NORTH CAROLINA HEALTH INFORMATION EXCHANGE AUTHORITY

Department of Information Technology
Eric Snider
DIT Deputy General Counsel, HIEA

NC HIEA Advisory Board Meeting
March 3, 2021, 2:30-4:30 pm

Revisions to NC HIEA Policies, 21st Century Cures Act Interoperability Rules Update

March 3, 2021

NC HealthConnex
Powering Health Care Outcomes

Overview

- **Consultation**
  - Feedback Process
  - Notice to Participants

- **NC HIEA Policies: Planned Revisions**

  - **User Access Policy**

  - **Privacy and Security Policies**
    - Information Blocking review and overview of new provisions
    - Other Substantive Revisions

- **Discussion and Questions**

Advisory Board Consultation

- **February 12, 2021:** Draft policies provided to Advisory Board Members

- Called meeting for **February 15, 2021**, cancelled due to extenuating circumstances

- **February 18 & 25, 2021**: Informal "office hours" meetings between NC HIEA staff and Advisory Board Members

- **March 3: 2021:** Regularly-scheduled Advisory Board meeting
  - Presentation of User Access Policy and Privacy and Security Policies
  - Further consultation and discussion with Advisory Board

- **March 4 or 5, 2021**: Notification to all Participants (per Participation Agreements)
  - Formal notice period provided during the 30 days before the proposed policy revisions become effective
  - As always, participant and stakeholder feedback welcome now and in the future

- **April 5, 2021:** Planned effective date of updated NC HealthConnex policies

Policy Revisions: User Access

Revisions (highlights):

- **Updates reflect the NC*Notify Feature**
    - Section 2: User Authorization & Access Roles
        - Clarifying language regarding "Unauthorized Access"
        - Memorialize new and combined user access roles

- **Revise for greater clarity and to support Participant Account Administrators**
    - Section 3: NC HealthConnex and DSM User Authentication
        - Updates address technical support for lockout of accounts; password security
    - Section 4: Audit Policy
        - Updates clarify parties' responsibilities with respect to auditing tasks

Policy Revisions: Privacy & Security

Goals of Revisions (illustrative):

Related to Information Blocking
- Facilitate the NC HIEA's compliance with 21st Century Cures Act prohibition on information blocking
- Establish written policies so the NC HIEA can utilize "safe harbors" in the Cures Act Final Rules
- Address patient access to their own records
- Create policy structures that enable the NC HIEA to identify opportunities and future needs more effectively

General Goals and Considerations
- Better align NC HIEA's policies with its evolving practices
- Bring current certain existing policies that require updates for clarity or because of new initiatives:
  - Alignment with Second Restatement of the DURSA
  - Treatment of Opt Out Data, implementation of Minor Opt Out
  - Emerging protocols with respect to research requests

Information Blocking: Review

§ 171.103 Information blocking.
(a) Information blocking means a practice that—

   (1) Except as required by law or covered by an exception set forth in subpart B or subpart C of this part, **is likely to interfere with access, exchange, or use of electronic health information;** and

   (2) If conducted by a … health information exchange, such … exchange **knows**, or **should know,** that such **practice is likely to interfere with**, prevent, or materially discourage **access, exchange, or use** of electronic health information…

Information Blocking: Review

The **eight exceptions** are divided into **two categories**:

Exceptions for *not fulfilling* requests to access, exchange, or use EHI

1. Preventing Harm

2. Privacy

3. Security

4. Infeasibility

5. Health IT Performance

Exceptions for procedures for *fulfilling* requests to access, exchange, or use EHI

6. Content and Manner

7. Fees

8. Licensing

Information Blocking: Review

Federal Resources:

- [Final Rule: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program](#) (May 1, 2020)

- [Interim Final Rule: Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency](#) (November 4, 2020)

- [21st Century Cures Act](#)

- [ONC Fact Sheets](#)

- [ONC FAQs](#)

NC HIEA Policies (current):
- [Privacy & Security Policy](#)
- [User Access Policy](#)

Policy Revisions: Privacy & Security

New Provisions Concerning Information Blocking and Interoperability:

- **Section 1: Definitions** (pp. 4 -8)

- **Section 15: Individuals' Access to Electronic Health Information** (p. 37)

- **Section 16: Requests to Access, Exchange, and Use Electronic Health Information; Prohibition Against Information Blocking; and Safe Harbors** (pp. 38 – 46)

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Policy Revisions: Privacy & Security

Information Blocking and Interoperability
Section 1: Definitions (pp. 4 - 8)

- 1.2 Approved Third Parties

- 1.16 Electronic Health Information (EHI)

- 1.17 Electronic Health Record (EHR)

- 1.24 Information Blocking

- 1.25 Information Blocking Rule

- 1.26 Interoperability Element

Policy Revisions: Privacy & Security

Information Blocking and Interoperability
Section 15: Individuals' Access to Protected Health Information (p.37)

- Statewide Health Information Exchange Act does not directly address patient access
  - N.C. Gen. Stat. § 90-414.4, Required Participation in HIE Network for Some Providers
    - "the State and covered entities in North Carolina need timely access"
    - "making demographic and clinical information available to the State and covered entities in North Carolina…" will lead to positive outcomes identified in statute

- Section 15 addresses Individuals' access to their data in NC HealthConnex and the NC HIEA's unique position when it processes these requests
  - 15.1 Patient Access to Protected Health Information
  - 15.2 Authorization and Verification
  - 15.3 Secure Transmission
  - 15.4 No Existing Patient Relationship (amendment to records)
  - 15.5 Incomplete or Denied Requests
  - 15.6 Incorrect Data

Policy Revisions: Privacy & Security

Information Blocking and Interoperability

Section 16: Requests to Access, Exchange, and Use Electronic Health Information; Prohibition Against Information Blocking; and Safe Harbors (pp. 38-46)

- 16.1 NC HIEA's Commitment to appropriate, lawful, and timely access, exchange, and use of EHI

- 16.2 NC HIEA Activities that Do Not Constitute Information Blocking

- 16.3 Other Applicable Law

- 16.4 NC HIEA Staff Training

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Policy Revisions: Privacy & Security

Information Blocking and Interoperability

Section 16: Requests to Access, Exchange, and Use Electronic Health Information; Prohibition Against Information Blocking; and Safe Harbors (pp. 38-46)

- 16.5 Information Blocking Safe Harbors (p.39)

- 16.6 Instances Resulting in the Denial of EHI Requests
  - Safe Harbors:
    - 16.6.1 Preventing Harm (p.39)
    - 16.6.2 Privacy (p.40)
    - 16.6.3 Security (p.41)
    - 16.6.4 Infeasibility (p. 42)
    - 16.6.5 Health IT Performance (p. 42)

Policy Revisions: Privacy & Security

Information Blocking and Interoperability

Section 16: Requests to Access, Exchange, and Use Electronic Health Information; Prohibition Against Information Blocking; and Safe Harbors (pp. 38-46)

- 16.7 Instances Resulting in the Complete or Partial Fulfillment of EHI Requests
  - Safe Harbors:
    - 16.7.1 Content and Manner (p.43)
    - 16.7.2 Fees (p.44)
    - 16.7.3 Licensing (p.45)

- 16.8 Information Blocking Reporting (p.45)

Policy Revisions: Privacy & Security

Other Revisions (Not Information Blocking)

- **Housekeeping:** Renumbering, updated sites and cites, new letterhead, policy update table

- **Introduction** (p.2)**:**
  - Aligned with User Access policy
  - Update regarding legal context

- **Section 1: Definitions added:**
  - 1.21 HIE Act (p.5)
  - 1.38 Participating Entities (p.6)
  - 1.41 Performance and Service Specifications (p.7)
  - 1.52 Specifications (p.8)
- **Section 1: Definitions deleted:**
  - Designated Institutional Review Board (old 1.9) (p.4)
  - Dispute Resolution Subcommittee (old 1.13) (p.4)
  - Emergency Medical Condition (old 1.17) (p.5)

Policy Revisions: Privacy & Security

Other Revisions

- **Section 2: Eligible Participants** (pp. 9-10)
  - Remove provision declaring restricted access
  - Clarifying revisions to description of Covered Entities and Business Associates
  - Include language about "Participating Entities" that echoes agreements
  - Remove provision concerning" Qualified Organizations"
  - Updated provision concerning arrangements with out-of-state entities

- **Section 3: Access to Protected Health Information for Treatment, Payment, and Health Care Operations; National EHealth Exchange Requirements** (pp. 11-14)
  - Revise eHealth Exchange "Permitted Purposes" with updated standards

- **Section 4: Minimum Necessary Requirement and Limitation on Use and Disclosure of Data (**pp. 15-16)
  - Updated treatment of Substance Use Disorder information
  - NC HIEA may receive such information if it consents in writing to receipt

Policy Revisions: Privacy & Security

Other Revisions

- **Section 5: Opt Out Rights** (pp. 17-19)
  - Updated citation
  - Removal of information about opt out information being used for treatment purposes in emergency situations
  - Revision to statement about restrictions on data that is *not* subject to an opt out request
  - Reference to opt out for minors treated for certain conditions

- **Section 6: Access Rights of the NC HIEA Workforce; Security Controls** (pp. 20-21)
  - Rewording of "Authorized Purposes" to add clarity

- **Section 7: Emergency Access to Records of Opted Out Individuals** (p. 22)
  - Section deleted

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Policy Revisions: Privacy & Security

Other Proposed Revisions

- **Section 7: Breach** (pp. 22-25)
  - Remove one-hour notification requirement concerning eHealth Exchange

- **Section 11: Access to Data by Government Agencies** (p. 30)
  - Include reference to "permitted" disclosures

- **Section 12: Access to Data for Research** (p. 31)
  - Express reference to NC HIEA research policies and protocols
  - Delete references to Appointment of Designated IRB

- **Section 14: Additional eHealth Exchange Requirements** (pp. 34-36)
  - Update references to controlling provisions from the Second Restatement of the DURSA
  - Remove language related to alternative dispute resolution and redirect to DURSA

Policy Revisions

- **Questions**

- **Additional discussion**

Integration Summary

NC DHHS and the NC HIEA are partnering to leverage the existing infrastructure in place at the NC HealthConnex health information exchange (HIE) to submit vaccine records to the COVID-19 Vaccine Management System (CVMS) on behalf of Participants.

- Flat-file extracts of demographics and vaccine administration data from provider and pharmacy systems

- Demographics data linked with HIE records for registering patients into CVMS

- Vaccine administration data automatically uploaded into CVMS to replace manual data entry

Goals
1. Increase vaccination rate by reducing dual documentation steps.
2. Improve user experience in CVMS by de-duplicating patient records using the NC HealthConnex master patient identifier (MPI).
3. Provide more timely and accurate reporting.

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Roles of Partners

The integration of vaccine data into CVMS requires collaboration across multiple State, vendor, and provider organizations. The following table outlines the high-level roles each entity plays in the integration process.

Organization	Actors	Potential Scope
NC DHHS	Integration Support Team; RPA/BOT Team	Processing records into CVMS; reporting of errors; Solution oversight and ownership.
NC HealthConnex	HIEA Staff SAS Technical Resources	Data sharing (BAA) agreements; Secure connectivity; Patient matching from demographics feed; Processing EHR extract; Transmitting error reports.
Provider Organization	Business Owner Technical Resources	Data sharing (BAA) agreements; Secure connectivity; Sending patient demographics feed; Creating EHR extract; Error handling.

Integration Requirements

In order to enable integration of vaccine data into CVMS, the following governance and technical components should be in place.

1. **NC HealthConnex Data Sharing Agreement**
   - Full NC HealthConnex Participation Agreement
   - Submission Only Amended Agreement with BAA
   - Retail Pharmacy Agreement

2. **Secure Connection to NC HealthConnex**
   - Secure file transfer (SFTP)
   - Direct secure messaging (DSM)

3. **Submission of COVID-19 vaccine data to NC HealthConnex**
   - NC COVID Vaccination Reporting (NCVR) file
   - CDC COVID Vaccine Reporting Specification (CVRS) file

NOTE: Additional submission of patient demographics via HL7 standard messages is requested where possible for patient matching to NC HealthConnex MPI and updates.

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CVMS Data Flows
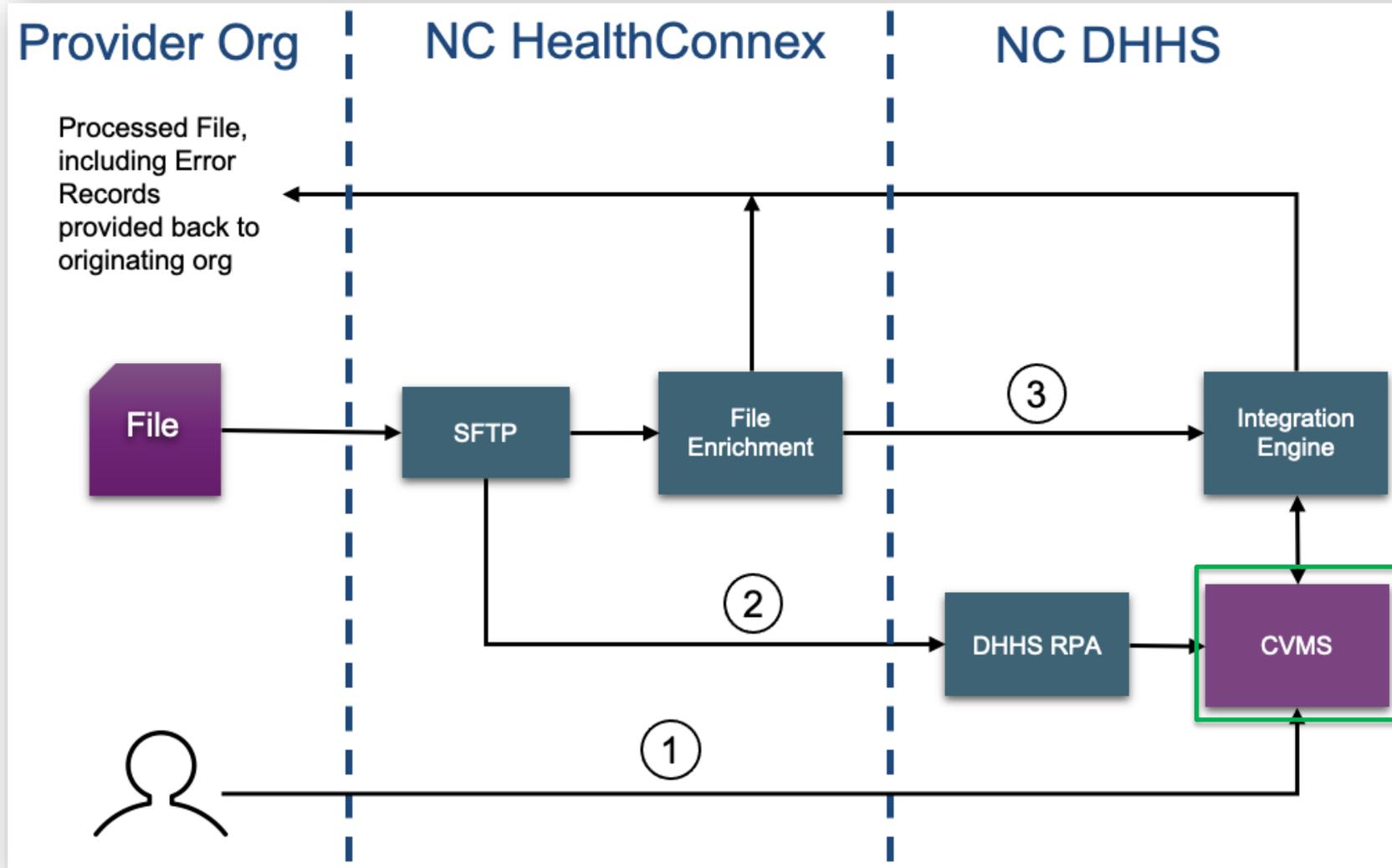
Options:

1. Manual user entry to CVMS for patient registrations and vaccine administration details.

2. Digital worker (RPA/BOT) solution for NCVR files. Will be replaced by the direct integration process.

3. Direct integration process, which is the long-term solution for COVID vaccine files.

Key Terms:

RPA - Robotic Process Automation or digital worker or BOT

RPA (BOT) Solution Overview

Automate end-to-end workflow across data entry for patient look up and registration, appointment booking, vaccination administration, and communication of results back to hospital systems

Retrieve and validate universal NCVR file
- ✓ Checks file layout in HIE folder
- ✓ Performs validations on the source file
- ✓ Separates the 'good' from 'invalid' records

Processes patient look up, registration, appointment booking, and vaccination in CVMS
- ✓ Looks up recipients and applies multi-factor criteria
- ✓ Creates or registers patient as needed
- ✓ Books appointments and processes vaccination records

Output and communications
- ✓ Sends completed email with high level metrics of records processed
- ✓ Uploads completed results file back in the HIE for hospitals to review as needed

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COVID Direct Integration Flow

ADT

VXU

CCD

NCVR

CDC CVRS

Integration Layer

HIE Platform

- Patients created from ADT/VXU/CCD
- NCVR file processed
- NCVR IDs matched to patient
  - NCVR demographics create patient

VAX Stage

HIE-MPI Updates

Enhanced CVR file

CVMS

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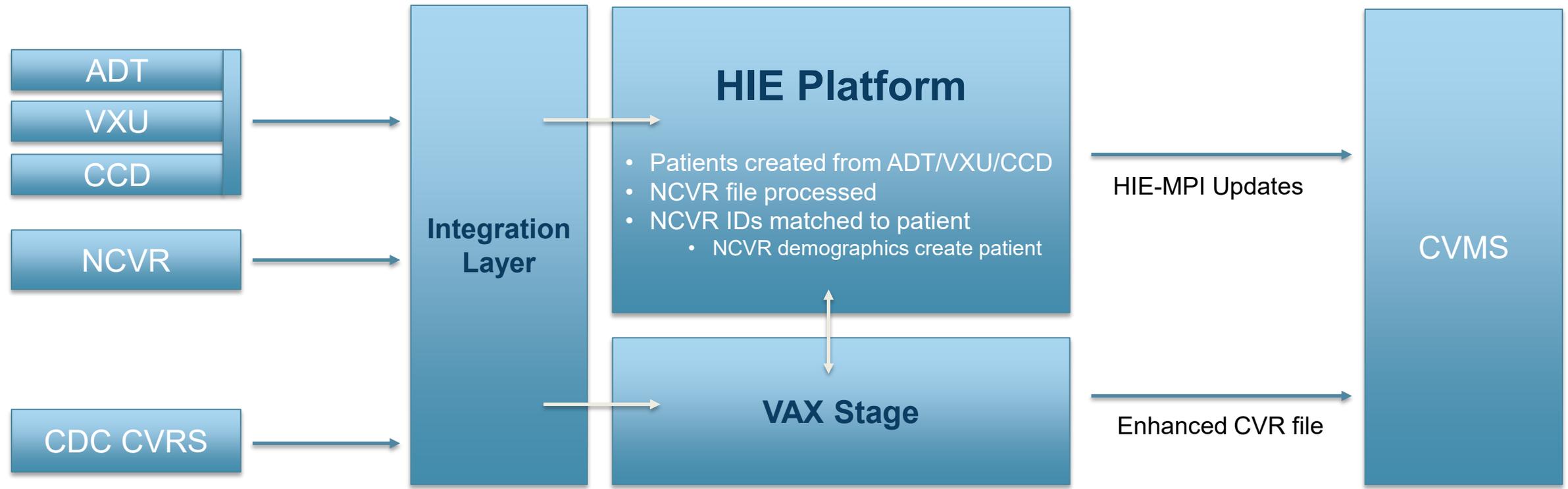
Vaccine Provider Groups

Organization	Program	Integration Approach	Current State
Pharmacy	Long Term Care (LTC)	CVS and Walgreens direct	Live as of 2/1
Health System	Health workers and general population	Direct from about 60 systems	Live on RPA/BOT, Pilots on Direct
Pharmacy	General population	Direct and vendor/aggregator	Initial connectivity
Local Health Dept	General population	EHR vendor and direct	Initial connectivity
FQHC	General population	EHR vendor and direct	Initial connectivity
Other	General population	TBD	Education sessions

Steps for Completing Integration

Prep	☐ **Verify all necessary agreements are in place with NC HealthConnex** ☐ **Confirm HL7 patient demographics feed is not being filtered and includes all ADT event types, if technically feasible.**

Build	☐ **Develop and test internal processes for creating NCVR file format**
	  • Recurring meetings will provide technical support, time for Q&A, etc.
	☐ **Establish secure connectivity method**
	  • A HIPAA-compliant secure connection is required to send NCVR data files into CVMS.

Test	☐ **Send NCVR files for validation**
	  • Initial test files <u>with no PHI</u> are requested for testing in pre-production environments.
	  • Subsequent test files <u>with PHI</u> are requested for validation.
	☐ **NCVR file validation / testing**
	  • NC HealthConnex and NC DHHS will confirm all fields in the file meet specification requirements.
	☐ **Error reporting**
	  • Errors are reported in an error file and sent via the same secure connection method (SFTP or DSM).

Live	☐ **Operationalizing and automation** • Once the files have passed end to end testing, components in NC HealthConnex and CVMS will be promoted to production.

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Wave Approach for Onboarding

Week #1 | Week #2 | Week #3 | Week #4 | Week #5 | Week #6 | Week #7 | Week #8 | Week #9 | Week #10 | Week #11

Kickoffs

Initial Q&A Pilot, small #s

Wave #1

Wave #2

Wave #3

Wave #4

Wave #5

Wave #6

Wave #7

Wave #8
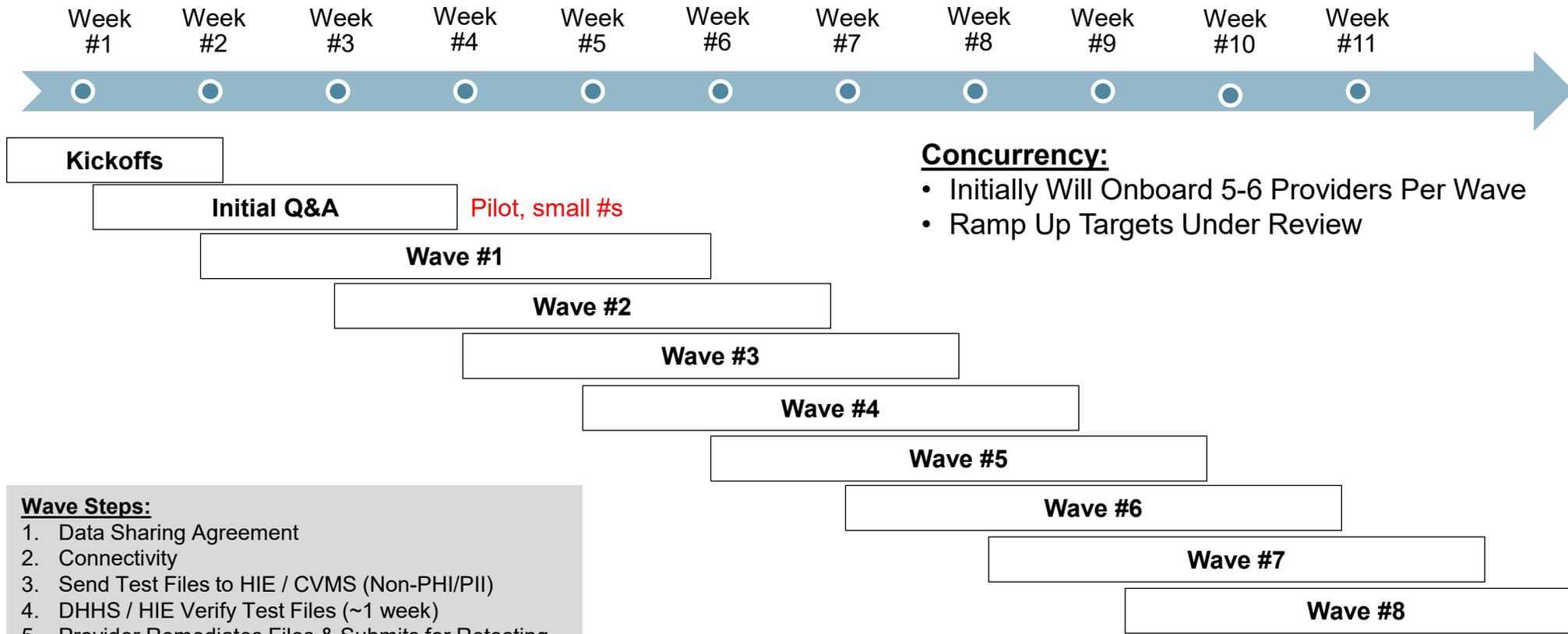
Concurrency:
- Initially Will Onboard 5-6 Providers Per Wave
- Ramp Up Targets Under Review

Wave Steps:
1. Data Sharing Agreement
2. Connectivity
3. Send Test Files to HIE / CVMS (Non-PHI/PII)
4. DHHS / HIE Verify Test Files (~1 week)
5. Provider Remediates Files & Submits for Retesting
6. QA & UAT (~1.5 weeks)
7. Provider Prepares for Production Launch
8. Go Live

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Current Status of Pilots+

Health System	Connectivity	Non-PHI File Received	Non-PHI File Validated	PHI File Received	PHI File Validated	BOT	Direct
UNC	Y	Y	IP	Y	IP		In Pilot
Duke	Y	Y	IP	Y	IP		In Pilot
Mission	Y	Y	IP				
New Hanover Regional MC	Y	Y	Y		IP	Next Wave	
Vidant	Y	Y	Y				
Atrium	Y	Y	Y	Y	IP	Live	In Pilot
Cape Fear Valley MC	Y	Y	Y	Y	Y	Next Wave	
WakeMed	Y	Y	Y	Y	Y	On Hold*	
Wake Forest Baptist	Y	Y	IP				
Columbus Regional	Y	Y	IP				
UNC Health Southeastern	Y	Y	IP	Y	IP	Next Wave	
First Health Of The Carolinas	Y	Y	Y	Y	Y	Next Wave	

File validation is an iterative process. As file issues are identified, providers will remediate and resend. Status is listed as In Process (IP) until completion of 2 clean runs.

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Outreach and Education

- January HIEA Update
- Onboarding packet and file specification distributed
- Webinars
  - Health System Onboarding (Feb 5)
  - Pharmacy Vendor & Stakeholder (Feb 19)
  - Teletown Hall – Local Health Dept and Community Health Centers (Feb 24)
  - Local Health Dept and FQHC Vendors (Mar 2)
- Recurring Meetings
  - Data Automation Morning Standup (daily)
  - CVMS Tech Call (twice weekly)
  - Pharmacy Data Reporting (weekly)

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Next Steps

- Continue outreach to providers and recurring meetings

- Expand RPA/BOT footprint behind Atrium success

- Pilot direct integrations (this week)

- Pilot stabilization (next week)

Thank you to NC DHHS and our Health System partners!

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Department of Information Technology
Christie Burris
Executive Director

Update

1. Operations Update

2. January Metrics

3. Legislative Discussion
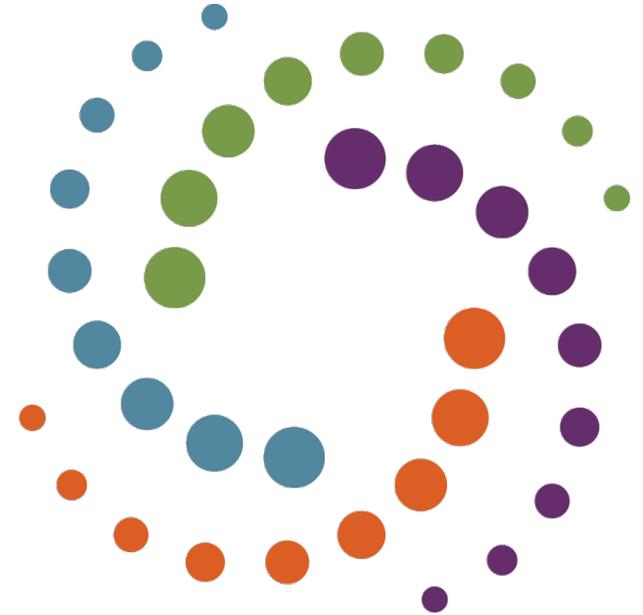
Operations Update

Quarter 1 2021 Activities:

- Staffing

- HITRUST Gap Analysis

- Public/Private Collaboration for Security Awareness/Threats

- HITECH Transition

- Use Cases – Colorectal Cancer Registry, Quality Program, Advance Care Plan document exchange

- NC*Notify V4

- Provider Outreach

Quality Measures

Partners: Office of Rural Health, Division of Health Benefits/Medicaid

ORH Quarterly Performance Measure Report

- Proof of Concept
  - 2 Measures
  - 2 Health Centers
- Goal: to replace manual reporting with HIE data

Medicaid Annual Hybrid Measures HIE Data Extract

- Data to support annual Hybrid Measures:
  - Diabetes
  - Hypertension
  - BMI
  - Depression Screening
  - Prenatal

Medicaid Quality Measure Initiative

- Identify key data elements needed to support ECQMs
- Improve data quality and completeness of providers submitting data to HIE for key
- Build dashboards for QMs based on near real time clinical data

Future Use Case – Sharing ACP Documents
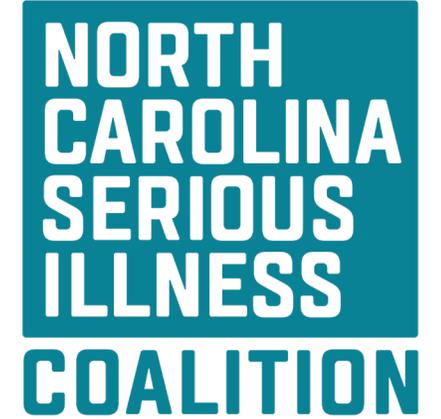
Advance Care Planning in North Carolina

ACP documents in North Carolina are currently siloed, residing in:
- **Health system Electronic Health Records,**
- **The NC Secretary of State's database,**
- **Private databases,**
- **Paper format in the homes of patients, and/or**
- **Possibly with rural primary care physicians**

There could be multiple versions in one or more of these places for the same individual.

Goals:
- Standardization for the sharing and delivery of ACP documents at the point of care
- Improved access to advance care planning and end-of-life care planning documents
- Electronic integration of ACP documents across provider and facility workflows
- The ability to share records without the need for scanning, copy, and faxing from one location to another
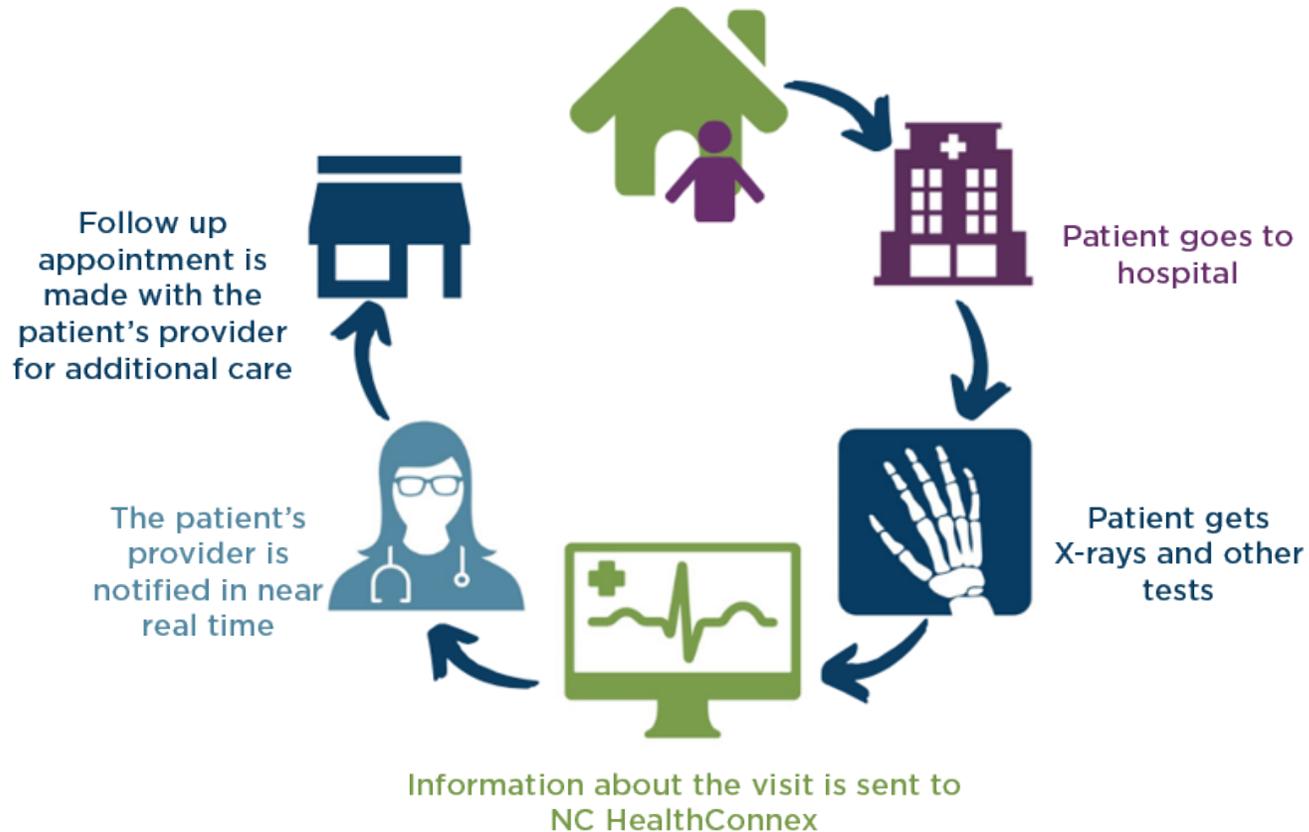
Version 4 Capabilities

- COVID Lab Result Alerts

- Dental Alerts

- Care Team Change

- High Utilizer Alerts

- Diabetes Registry & Pre-Diabetes Alerts

- Place Of Service Enhancements

- Chronic Care Management Alerts

Clinical Data Volumes - January Metrics

HL7 Messages:

ADTs
- 25,557,836

ORUs
- 5,385,104

Rad
- 299,660

CCD Messages:

CCD
- 11,010,453

- 16   Facilities Live in Jan
- 6,779   Total
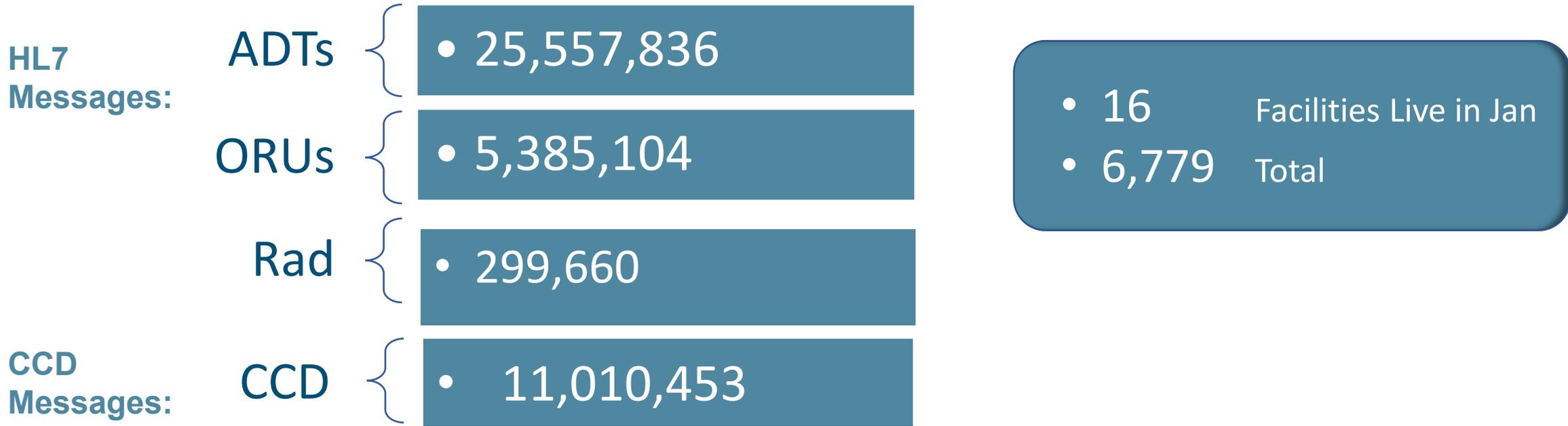
Exchange:

Metric	Patient Discovery (ITI-9)	Patient Demographic (ITI-47)	Document Query (ITI-18)	Retrieve Document Set (ITI-43)	Retrieve Doc. Set (ITI-43) % Change since last month
January Total	909,566	3,375,817	603,544	829,649	47.5%

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Legislative Discussion

NC HIEA Goals for consideration in amending the HIE Act:

1) Alignment with the NC HIEA's Mission - To connect health care providers and enhance their ability to safely and securely share health information through a trusted network to improve health care quality and outcomes for North Carolinians.

2) Do No Harm to Patients - As currently written, the HIE Act, directs payers to withhold/deny claims payments if a provider is not connected to the HIE. State employees and retirees will be negatively impacted if a provider's claim is rejected and the cost of services passes directly to the patient.

3) Incentivize/Reward Connectivity – Much progress has been made to build out statewide connectivity. In the midst of a Pandemic, developing a model that incentivizes health care provider connectivity - instead of denying payment or levying fines – aligns not only with federal initiatives to Promote Interoperability but also with value-based/managed care payment arrangements.

4) Articulate the NC HIEA's role for patient access to electronic health information when the HIEA does not have a provider patient relationship with individuals.

HB 179 - Amend HIE Participation Enforcement Mechanism

Introduced February 25, 2021
Sponsors: Representatives Lambeth and Goodwin

- Requires the HIE Authority to assess a civil money penalty to providers who fail to connect to the HIE Network, not to exceed $10 per claim

- Within 30 days after receiving a notice of civil penalty assessment under this subsection, a provider or entity shall do one of the following:

  (1) Pay the full amount of the civil penalty.
  (2) Contact the HIE Authority and execute a participation agreement.
  (3) Contact the Department of Information Technology to request an exemption under subsection (a2) of this section or contact the Department of Health and Human Services to request a hardship extension under subsection (a3) of this section.
  (4) File a petition for a contested case with the Office of Administrative Hearings.