corrected orders. This generally involves re-opening a previously submitted order, updating the necessary fields, and then submitting a corrected HL7 order to DCLS.

Step 4 – Lab Order Message Manual Review

1. Once the HL7 message is developed, the Participant will email a sample Test Lab Order message (.txt file) to DCLS Messaging Support.
2. DCLS Messaging Support will review the message for HL7 structure and content.
3. Any issues or other findings will be communicated to the Participant and if needed, a meeting will be scheduled. The Participant will correct any deficiencies and provide a corrected message for another round of review. This process will be repeated until all reported items are corrected and manual review of the HL7 message is completed.

Step 5 – DBS Card Label Review

1. Once the DBS Card label is developed, the Participant will email a maximally populated sample card label to DCLS Messaging Support.
2. DCLS Messaging Support will review the card label for size, formatting, and content.
3. Any issues or other findings will be communicated to the Participant and if needed, a meeting will be scheduled. The Participant will correct any deficiencies and provide a corrected label for another round of review. This process will be repeated until all reported items are corrected.
4. Once the emailed label looks good, DCLS will need to check the printed labels. This will require label printing to be configured on the Participant end. DCLS will mail a few ‘test’ DBS cards to the Participant. The Participant will print sample labels, attach them to the cards, and mail them back via courier to DCLS to allow DCLS staff to validate the printed labels on the cards. Once this step is completed, the Participant is ready to begin the lab order test cases.

Step 6 – Complete Test Cases for Lab Orders

1. Participant will generate a series of test lab order messages from their TEST environment based on the test cases on DCLS's webpage. The Participant will also generate screenshots of the electronic labels for each test case. Generally, one or two test cases are performed at a time.
2. Participant will send the test messages to the DCLS TEST endpoint. Corresponding screenshots of the labels should be emailed to DCLS Messaging Support.
3. DCLS will validate the test messages and labels for all test cases. The data will be parsed and loaded into DCLS's LIMS TEST system. The HL7 messages will be validated based on content and structure. The data on the labels will be verified to match the data in the system.
4. For each test message, an HL7 ACK will be returned to the Participant acknowledging that the message was successfully received at the DCLS endpoint. The Participant will confirm receipt of the ACK.
5. Participants will receive an HL7 NACK if the message contains any errors and fails structural and/or content validation. There is a test case for an 'intentional NACK' scenario. The Participant will demonstrate their ability to submit a corrected order.
6. For any test cases that do not pass, DCLS will work with the Participant to work through any issues.
7. Once Test cases are all successfully completed, the teams are ready to move onto the final sign-off phase.

Step 7 – Lab Orders Sign-off

1. DCLS will obtain PROD sign-off from all parties including the Participant, VHI/CRISP, and VDH and will coordinate a date to move the Participant's transmissions for the Lab Order message from TEST to PROD and the Participant status to "In Production."
2. A reminder email will be sent out by DCLS the evening before the Production date.

Lab Results Implementation

This section provides an overview of the project steps associated with implementing electronic data exchange of NBS Lab Results from DCLS to the Participant.

Step 1 – Obtain Implementation Guide and Test Case Documentation

1. Obtain the current version of DCLS's NBS Lab Results Implementation Guide. This can be found on DCLS's webpage. This guide contains detailed specifications and all the data elements for consuming, parsing and loading the NBS results sent from DCLS to the Participant.
2. Also available on DCLS's webpage are the Test Scenarios for NBS Results. Sample HL7 messages are provided and can serve as a good reference throughout the Participant's development phase.

Step 2 – Establish a Project Timeline and Meeting Schedule

1. Establish a project plan and project timeline.
2. Identify project resources, roles, and contact information.
3. Establish a meeting schedule (this is typically weekly or bi-weekly). Meetings are used throughout the project to share updates and address any questions or challenges that may come up. Additional meetings can be held to go over more in-depth questions regarding specs or anything else. Questions can also be emailed to DCLS Messaging Support at any time.

Step 3 – Develop Required Components

1. Develop all components necessary on the Participant end to receive and process the HL7 results. This will involve sending an ACK back to DCLS to indicate successful receipt of the message.
2. Develop all components necessary on the Participant end to map all data elements and display the results in a format that can be used by the end-users to view the data, just as they would a paper report. It is important to have a way to receive multiple reports and display preliminary, final and amended results for a single NBS order. It is also important to have a way to receive results for multiple NBS orders for the same patient.

Step 4 – Lab Result Message Initial Test

1. Once the Participant has completed all necessary development to receive, parse, and load NBS Results data, DCLS will email a test lab results message (.txt file) to the Participant.
2. Participant may load the message manually and check for any errors.
3. Any findings may be communicated to DCLS Messaging Support and if needed, a meeting will be scheduled. DCLS will work with the Participant to address any issues. This process will be repeated until all issues are addressed. Then the Participant is ready to begin the Test Case suite. Testing will be scheduled and coordinated.

Step 5 – Complete Test Cases for Lab Results

1. Participant will generate a series of test lab order messages from their TEST environment and send to the DCLS TEST endpoint. These lab orders will be resulted by DCLS to complete the test cases for NBS results. Generally, one or two test cases are performed at a time.
2. DCLS will generate results for each of the orders and will send the results back to the Participant's TEST endpoint. DCLS will email a corresponding PDF report to the Participant. As part of the validation process, the Participant will need to ensure that the electronic data displayed to the end user matches the data on the PDF.
3. Participant will receive and process the test result message. An ACK will be returned to DCLS acknowledging that the message was successfully received at the Participant's endpoint. If an ACK is not received, DCLS will work with the Participant in troubleshooting.
4. Upon successful receipt of the NBS results, Participant will parse and load the data. Participant will verify that all the data loaded as expected and that the data displayed in the system matches the data in the corresponding PDF report. It is important to have real end users involved in this validation process. The teams will work accordingly to resolve any issues found.
5. Once Test cases are all successfully completed, the teams are ready to move onto the final sign-off phase.

Step 6 – Lab Results Sign-off

1. DCLS will obtain PROD sign-off from all parties including the Participant, VHI/CRISP, and VDH and will coordinate a date to move the Participant's transmissions for the Lab Results message from TEST to PROD and the Participant status to "In Production."
2. A reminder email will be sent out by DCLS the evening before the Production date.

Frequently Asked Questions (FAQs)

1. **Questions about connecting to VHI's Public Health Reporting Pathway (PHRP)?**
   Send an email to VHI: **phrsupport@vhi.org**
2. **Other than HTTPS, are there other transport methods that can be used to connect to VHI's PHRP?**
   Another transport method that can be used is VPN. Both HTTPS and VPN utilize the same level of security and encryption and both methods meet HIPAA security standards. VHI can assist with technical and security requirements and any additional information about setting up a VPN connection.
3. **Questions about HL7 message content or any of DCLS's Implementation documentation?**
   Send an email to DCLS Messaging Support: **DCLS_MSG_SPPT@dgs.virginia.gov**
4. **How many OIDs does my organization need?**
   Each hospital within a hospital system will need a separate facility OID. If all hospitals use the same main application, then only one application OID is needed.
5. **What is the Facility OID for the DCLS laboratory?**
   VA PHL Richmond^2.16.840.1.114222.4.1.9977^ISO
6. **What is the Application OID for the DCLS laboratory?**
   VA StarLIMSv10 Prod^2.16.840.1.114222.4.3.3.2.2.4^ISO