Virtual Lifetime Electronic Record (VLER) Health Exchange

VA Business and Technical Requirements (VBTR) Document

Final

July 2015

VLER HEALTH EXCHANGE VBTR DOCUMENT

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1 PURPOSE AND SCOPE

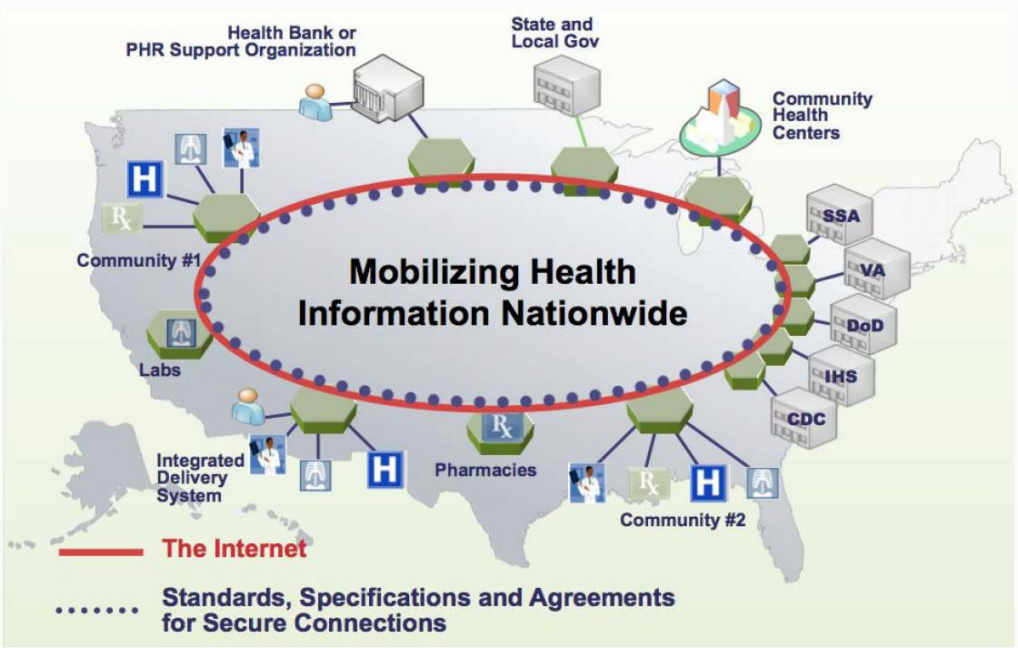
President Barack Obama announced the Virtual Lifetime Electronic Record (VLER) initiative on April 9, 2009, stating the Department of Defense (DoD) and Department of Veterans Affairs (VA) would "work together to define and build a seamless system of integration so that when a member of the Armed Forces separates from the military, he or she will no longer have to walk paperwork from a DoD duty station to a local VA health center. Their electronic records will transition along with them and remain with them forever."

The VLER Initiative was launched by this announcement in both VA and DoD, via the DoD/VA Interagency Program Office (IPO), to address gaps in electronic availability and compatibility of a Servicemember's or Veteran's lifetime health and administrative records. Later in 2009, VLER Health was the first VLER Program to deploy a technological solution to exchange health information with private sector providers based on national standards over a secure, trusted network.

In 2013, VA and DoD separated their respective VLER Health Programs from the DoD/VA IPO. Today, the VA VLER Health Program is being implemented within the Veterans Health Administration Office of Informatics and Analytics.

The VLER Health initiative is intended to provide portability and accessibility of health data for Veterans. It will enable secure, seamless, cross-boundary information sharing among VA, and participating private sector partners nationwide by leveraging and advancing comprehensive standards and best business practices for Health Information Technology (IT). In doing so, it will result in improved quality of care for our Veterans.

The scope of the VLER Health program is to deliver the capability to exchange clinical health data of veterans with Private Sector Providers using the eHealth Exchange



Visual Depiction of the eHealth Exchange

The purpose and scope of the VLER VA Business and Technical Requirements (VBTR) Document is to document unique VA business, technical, and content requirements as well as scope definition for onboarding with VLER Health. The VBTR is intended to serve as the authoritative project document for this information. The VBTR is in addition to each VLER partner's requirement; architecture/design and/or development related to onboarding the eHealth Exchange.

<u>This VBTR is for the query-based Exchange. VLER Health program has a separate VBTR for the Directed project.</u>

The VLER Health Exchange VBTR is organized as follows:

1. Purpose and Scope
2. VLER Health Exchange Objectives
3. Assumptions
4. VLER Health Exchange unique requirements
5. VLER Health Exchange onboarding process

2 VLER HEALTH EXCHANGE OBJECTIVES

2.1 Use Case

Missing from the Veteran's electronic health record is important information based on care provided by private sector healthcare systems. Since the majority of Veterans receive a portion of their health care from private providers, a significant, often critical, piece of the "story" of the lifetime health record is missing, or at least disjointed and unavailable electronically. VLER Health Exchange was initiated by VA and chartered as a program at the IPO to pursue health record interoperability with private sector providers in order to acquire and share this missing health component of VLER. The use cases include continuity of care and transfer of care scenarios.

2.2 Workflow

VLER Health Exchange gives clinicians from eHealth Exchange participating organizations immediate access to important health record information at the point of care and has the potential to improve care for Veterans. VLER Health Exchange is a **query-based exchange** where a clinician from one organization can request, receive, and display health information from other participating organizations that know the patient.

The health information exchanged between VLER Health Exchange partners for shared patients who opted in the exchange is primarily a health summary document (known as a Continuity of Care Document (CCD or C32) and clinical notes (C62).

2.3 Business Objectives

VA management priorities guiding the development of the VLER Health Exchange program include the following priorities:

1. Support the VLER Health Exchange initiative by:
    - Increasing the rates of adoption at existing locations
    - Adding partners based on mutual identification of business drivers, Ability to engage in high volume high quality exchanges
        - Trait Matching, health information exchange (HIE) maturity, Exchange Volume, Standards Use, Population
    - Emphasizing "gaps" to promote regional health exchange (i.e., Southeast, Intermountain West)
    - Adding exchange partner at iEHR Initial Operating Capability (IOC) Sites: San Antonio, Hampton Roads
2. Maximize Return on Investment (ROI)

2.4 System Overview

To implement this standard-based solution, each organization needs to implement 2 basic components: a Gateway and an Adapter (see Figure 1). The Gateway communicates with other Gateways securely over the Internet. VA VLER uses the publicly available CONNECT gateway (version 4.2.2.1). The Adapter translates between the Gateway and the organization backend system or EHR. The User

Interface (VistAWeb) initiates data queries over the eHealth Exchange and displays this data to clinician end users. The patient databases (VistA) are used to extract the data which is then transformed into CCD documents by the Adapter to respond to queries from VLER Health Exchange partners. The Master Veteran Index (MVI) enables patient identification (ID) matching to ensure requestor and responder are communicating about the same patient. The Veterans Authorization Preferences (VAP), a required component, serves the VA to record patient consent directives and enforce them through a policy decision engine, as well as audit transactions in order to meet disclosures accounting obligations.

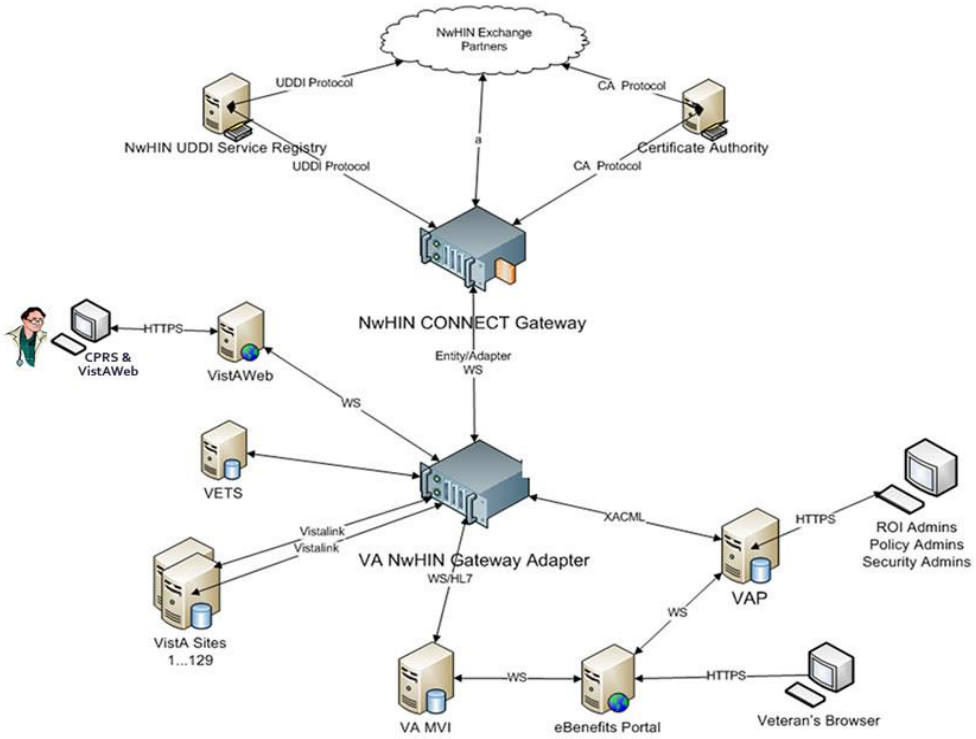


Figure 1: VA systems, at a high level, that support VLER and eHealth Exchange

2.5 Performance Evaluation Overview

A comprehensive, transparent assessment and evaluation of the VLER Health Exchange production pilot program was initiated in 2009. Between October 1, 2011 and March 31, 2012, the performance of these pilots was the subject of rigorous measurement and data collection. A summary of key findings is discussed around these domains: 1) **Technical Capability; 2) Value and Usability; and 3) Readiness**. It provided a status of the current pilots and a summary of significant findings, and it informed a set of options for future engagement in HIE activities for VA. The findings provided an assessment of factors considered essential to national

deployment, such as Department system capability, private sector capability, standards maturity, privacy, security, consumer choice, patient matching, usage, data content quality and availability and consumer and clinician perceived value.

VLER Health Exchange Partners participated in the previous performance evaluation. In particular, they facilitated interviews with their providers and patients. VLER Health Exchange Partners participation in future performance evaluation program would be welcome.

3 ASSUMPTIONS

3.1 eHealth Exchange Onboarding

VLER Health Exchange partners have completed successfully the eHealth Exchange onboarding process as coordinated by The Sequoia Project [http://www.sequoiaproject.org/ehealth-exchange/onboarding].

3.2 eHealth Exchange Specifications Overview

VLER Health Exchange Partners solutions shall support the following eHealth Exchange Specifications, found here: http://sequoiaproject.org/resources/exchange-specifications

NOTES:

- VA supports 2010 and 2011 specifications.
- eHealth Exchange specifications may not be backward compatible, but CONNECT helps with that. It checks the UDDI info, identify what version the participant supports, and adapt its messaging to that version.

References:

Data Use and Reciprocal Support Agreement (DURSA) Executable Version dated 30 Sept 2014 > http://sequoiaproject.org/ehealth-exchange/onboarding/dursa/

- Health Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component dated July 8, 2009 Version 2.5 http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32

- HITSP Unstructured Document Component dated July 8, 2009 Version 1.1 http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=62

4 VA VLER HEALTH EXCHANGE UNIQUE REQUIREMENTS

4.1 Business Requirements

4.1.1 Content rich information

VLER Health Exchange partners are expected to send and receive patient health summaries (C32 documents) and clinical notes (C62s). Regarding the patient health summary (C32), VLER Health Exchange Partners are expected to populate a minimum number of the C32 content modules as shown in **Table 4.10**. In addition, VLER Health Exchange Partners are encouraged to send and receive clinical notes (C62s), with in priority the note types shown in **Table 4.2**.

4.1.2 Promoting use of the system: pre-fetch, clinician training, and patient enrollment

To promote use of health information exchange, it is essential that the system is responsive, the users are well trained, and patients are recruited to provide authorization and participate.

Pre-fetch

It is recommended that VLER Health Exchange partners consider the implementation of a ‘pre-fetch’ capability. A pre-fetch capability would trigger the query and retrieval of patient health information ahead of an actual encounter. This strategy will improve response time and make it more likely that health information exchange will be used during an encounter when clinician users need and request the information from the system. The information will be cached and ready to serve. This will in turn improve clinician’s adoption of health information exchange.

Implementation of the pre-fetching capability can vary. For instance, on a daily basis, the system could identify correlated patients with a visit appointment on that day and query and save their health information ahead of time. VLER Health Exchange has defined the following requirements for its own implementation of the ‘pre-fetch’ feature:

- System shall identify Veterans that are correlated with an eHealth Exchange partner.
- System shall initiate retrieval of partner data no more than 24 hours prior to a scheduled appointment or scheduled admission for an eHealth Exchange participating patient.
- Data retrieved shall be temporarily stored inside the VA firewall.
- The clinician GUI (VistaWeb/iEHR/etc) shall retrieve eHealth Exchange data from the temporary storage location.
- Clinicians shall have the ability to refresh/update the eHealth Exchange data as needed by initiating real time retrieval.
- System shall have the ability to display any new data retrieved via the real time retrieval.

Clinician training
It is recommended and expected that VLER Health partners provide training to clinician users on health information exchange.

At least 20 users should be trained on the partner system before go-live date. This will ensure a minimum amount of use of the system, feedback on the performance of the system, and benefits for patients.
It is expected that gradually, each VLER Health Exchange partner will have in place a training plan for all users.

Patient enrollment
If a VLER Health Exchange partner requires patient consent prior to health information exchange (as VA does), then an active program for patient enrollment will be required in order to ensure a minimum return on investment in this technology.

VLER Health Exchange partners need to demonstrate that an active program for communication and patient recruitment is in place to gradually increase the benefits of health information exchange to all Veterans treated in the private sector.

4.1.3 Promoting usability: single sign on, patient context, notification, and data integration

The following capabilities are essential to make the system user-friendly, lessen the time requirement to access eHealth Exchange data, and help with adoption of health information exchange.

Single sign on
Single sign on allow clinical users to request and receive health information from other organizations without having to leave their clinical information system and login another system.

Preserving patient context
If a user must move to another system to request, receive, and view health information from other organizations, it is very helpful if the patient context is preserved between the original system (e.g., EHR) and the Health Information Exchange (HIE).

Notification
Notification refers to the capability of the system to indicate when a patient has information available from external sources.

Data integration

Clinicians find that data integration across all data sources more helpful than reviewing data from each source separately. For instance, presentation of a one aggregated medication profile is more useful than showing multiple medication lists. The next level of sophistication would be to assist with data reconciliation.

Identity traits
Ability to send *available identity traits* in patient discovery message, such as: full legal name, date of birth, gender, Social Security Number (SSN), address, and phone number to improve patient matching.

Training Plan
Plan to train health care providers on how to access VA data

Electronic health record (EHR) alerts
Capability for EHR alerts informing clinicians that VA health data is available for viewing.

Pre-Fetch
Ability for EHR to *"pre-fetch"* Veteran health data prior to patient encounter.

4.2 Technical Requirements

4.2.1 eHealth Exchange Specifications: Messaging Platform

WS-I Security Profile 1.1

To onboard the eHealth Exchange , a participant needs to support all of the encryption methods, including FIPS 140-2. VLER Health Exchange and other Federal Agencies require FIPS 140-2 compliant encryption. Private sector eHealth Exchange participants may not. This means that Private Sector participants who want to connect with VLER Health Exchange will need to support FIPS 140-2 encryption.

For more information, see: http://www.ws-i.org/Profiles/BasicSecurityProfile-1.1.html

Table 2: WS-I Security Profile

Specification	Version	Notes
Symmetric Encryption Algorithm and Key Length	AES 128-bit	AES = Advanced Encryption Standard **VLER requires FIPS 140-2 compliant encryption –**

Specification	Version	Notes
		TLS v1.0

4.2.2 eHealth Exchange Specifications: Authorization Framework

The Nationwide Health Information Network Authorization Framework is defined in Authorization Framework Production Specification v2.0. See table 2 above.

Additional clarification and scope limitations unique to VLER Health Exchange are provided below.

Subject

The <Subject> element shall identify the Subject of the assertion. This element also includes a NameID Format attribute which declares the format used to express the value contained in this element – the person making the request at the initiating organization:

UID=user ID,
CN=First name and last name,
O=name of the organization.

Filling in these values correctly helps with compliance testing.

Note that the term "subject" in SAML and XACML refers to the individual making the request. In this specification, the term "User" is generally used with the same meaning, but when referring to attributes defined in SAML or XACML, the naming convention of the standard is retained.

```
<saml:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:subject-id">
 <saml:AttributeValue>Walter H.Brattain IV</saml:AttributeValue>
</saml:Attribute>
```

Organization-id

"urn:oasis:names:tc:xspa:1.0:subject:organization-id" A unique identifier for the organization that the user is representing in performing this transaction shall be placed in the value of the <AttributeValue> element. This organization ID shall be consistent with the plain-text name of the organization provided in the User Organization Attribute. The organization ID may be an Object Identifier (OID), using the urn format (that is, "urn:oid:" appended with the OID); or it may be a URL assigned to that organization.

OrganizationID holds an OID of the facility. When a partner is identifying a trust community, they need to look at the HomeCommunity ID and not the more detailed OrganizationID.

HomeCommunityId

```
<saml:Attribute Name="urn:N HIN:names:saml:homeCommunityId">
   <saml:AttributeValue>urn:oid:2.16.840.1.113883.3.190</saml:AttributeValue>
</saml:Attribute>
```

Due to a CONNECT 2.4.7 defect, each VLER Health Exchange partner's Home Community ID must match its Assigning Authority ID. This is no longer true for newer versions of CONNECT (e.g., 3.1+). Partners running v2.4.7 will still face this issue.

Subject: Role Value Set

HITSP/C80 v2.0 Jan 2010 - 2.2.3.15.6 Author Role - Table 2-154 Author Role Value Set 2.16.840.1.113883.3.18.6.1.15 (Author Role was replaced with Subject Role). The following table shows the 'Roles' currently supported by VLER Health Exchange.

Table 4-1: Subject:Role Value Set

Concept Code (SNOMED CT)	Concept Name
112247003	**Medical doctor**
224608005	**Administrative healthcare staff**

Clarification is needed for the role when using Patient Discovery. It is intended to be the user who initiated the patient discovery process and could be Administrative healthcare staff. That is the role VLER Health Exchange uses when initiating Patient Discovery.

The Role used for Query for Document and Retrieve Documents in VLER Health Exchange should be 112247003 Medical Doctor. However, there may be partners using other roles beside 'Medical Doctor'. VLER Health Exchange does not check the role of incoming PDs, or QDs or RDs. VLER Health Exchange (and Partners) need to debate internally their policies as to what to authorize or not.

An example of the syntax of this element is as follows:

```
<saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:subject:role">
    <saml2:AttributeValue>
        <hl7:Role xmlns:hl7="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" code="224608005"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED_CT"
displayName="Administrative healthcare staff" xsi:type="hl7:CE"/>
    </saml2:AttributeValue>
</saml2:Attribute>
```

Purpose of Use Value Set

The value set for Purpose of Use currently supported by VLER Health Exchange is listed in the following table.

Table 4-2: Purpose of Use Code Descriptions

Purpose of Use Vocabulary	Code
Treatment	**TREATMENT**
Permission cannot practicably be provided because of the individual's incapacity or an emergency	**EMERGENCY**
Disclosures for insurance or disability coverage determination	**COVERAGE**

An example of the syntax of this element is as follows:

```
<saml:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:purposeofuse">
 <saml:AttributeValue>
    <PurposeForUse xmlns="urn:hl7-org:v3" xsi:type="CE" code="OPERATIONS"
        codeSystem="2.16.840.1.113883.3.18.7.1" codeSystemName="N HIN-
purpose"
        displayName="Healthcare Operations"/>
  </saml:AttributeValue>
</saml:Attribute>
```

Note that the Patient Discovery should be made based on purpose of use = TREATMENT (see Section 6.1.6.7.1).

VA outbound Patient Discovery are only 'Treatment', but inbound Patient Discovery can be 'Treatment' or 'Coverage' or 'Emergency'.

Very Helpful Patient Discovery Request Parameters

There is not a common set of demographics for exchange other than those in the specifications. Since the initiator does not know what the responder's algorithm is they should send as many demographics as allowed in the specifications.

In particular, the Social Security Number (SSN) plays a critical role in the success of patient ID matching and SHOULD be included in the Request Parameters as well as the Response Parameters.

When specified within the request, the SSN is specified in a LivingSubjectId element – potentially one of several. When specified within the response, the SSN is specified as in an OtherIDs element. SSN is designated using the OID 2.16.840.1.113883.4.1.

VA requires that a LivingSubjectId field with the partner's assigning authority and unique patient ID be present in the Patient Discovery message to VA. Without this, VA cannot create a correlation. Partner Document Queries undergo a policy check that requires VA's identity management system have a correlation or the inbound Document Query will fail.

With SSN, VA can achieve over 80% matching success rate, whereas this success rate degrades down to 20% without it.

4.2.3 eHealth Exchange Specification: Query for Documents

VLER Health Exchange Partners will ignore date ranges for queries for C32s, but not for C62s. A C32 is returned without regard to the date range provided, but C62s/unstructured documents do respect the date range provided in the query.

Further, in queries for C62s/unstructured documents, a partner has the option of returning the XDSTooManyResults error if the serviceStartTimeFrom and serviceStartTimeTo parameters indicate a wider time range than the partner is willing to support. When this error is returned, additional free text shall also be included in the error message to indicate the maximum time range supported by that partner. This text information must make sense to the remote user so they can modify their query to successfully get data back. The initiating partner should respond to the XDSTooManyResults error message by surfacing the error to the end user and should include the free text part of the message so that the user has some idea how to change their query to perform a Query for Documents without receiving this error. See the IHE technical framework revision 7, volume 3, section 4.1.13 "Error Reporting" for the structure of a registry error.

If a partner receives a request for a class code for which they either do not have any documents for the specified patient or they do not have internally mapped at all, that partner should simply return an empty list.

If a query is received without document code, then VLER Health Exchange returns all document types it has about the patient.

The specifications miss specifying the need and how to populate this attribute: 'XDSdocentrystatus'. It needs to be populated, describing the 'statustype' that is either 'approved' (approved for delivery) or 'deferredcreation' (on demand of the requestor – an attribute added by EHealth Exchange Specifications Factory beyond the IHE profile). An example of the syntax of this element is as follows:

```
<ns3:AdhocQuery id="urn:uuid:14d4debf-8f97-4251-9a74-a90016b0af0d">
  <ns3:Slot name="$XDSDocumentEntryStatus">
          <ns3:ValueList>
```

```
                        <ns3:Value>('urn:oasis:names:tc:ebxml-
regrep:StatusType:Approved',
'urn:ihe:iti:2010:StatusType:DeferredCreation')</ns3:Value>
                </ns3:ValueList>
        </ns3:Slot>
```

Query for Documents Parameters

Class Code

VLER Health Exchange supports the following Class Codes in Query for Document requests.

Table 4-3: VLER Health Exchange Document Class Code scope

Concept Code	Concept Name (LOINC Short Name)
11488-4	**Consultation Note**
18726-0	**Radiology Studies**
18761-7	**Transfer Summarization Note**
18842-5	**Discharge Summarization Note**
26441-6	**Cardiology Studies**
26442-4	**Obstetrical Studies**
27895-2	**Gastroenterology Endoscopy Studies**
27896-0	**Pulmonary Studies**
27897-8	**Neuromuscular Electrophysiology Studies**
27898-6	**Pathology Studies**
28570-0	**Procedure Note**
28619-5	**Ophthalmology/Optometry Studies**
28634-4	**Miscellaneous Studies**
29752-3	**Perioperative Records**
34117-2	**History and Physical Note**

Concept Code	Concept Name (LOINC Short Name)
34121-4	Interventional Procedure Note
34122-2	Pathology Procedure Note
34133-9	Summarization of Episode Note
47039-3	Admission History and Physical Note
47045-0	Study Report
47046-8	Summary of Death Note

For Patient Summary (C32) Document requests, the LOINC Class Code is still 34133-9.

For Unstructured Document exchange, the functional areas listed below will be mapped to the indicated LOINC Class Codes:

Table 4-4: Functional Area / LOINC Class Codes Mapping

Functional Area	LOINC Class Code
Discharge Summaries	18842-5: Discharge Summarization Note
	18761-7: Transfer Summarization Note
	47046-8: Summarization of Death Note
Consults/Referrals	11488-4: Consultation Note
	34140-4 : Transfer of Care Referral Note
History & Physical	34117-2: History and Physical Note
	47039-3: Admission History and Physical Note
Procedure Notes & Results of Diagnostic Studies	28570-0: Procedure Note
	34121-4: Interventional Procedure Note
	47045-0: Study Reports

Functional Area	LOINC Class Code
	26441-6: Cardiology Studies
	26442-4: Obstetrical Studies
	27895-2: Gastroenterology Endoscopy Studies
	27896-0: Pulmonary Studies
	27897-8: Neuromuscular Electrophysiology Studies
	28619-5: Ophthalmology/Optometry
	28634-4: Miscellaneous Studies
Radiology Study Reports	**18726-0: Radiology Studies**
Pathology Studies	**27898-6: Pathology Studies**
	34122-2: Pathology Procedure Note
Operative / Surgery Notes	**29752-3: Peri-operative Records**

If multiple Class Codes are included then all documents matching any of the codes should be returned. (i.e., OR semantics should be used when multiple Class Codes are included in the request).

ServiceStartTimeFrom / ServiceStartTimeTo and ServiceStopTimeFrom / ServiceStopTimeTo

It is strongly recommended that all queries for Unstructured Documents include one or more of the service Start/Stop From/To parameters to keep searches for data in source systems targeted at specific data sets rather than just “asking for everything”. Responding systems have the option of responding with a “XDSTooManyResults” error if the time range indicated by these parameters is considered to be “too broad”.

For Unstructured Document exchanges, these parameters MAY be provided in the Query for Documents by the Initiating Gateway and MUST be used if provided to filter and search for matching notes to share back in the response from the Responding Gateway.

DocumentEntryStatus

Document entry status means different things depending on whether the document is already created or assumes deferred creation. The example below shows either.

```
      <rim:Slot name="$XDSDocumentEntryStatus">
        <rim:ValueList>
                <rim:Value>('urn:oasis:names:tc:ebxml-
regrep:StatusType:Approved',
'urn:ihe:iti:2010:StatusType:DeferredCreation')</Value>
        </rim:ValueList>
```

The Initiating Gateway shall accept a Document Entry without size, hash, creationTime values when availabilityStatus="DeferredCreation". The Initiating Gateway may retrieve the referenced document via a normal XCA Cross Gateway Retrieve.

VLER partners MUST include one or more DocumentEntryStatuses in a Document Query Request to indicate that they are requesting a filtering (narrowing) of the results to a particular set of DocumentEntryStatuses.

Responding VLER partners MUST filter their results based upon the DocumentEntryStatus. It is recommended that partners always include both "urn:ihe:iti:2010:StatusType:DeferredCreation" and "urn:oasis:names:tc:ebxmlregrep:StatusType:Approved" statuses so that both existing and "generate on demand" documents will be included in the response.

Format Code

Note that for the Format Code parameter, responding Gateways must minimally honor a request to filter out document formats that do not match what was requested even if they do not have the capability to search internally within their communities using these fields.

The VLER Health Exchange supported value set is listed in the following table.

Table 4-5: The FormatCode Value Set Supported by VLER Health Exchange

Concept Code	Concept Name
urn:ihe:pcc:xphr:2007	**HL7 CCD Document**
urn:ihe:iti:xds-sd:pdf:2008	**PDF embedded in CDA per XDS-SD profile**
urn:ihe:iti:xds-sd:text:2008	**Text embedded in CDA per XDS-SD profile**

A Responding Gateway should include CCD/C32 style Patient Summary(s) if a Class Code = 34133-9 is included in the Class Code parameter and the FormatCode parameter is either blank or includes a value of "urn:ihe:pcc:xphr:2007" (CCD). Note that it is theoretically possible that a partner may at some point have Patient Summary documents that have been scanned in from paper and could then be shared as Unstructured Documents rather than in CCD format. Therefore, if a partner happens to only be interested in CCD/C32

style Patient Summaries to use the structured data content then a FormatCode = “urn:ihe:pcc:xphr:2007” should be indicated in the request.

The Document Format is an optional parameter in Query for Document requests, but filtering based on this parameter is required on the part of the Responding Gateway.

VLER Health Exchange partners MAY include one or more Format Codes in a Document Query Request to indicate that they are requesting a filtering (narrowing) of the results to a particular set of Format Codes.

Author Specialty Code (optional)

While an author’s specialty can be pre-coordinated into a LOINC code, the standards community at large has been taking the general approach of using only the high-level LOINC-based “Class Codes” to designate the class of document and encoding any specialty information with a separate “authorSpecialty” code (SNOMED-CT based C80 “Clinical Specialty” codes; Table 2-149).

The VLER partners recommend following this approach of using the authorSpecialty code to represent the author’s specialty in the Document Query and Document Query Response transactions.

VLER partners MAY include an authorSpecialty code in a Query for Documents to indicate that they are requesting a filtering (narrowing) of the results to a particular specialty.

Responding VLER partners are NOT required at this time to filter their results based upon an authorSpecialty code (i.e. the authorSpecialty code may be ignored- in such a case an unfiltered list of documents corresponding to the rest of the query parameters [e.g. class code and date range] will be returned)

4.2.4 eHealth Exchange Specifications: Retrieve Document

Data Content for Unstructured Document Exchange

VLER partners will comply with All HITSP, IHE and HL7 specifications for Unstructured Documents (C62)

Data Content will be handled with the “Virtually Scanned Documents” context, as described in XDS-SD”:

- *"Virtually Scanned" electronic documents are existing electronic documents not derived from legacy paper or film that either are PDF/A or plaintext format or have been converted to one of these formats for the purposes of sharing.*

The C62/XDS-SD Data Enterer in our "virtually scanned" scenario is software, not a person. Only the Template ID, Enterer Time and the ID are required for the dataEnterer element (a person's name is not required). Thus, the following implementation is recommended in "virtually scanned" situations:

- Set the dataEnterer/time to the date/time the document was created by the software
- Set dataEnterer/id to an identifier representing the software
- Do not include the assignedPerson element (including the name subelement), as these are optional and not relevant in the "virtually scanned" scenario

The ClinicalDocument/component/nonXMLBody/text element contains the base64 encoded content for the Unstructured Document. The "mediaType" attribute of this "text" element MUST contain one of the following values depending on whether the content is formatted as plain text or PDF/A: "plain/text" or "application/pdf". The "representation" attribute of this "text" element MUST be set to "B64" to indicate base64 encoding. The "compression" attribute will not be used so no compression of the content will be supported for VLER Health Exchange.

4.2.5 eHealth Exchange Specifications: Patient Discovery

Initiating and Responding to Patient Discovery

The following table describes how VA initiates and responds to patient discovery requests.

Table 4-2: Patient Discovery Workflow for VA

Partner	Patient Discovery Workflow
VA	The VA will send patient discovery requests to the private sector partners as part of multiple workflow processes. VA does not require a patient authorization to determine patient discovery for the purpose of treatment. VA does require patient authorization before VHA health information can be shared with any VLER partner. 1. Patient discovery is initiated thru the VAP application by a VA staff member. Many are initiated at the time the VLER Health Exchange authorization is obtained from the Veteran. 2. VLER Health Exchange partners will respond to these patient discoveries in real-time.
Note: from time to time, VA may initiate large **batches** of patient discoveries. These Patient Discovery queries will NOT be done out to all parties. VLER Partners will be	

Partner	Patient Discovery Workflow
notified in advance.	

Patient ID Matching Algorithms

The following table defines the patient matching algorithms used by VA:

Table 4-3: VA Matching Algorithms

Partner	Matching Algorithm	Description
VA	Probabilistic	The probabilistic algorithm for VHA's Identity Management Service is a COTS product that has been customized to operate with VHA's Identity Management application. Probabilistic matching compares data traits that are common between two records. Based on this common data a score is developed for each trait/trait set. The score for each trait is at a maximum if the traits match exactly. If the traits do not match exactly, the score is scaled in accordance to the "distance" the traits are apart. Based on the trait, the "distance" is measured differently. For instance, the name field looks at nicknames, common alternative spellings of the same name and how the name sounds to determine distance. The higher the score the closer these traits match. The distance may reduce the score and may result in a negative score. In addition, each trait is assigned a "weight" which is determined by the usefulness of the trait in the uniqueness of the entry. The score for each trait/trait set pair is aggregated to produce an overall score for the match. The overall score can result in a match or a no match based on established threshold.

Matching Attributes

The following table documents the traits VA **sends** when initiating or responding to patient discovery:

Table 4-4: VA Patient Discovery Traits

		Traits VA Sends During Patient Discovery

Traits VA Sends During Patient Discovery														
Partner	First Name	Middle Name[1]	Last Name	SSN	DOB	Gender[5]	Home Phone	Marital Status	Address[2]	City	State[4]	Zip[3]	Race	**Key** R: Required RA: Required if allowable and available O: Optional x: Provided y: Provided if allowable and available n: Available, not sending
PD Spec[6]	*R*	*O*	*R*	*RA*	*R*	*R*	*RA*	*O*	*R A*	*R A*	*R A*	*R A*	*O*	
VA	x	x	x	y	x	x	y	n	y	y	y	y	n	

Notes
1. Middle Name for VA.
2. Address = Street Address has 1, 2, 3 lines
3. Zip is a 9 digit code
4. State is the FIP code
5. M, F or Null
6. See eHealth Exchange Specifications on Patient Discovery parameters optionality

The following table documents the traits VA **uses** for matching:

Table 4-5: VA Patient Matching Traits

Traits VA Uses for Patient Matching														
Partner	First Name	Middle Name	Last Name	SSN	DOB	Gender	Home Phone	Address	City	State	Zip	Mother's Maiden Name	POB City/State	**Key** x: Required y: Used if provided h: Highly Desired
VA[2]	x	h	x	h	x	x	y	y	y	y	y	y	y	

Notes
1. If any primary identity fields are not provided, the partner will need to provide additional traits such as Address, Phone Number, MMN, POB City, and POB State to increase the probability of matching.

VA consent models

Before Veteran Health data can be shared with external partners, Veterans in the VA health system must authorize participation in VLER Health Exchange. Participation in VLER Health Exchange is optional, and Veterans can opt-out at any time.

In order to share patient data, VLER partners may or may not require authorization or consent from their patients. The following table describes the VA requirements for patient authorization/consent to share data.

Table 4-6: VA Authorization/Consent Requirements

Partner	Patient Authorization/ Consent for Sharing Data	Description
VA	Yes	VA requires a Veteran signed authorization form to exchange VA health data with all eHealth Exchange partners except DoD. After a Veteran completes an authorization form, the identity of the Veteran must be authenticated, and the authorization form must be validated and entered into the Veterans Authorization and Preference. This process is referred to as the "opt-in" process. The Veteran authorization is required as per Title 38 USC 7332. It is valid for 5 years for treatment, payment, and health care operations purposes of use and 2 years for coverage purpose of use. 'Payment' is currently not a supported purpose of use.

Furthermore, VA policies have recently changed. Patient authorization status is now checked only for

- Inbound Query for Documents (i.e., requests by partners for VA records)
- Inbound Document Retrieve (i.e., requests by partners for VA data)

Authorization checks for the following are not performed for the following:

- Inbound and Outbound Patient Discovery (i.e., exchange of demographic traits for patient ID matching)
- Outbound Query for Documents
- Outbound Document Retrieve

4.3 Non-Functional Requirements

4.3.1 Response Times

There are no VA response time requirements for VLER Health Exchange. However, partners shall determine average response times for Patient Discovery, Query for Documents and Retrieve Documents transactions to support the development of baseline response times.

Also, the 'pre-fetch' strategy should improve response time to clinician end-users and therefore enhance adoption.

4.3.2 Gateway Port

When communicating with VA we support the "normative" eHealth Exchange ports, 443, 4437 or 14430, for test and production systems.

This is identified in the Nationwide Health Information Network Messaging Platform Specification v3.0 section 2.3 Operational Management.

4.3.3 Encryption

FIPS 140-2 compliant encryption TLS version 1.0 is the required encryption method.

4.4 Content Requirements

The following sections describe the requirements related to VLER Health Exchange content payload.

4.4.1 Continuity of Care Document (CCD) - HITSP C32

The following table defines the content VA will provide to VLER partners and will be able to receive and display from VLER partners.

Table 4-7: C32 Health summary payload requirements for VLER Health Exchange

HITSP Component	Content Module	HISTP C32	VA C32	VA C-CDA CCD
C32 section 1	Person Information	R	Yes	Yes
C32 section 2	Language Spoken	O	Yes	Yes
C32 section 3	Support	O	Yes	Yes
C32 section 4	Health Care Provider	O	Yes	Yes
C32 section 5	Insurance Provider	O	No	Yes
C32 section 6	Allergy/Drug Sensitivity	O	Yes	Yes
C32 section 7	Problem/Condition	O	Yes	Yes
C32 section 8	Medication - Prescription & Non-Prescription	O	Yes	Yes

HITSP Component	Content Module	HISTP C32	VA C32	VA C-CDA CCD
C32 section 9	Pregnancy	O	Yes	Yes
C32 section 10	Information Source	R	Yes	Yes
C32 section 11	Comment	O	Yes	Yes
C32 section 12	Advance Directive	O	No	Yes
C32 section 13	Immunizations	O	Yes	Yes
C32 section 14	Vital Signs	O	Yes	Yes
C32 section 15	Results (initially Lab – Chemistry/ Hematology)	O	Yes	Yes
C32 section 16	Encounters (List of Encounters)	O	Yes	Yes
C32 section 17	Procedures (List of Procedures)	O	Yes	Yes
C32 section 18	Plan of Care	O	No	Yes
Smoking Status	Social History	O	No	Yes

VLER Partners are expected to populate at least 7 out of 8 of the sections in red in the table above.

4.4.2 HL7 Consolidated Clinical Document Architecture (C-CDA) Continuity of Care Document (CCD)

VA will be implementing query and retrieval of the HL7 C-CDA in the Fall 2015 timeframe. VA will be developing a table similar to section 4.10 above. In the interim, the C32 content guidelines should be used.

4.4.3 Additional VA CCD Recommendations

In addition, VA has additional recommendations for creating Continuity of Care/Health Summary Documents (C32/C-CDA CCD):

- **User more specific display of data sources.** Using the HIE name as the source of the document is not informative to clinicians. It is suggested to list the hospital(s) or health care organization(s) instead.
- **Provide an informative response message when there is no CCD document available, no data for a particular section of the CCD, or no specific data element in a section is available;** C32 schema data

requirements do not seem to match the real world data that are available. This leads to padding xml documents with “UNKNOWN” data structures.

Beyond a well composed (CDA error free xml) document – see section on CDA Validation Tools, there is additional data quality issues to consider when populating the data. In other words, a technically valid document may not be a clinically valid document.

- Quality of the data (e.g., small or no clinical data included making the investment in time not worth it. Also, inconsistencies can make the reader mis-trust the whole document – e.g., ‘no known allergies’ listed together with actual drug allergies). Some providers document better than others. Some sources have better data than others – e.g., encounters without a reason for visit. unclear abbreviations (e.g.., RCR)
- Incomplete details can make the data not has helpful – e.g., PSA test without reference range, medications without a sig.
- Document does not represent a well formed health summary. Rather, it is a ‘dump’ of transactional data. For instance, partial and complete lab panels are included, ADT messages are included. This adds to the volume and noise in the data and takes away from its value. Another example of this is with inpatient data. Administrated medications are recorded one tablet at a time.
- Methods for decreasing data duplication when the same data elements are received from multiple sources – e.g., conditions section will have the same list of problems repeated several times, one per each provider and encounter.

CCD Data Limits

It is recommended that VLER Health Exchange Partners adopt data limits and describe them inside the C32/C-CDA CCD. Explicit definition and display of the data filters used to populate each section of the CCD are necessary in order to inform end users, control volume of data, and improve response time. Each CCD section may have its own data limits based on date ranges and/or maximum number of occurrences. For instance, VA data limits are listed in Table 4-11 below.

Table 4-11: VA CCD data limits

CCD Module	Business Rule Text	C32 Data Limits	C-CDA Data Limits
Support/Contact	This section contains primary next of kin and primary emergency contact information.	**Current**	**Current**
Healthcare Provider	This section contains the names of all providers associated with the patient’s condition(s)	**All Problem List Providers**	**All Problem List Providers** **After June 23, 2015:**

			All Problem List and All Primary Care Providers
Insurance Provider	This section contains the names of all active insurance providers for the patient.	**All**	**All**
Advanced Directive	This section contains ALL of a patient's completed or amended VA Advance and Rescinded Directives. Entries below indicate that a directive exists for the patient, but an actual copy is not included with this document.	**Not supported**	**All**
Allergy/Drug	This section contains all patient allergy information from all VA treatment facilities. It does not contain patient allergies that were deleted or entered in error.	**All**	**All**
Condition/Problem	This section contains patient conditions (active and inactive) information from all VA treatment facilities. It does not contain patient conditions that were deleted.	**All**	**All**
Medications	This section contains patient medications (outpatient and self-reported) information from all VA treatment facilities for which the dispense date was within the last 15 months. Only medications that have an active or non-active prescription status are listed.	**Last 15 months**	**Last 15 months**
Immunization	This section contains patient immunizations information from all VA treatment facilities. Only administered (i.e., not refused) immunizations are included.	**All**	**All**
Vital Signs	This section contains information from the ten most recent patient vital signs (inpatient and outpatient) from all VA treatment facilities for which the panel date taken was within the last 12	**Last 12 months or 10 most recent.**	**Last 12 months or 10 most recent.**

	months. **Note:** If more than one panel was taken on the same date, only the most recent panel is populated for that date.		
Lab Results	This section contains the five most recent patient's Chemistry and Hematology lab results from all VA treatment facilities for which the result date was within the last 12 months.	**5 most recent panel results within the last 12 months.**	**5 most recent panel results within the last 12 months.** **After June 23, 2015:** **Adds Pathology and Radiology Reports, 20 most recent in the last 24 months.**
Encounters	This section contains information for the 25 most recent historical outpatient encounters (completed) for the patient from all VA treatment facilities for which the encounter date was within the last 36 months. **Note:** Ancillary visits are not included. Lists of associated note titles for each encounter are limited to a maximum of 10.	**Last 36 months up to a maximum of 25 most recent.**	**After June 23, 2015:** **Adds Encounter Notes, 10 most recent notes for each encounter.** **After Oct 1, 2015:** **Adds 150 most recent outpatient encounters within the last 36 months plus 10 most recent notes associated with each**

			encounter
Procedures	This section contains information for the 25 most recent historical (completed) surgical and radiological procedures for the patient from all VA treatment facilities for which the procedure date was within the last 12 months.	**Last 12 months and up to 25 maximum**	**Last 12 months and up to 25 maximum** **After June 23, 2015 adds:** **Up to 10 notes for each surgical procedure.** **Up to 20 most recent Clinical Procedure Notes within the last 36 months.**

4.4.4 HITSP C62 / HL7 Unstructured Documents

The following table defines the expected content from VLER partners C62s.

Table 4-12: Data Content Returned as Unstructured Documents

HISTP/HL7	Functional Document Categorization	VA
C62 / HL7 UD	Consults/Referrals	Yes
C62 / HL7 UD	Discharge Summaries	Yes
C62 / HL7 UD	Procedure Notes/Results of Diagnostic Studies	Yes
C62 / HL7 UD	History and Physical	Yes
C62 / HL7 UD	Radiology Reports	Yes
C62 / HL7 UD	Pathology	Yes
C62 / HL7 UD	Surgery/Operative Notes	Yes

All partners shall be able to send, receive, and display unstructured documents which follow either the HITSP C62 (IHE TF XDS-SD) or HL7 Unstructured Documents specifications/templates; the VA will generate Unstructured Documents that adhere to both templates. This is preferred over including clinical reports inside a C32 health summary.

VA will return all clinical notes that match requester's query document class codes, with the following data limit: all completed and signed notes, up to a max of 200, within requested date range.

HITSP C62, XDS-SD and HL7 Unstructured Documents

Proposed implementation of C62/XDS-SD/HL7 Unstructured Documents will allow documents to be compliant with both the C62/IHE XDS-Scanned Documents, as well as the newer, more widely used HL7 Unstructured Documents spec. All segments are planned to be required by any of the specifications and therefore agencies will be able to claim conformance to them all (C62/XDS-SD; HL7 Unstructured Doc/General Header Constraints). All partners should plan to enable display of C62s with both plain text and PDF/A content.

There is tremendous overlap between C62/XDS-SD and HL7 Unstructured Doc. Essentially, they are all the same, except for varying header segment optionality (one will be an R, whereas the other will be an R2 or an O) and HL7 allowing for more data types than just PDF/A and plain text. The following table indicates the optional and required attributes of the specifications, comparing to what will be optional and required for VA when generating Unstructured Documents.

Table 4-13: Content Module Optionality of C62 & HL7 Unstructured Docs

Content Section/Subsection	VLER C62 / Unstructured Document (VA)	HITSP C62 / IHE XDS-SD	HL7 CDA R2 Unstructured Document
CDA HEADER	R	**R**	R
Person Information (clinicalDocument/recordTarget)	R	R	R
Original Author (author of original content) (clinicalDocument/Author)	R	O	R
Scanner ("virtual scanner" device/software & Facility/Organization) (…/author/…/assignedAuthoringDevice) (…/author/…/representedOrganization)	R	O	R

Content Section/Subsection	VLER C62 / Unstructured Document (VA)	HITSP C62 / IHE XDS-SD	HL7 CDA R2 Unstructured Document
Data Enterer (Person that scanned) (clinicalDocument/dataEnterer)	R	R	O
Custodian (ClinicalDocument/custodian)	R	R	R
Legal Authenticator (ClinicalDocument/legalAuthenticator)	O	O	O
Documentation Of (date range of document) (ClinicalDocument/documentationOf)	R	R	O
NON XML BODY	R	R	R
R = Required	R2 = Required if Available	O = Optional	

In many cases, a functional area is mapped to multiple LOINC Class Codes for use in metadata and Query for Document parameters. When acting as the responding Gateway, each partner should map their internal documents/notes/reports to the Class Codes on the above list that they believe is the best fit based on the constraints of their existing systems. If requesting partners use the functional areas above in their GUI, they should include all of the Class Codes listed beneath that functional area in the table above regardless of how they themselves map documents/notes/reports to the Class Codes. (i.e., to request Discharge Summaries, include Class Codes 18842-5, 18761-7 and 47046-8 in the query even if only 18842-5 is used in responses from your community). This will support the expected variation in mapping to the Class Codes based on the constraints of existing legacy systems.

Individual partners may choose to break out some of the individual Class Codes listed under a functional area in their internal GUI. For instance, some partners may wish to display Radiology Study Reports separately from the other Procedure Notes/Results of Diagnostic Studies to better fit how their users are accustomed to viewing this data within their systems today. However, if some partners use the generic “47045-0: Study Reports” Class code for reports that users in other systems might consider to fall under the category of “Radiology Study Reports”, this break out into more specific categories may result in some documents/notes/reports showing up in categories that are unexpected from the perspective of end users of the requesting system. Although not ideal, this situation is simply an expected result of mapping legacy systems to the LOINC

Class Codes and the current lack of established hierarchical structure built into the LOINC document ontology itself.

If a Class Code is provided in the query, then responding VLER Partners MUST filter their results based upon Class Code(s).

Details about VA implementation
The Functional Area named “Procedure Notes & Results of Diagnostic Studies” was mapped to all Class Codes from the HITSP C-80 Table 2-144 that can correspond to this functional area. Unfortunately, some of these Class Codes have overlapping meanings. For example, a “Cardiology Study” (LOINC Code 26441-6) is a specific kind of “Study Report” (LOINC Code 47045-0) and some systems may not distinguish between “Study Reports” (LOINC Code 47045-0 indicating a report for a diagnostic study) and “Procedure Notes” (LOINC Code 28570-0, which could be interpreted to include all procedures reports including those for diagnostic studies, or be interpreted to refer only to procedures performed for treating a patient condition). This results in possible implementation issues that each VLER/eHealth Exchange partner should be aware of:

- VA mapped each note to multiple individual Class Codes from the HITSP C-80 Table 2-144 that a user might consider as a classification of that note to ensure that each note could be found regardless of the classification a user may attempt to use when searching for a note. The result is that a request for both “Cardiology Studies” and “Procedure Notes” may result in a single note from the VA EHR being provided twice—once with a classification of “Cardiology Studies” and again with a classification of “Procedure Notes”. The metadata for the clinical note returned for the "Procedure Note" class code will contain the Procedure Note Document Class code as the documentType code (ClinicalDocument/code/@code), a unique Document ID, Service StartTime, Service StopTime and the Document Title ("Department of Veterans Affairs" + VA Standard Note Title). The metadata for the clinical note returned for the "Cardiology Studies" class code will contain the Cardiology Studies Document Class code as the documentType code, a unique Document ID (different from the Procedure Note unique Document ID), Service StartTime, Service StopTime and the same Document Title ("Department of Veterans Affairs" + VA Standard Note Title). If the requestor's user interface displays the results of all requested Document Class Codes from the Query For Documents response in a single view, or list, and then displaying only one version of the VA note may be accomplished by filtering on the ServiceStart/ServiceStop Times and the Document Title. This filtering approach may not be appropriate for documents returned from other eHealth Exchange partners since it is conceivable that some partners may return multiple documents with the same ServiceStart/ServiceStop date/times and Document Titles but containing different note content from the sending partners EHR. Thus, this filtering method should only be used to filter out duplicates from a partner after getting acknowledgment from that partner that the algorithm cannot inadvertently filter out documents with differing content.
- A VLER/eHealth Exchange Partner may wish to subdivide the “Procedure Notes & Results of Diagnostic Studies” Functional Area indicated by the ICIB into smaller groups of Class Codes and include only these smaller groups (or single) Class Codes in a request to partners. However, since it is unknown how each partner will map their EHR content and document repositories to these Class

Codes, it is possible that a requesting partner may receive no documents for some of the Class Codes. For this reason, this VBTR recommends that partners treat the entire "Procedure Notes & Results of Diagnostic Studies" functional area as a single entity and always request the entire list of corresponding Class Codes. In this case, it is possible that a requesting partner may receive the same, or duplicate, documents for more than one class code.

Future considerations:

- The long term solution to this issue is for the eHealth Exchange Spec Factory to either define a definitive list of Class Codes or choose such a list from a standards body which does not contain codes with overlapping meaning. It is also important that this finalized list of Class Codes contain codes with well-defined, recognized meaning through the industry and which most EHRs should be able to successfully map to. It is very important that this list contain only broad classifications and that other metadata elements such as DocumentTypeCode, PracticeSettingCode, Specialty, and/or HealthCareFacilityType be used to separately support users in refining search criteria to find specific documents.
- Additional clarification in the eHealth Exchange specifications should also be provided for the various metadata elements to standardize the methodology for handling filtering when one of these elements is provided in a query, but a specific partner or document doesn't have that particular metadata element populated.
- Additional clarification for a standard way to classify a document that either doesn't appear to fit within the approved list of Classification Codes or could be interpreted to fall within multiple Classification Codes should be made explicit to avoid multiple approaches across partners as has occurred by VA.

4.4.5 Use of CDA Validators

The HITSP C32 V2.5 specification with its associated C83 and C80 documents is the normative specification that should be followed for Patient Summary (C32) document generation. The HL7 Unstructured Documents DSTU v1 is the normative specification that should be followed for Unstructured Document generation, with VA additionally declaring adherence to the HITSP C62 v1.1 specification. Although the normative content of these specifications are the only official source of requirements for the proper creation of document content, the validators on the NIST site are being used to demonstrate minimum adherence to these specifications. All VLER Partners agree to make use of the NIST Validator for the C32 exchanges (C32 v2.5 validator) as well as for the C62 exchanges (CDA4CDT validation). These efforts will be accomplished with the ultimate goal to proceed until achieving 'no errors' when using an errors-only constraint.

http://xreg2.nist.gov/cda-validation/validation.html

For the other C62/HL7 Unstructured Document 'xml body' aspects that fall outside what the NIST Validator can currently check, VLER partners are encouraged to leverage other available tools such as the Lantana website-offered validator

(https://www.lantanagroup.com/validator) to help in achieving compliance with the standards although it is possible that these tools may be either more lax or more strict than the specifications themselves.

In both instances, and while enhancements to the NIST Validator progress, the new eHealth Exchange content wg will serve to manage these same efforts and progress them via the eHealth Exchange new onboarding process accordingly and/or act in parallel in serving VLER needs with the ultimate goal of attaining 100% compliance with the content standards and supporting plug and play content payload.

VLER testing of VA, and Partners C32s produced one or more errors. Some common errors include:

Standards Document	General Category of Error	Notes/Description
CCD	Service Event - Documentation	A CCD SHALL contain exactly one ClinicalDocument / documentationOf / serviceEvent.
CCD	Observation/Value Unit of Measure	Where Observation / value is a physical quantity, the unit of measure SHALL be expressed using a valid UCUM expression.
CCD	Problem Status	The value for "Observation / value" in a problem status observation SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode STATIC 20061017.
CDA R2	Pattern validity error	cvc-pattern-valid: Value 'IV PUSH' is not facet-valid with respect to pattern '[^\s]+' for type 'cs'.
CDA R2	Attribute value error	cvc-attribute.3: The value 'IV PUSH' of attribute 'code' on element 'routeCode' is not valid with respect to its type, 'cs'.
CDA R2	Medications	cvc-attribute.3: The value 'mg/1 mL' of attribute 'unit' on element 'doseQuantity' is not valid with respect to its type, 'cs'.
CDA4CDT	H and P Note General Header Constraints	CONF-HP-7: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements SHALL have an addr and telecom element.
HITSP/C32 v2.5 -- HITSP/C83 v2.0	Medication Information - Improper Coding	Error: HITSP/C83 Medication Information, the coded brand name SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.7 Medication Brand Name or Section 2.2.3.3.10 Medication Packaged Product. See HITSP/C83 Section 2.2.2.8.12, rule

		C154-[DE-8.14-1].
HITSP/C32 v2.5 -- HITSP/C83 v2.0	Information Source - Missing Author Elements	Error: HITSP/C83 Information Source, Author Time is a required, non-repeating data element. See HITSP/C83 Table 2-14, Data Element 10.01.
HITSP/C32 v2.5 -- HITSP/C83 v2.0	Insurance Provider Component	Error: HITSP/C83 Insurance Provider modules SHALL declare conformance to the IHE Coverage Entry by including a templateId element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.17. See HITSP/C83 Section 2.2.2.5.1, rule C83-[DE-5-CDA-2].
HITSP/C32 v2.5 -- HITSP/C83 v2.0	Allergy/Drug Sensitivity	Error: HITSP/C83 Allergy/Drug Sensitivity, Adverse Event Type is a required, non-repeatable data element. See HITSP/C83 Table 2-10, Data Element 6.02.

Primary error types were related to:

- General header constraints (e.g., details of the author of the document are not provided properly)
- Undefined attributes (e.g., attribute that is unrecognizable by the rules/requirements provided by the XML schema)
- Pattern validity errors (e.g., programming technique used for processing XML data is not using a recognizable pattern)
- Improper coding of data
- Missing required information for document processing

4.4.6 Narrative Block for CDA R2 Structured Documents

The Narrative Block is defined by the CDA R2 specification as required content using the following language:

"If the CDA Body is structured, the attested narrative contents of a section must be placed in the Section.text field, regardless of whether information is also conveyed in CDA entries."

The CDA R2 specification further states that:

"A recipient of a CDA document is not required to parse and interpret the complete set of CDA entries contained within the CDA body."

Thus, a CDA document recipient should be able render just the Narrative blocks (Section.text) of each section to produce a human readable view of the information. The CDA R2 specification also provides a way to indicate the special case where the Narrative Block is completely derived from the CDA structured entries:

"The entry relationship "DRIV" (is derived from) can be used in the special case where the narrative is fully derived from CDA Entries. When a report consisting entirely of structured entries is transformed into CDA, the encoding application must ensure that the authenticated content (narrative plus multimedia) is a faithful and complete rendering of the clinical content of the structured source data. This ensures that the narrative plus multimedia represents, as in all CDA documents, the complete authenticated content of the Section. In this case, narrative plus multimedia does not contain any clinical content that is not present in the Entries."

This entry relationship is indicated by setting the section/entry/@typeCode="DRIV". The VLER partners have been focused primarily on exchanging computable data in the CDA Structured Entries and partners have been rendering received CDA documents using only these structured entries. This has led to a lack of emphasis on the CDA R2 requirement that a true, complete and human readable rendering of structured CDA documents should be achievable by rendering only the Narrative Block included in each section of a structured CDA document. For VLER Health Exchange it is required that each partner include an appropriate narrative block for each section which adheres to the guidelines quoted above.

5 VLER HEALTH EXCHANGE ONBOARDING PROCESS

The VLER Health Exchange Onboarding Process ensures that VLER partner systems are ready and can meet the business, technical and content requirements for systems compatibility for proper data exchanges with VA, as per the VLER Health Exchange specifications in this VBTR document.

To begin on-boarding as an eHealth Exchange partner with VA, your organization must meet the following criteria:

- Be an eHealth Exchange participant
- Certified on 2010 and/or 2011 eHealth Exchange Specifications
- Ability to exchange Summary of Care Document (C32) data and C-CDA CCD in the future

The VLER Health Exchange Onboarding Process

VA VLER Health Exchange Partner Milestones

Milestone	Partner Milestones	Standard or Fast Track
PARTNER: eHealth Exchange On-boarding Process Completed	1	S, F
PARTNER and VA: VLER Health Business Survey Completed and Reviewed	2	S, F
PARTNER and VA: VA Partner Testing begins between Partner and VLER Health Partner Integration Team	3	S
PARTNER and VA: VLER Health Partner Integration Testing Completed	4	S
VA: Partner Business Survey and Testing Results (if required) Reviewed by VLER Health Leadership for Approval	5	S, F
PARTNER: If Not Approved: Address the Issues, Re-Test, Review the Results with VLER Health Leadership, and Return to Milestone 3	5a	S, F
PARTNER and VA: VA and Partner Move Software Capability to Production	6	S, F
PARTNER and VA: Partner and VLER Health Team Perform Production Software Validation	7	S, F
PARTNER and VA: VLER Health Program Office and Partner Meet with Local VA Medical Center Leadership to Present VLER Health Exchange New Partner	8	S, F
PARTNER and VA: Partner and VA to Implement Training Education and Support Programs	9	S, F
PARTNER and VA: Partner and VA Monitor Performance and Sustain Operations and Maintenance	10	S, F

VETERANS HEALTH ADMINISTRATION

For more information, e-mail VAExchangeInformation@va.gov

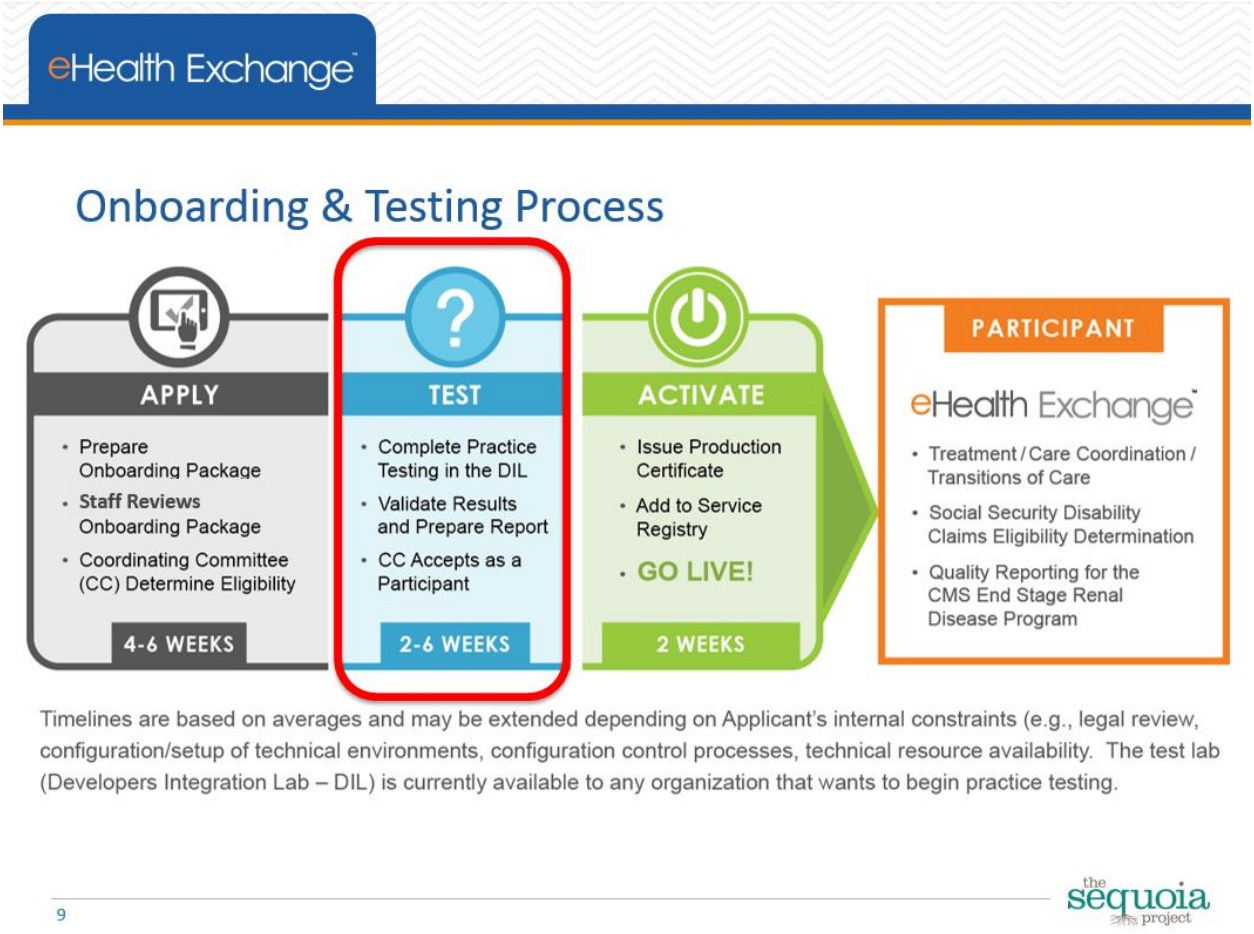
Note: VLER Health Exchange Fast Track on-boarding leverages a non-VA partner's testing with ehealth Exchange to bypass VA testing and move directly into production, thereby eliminating on-boarding milestones 3 and 4. You must meet the on-boarding criteria and use an eligible Health Information Exchange (HIE) Gateway product.

With the Fast Track on-boarding process non-VA partners report saving two to three months of valuable time and associated resources giving their providers access to Veteran health data sooner.

5.1 Milestone 1: eHealth Exchange On-boarding Process Completed.

- Complete successfully the eHealth Exchange (eHEX) onboarding process
  - Submit an application package to The Sequoia Project which includes:
    - Application for Participation
    - Signed DURSA
    - Participation Agreement

  - Complete and pass eHealth Exchange Participant Testing
  - Acquire Certificate
  - Enter production OID and endpoints (VA requires port 443, 4437 or 14430) in production UDDI



5.1.1 Security Certificates

eHealth Exchange (eHEX) partners must have their security certificates for their gateway setup correctly for testing and production environments to work. Certificates are issued through The Sequoia Project.

Once you have completed Participant Testing with eHealth Exchange, send an e-mail to techsupport@ehealthexchange.com requesting certificates. You will receive a response with the forms and instructions.

5.1.2 Organization Identifier (OID)s and Endpoints

Your test and production OID should be properly registered with The Sequoia Project and available in the test (validation) UDDI along with your system's endpoints. Additionally, endpoints must utilize port 443, 4437 or 14430 both in test and production for proper communication with the VA. OIDs are manually configured in several VA dependency systems so we urge partners to retain the same OID(s) in test and production and minimize the need for changes to these values as much as possible.

5.2 Milestone 2: VLER Health Business Survey Completed and Reviewed

5.2.1 Business Survey

The Business Survey's goal is to understand the operational maturity of the VLER partner health information exchange platform.

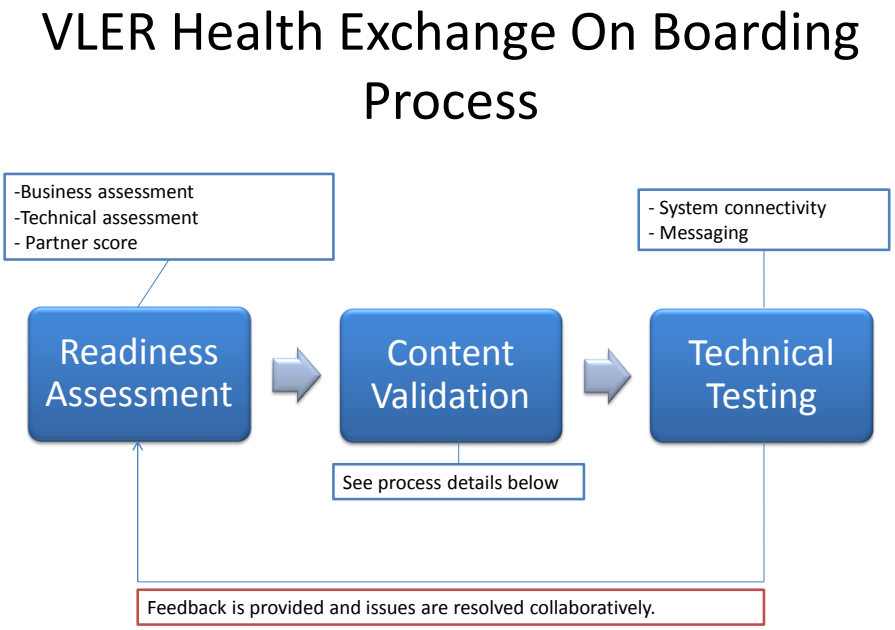
This survey is intended for organizations interested in exchanging health information with VA via eHealth Exchange . The intent of this survey is to open a dialog between your organization and VA to identify and address barriers to successful implementation early on in the process. The questions asked here have been compiled based on the lessons learned through implementation of multiple Exchange pilot communities. It is not required that all questions be answered prior to engaging in a dialog with VA, however, answering the questions will provide a better basis of discussion to help with future planning efforts.

The **Business Survey** will be sent to you by the VLER Health Exchange program manager.

5.2.2 Business Survey Evaluation

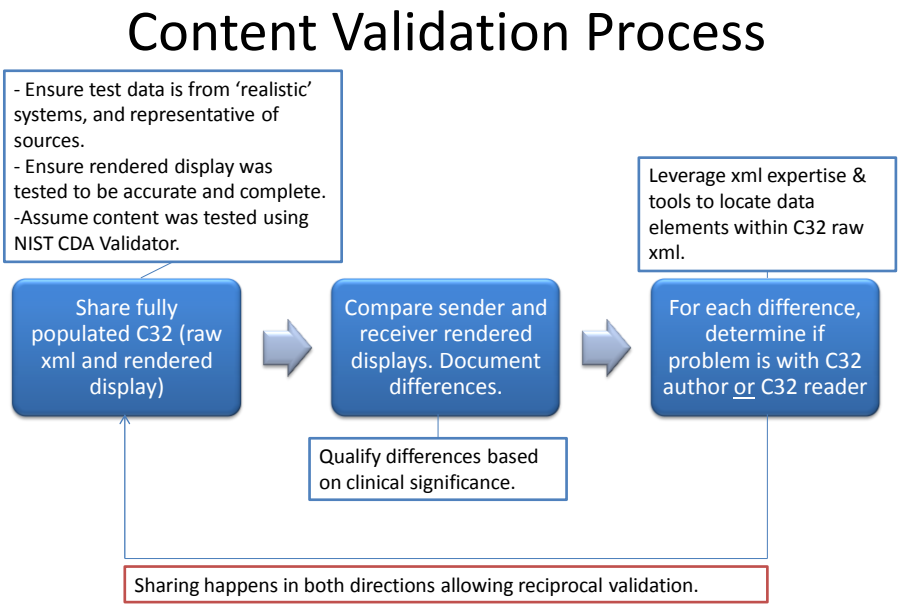
The VLER Health Exchange team will evaluate the partner's business survey to estimate the likelihood of the exchange with a given partner to produce positive outcomes for Veterans population.

5.3 Milestone 3: VA Partner Testing begins between Partner and VLER Health Partner Integration Team



5.3.1 Content assessment process is described below.

- **Partner** will
  - Construct a test C32 xml file as fully populated as their system can achieve
  - Submit this C32 to the NIST CDA Validation tool and ensure there is no error (add URL and options on how to run the NIST tool).
  - The VLER Health Exchange Partner Integration team will also run the received sample against the NIST tool.
  - Create a rendered display of this C32 using your own style sheet and save it as a PDF or Word document. Ensure the display is accurate and complete, reflecting all sections and data elements contained in the xml document.
  - Share the xml file, PDF/Word document, and the NIST error report with VLER Health Exchange team.
- **VLER Health Exchange team** will
  - Share the same 3 files describe above with Partner
- **Both Partner and VLER Health Exchange team** will
  - Compare sender and receiver rendered displays and document the differences.
  - For each difference, determine if problem is with C32 author or C32 reader (i.e., style sheet). XML expertise will be needed to locate data elements within C32 xml files.



In addition, it is recommended that VLER Partners share their respective style sheets so they can see how their content will display at the partner's system, and identify and address any errors in advance.

5.3.2 Technical Testing

Technical testing takes place in an Software Quality Assurance (SQA) environment. Test plan, scripts, and patients will be shared with VLER Health Exchange Partners. The technical testing includes:

a) System connectivity is established and tested
b) Messaging is established and tested
c) Data content testing occurs

Any data content issues must be resolved by the partner and/or VLER Health Exchange before proceeding.

5.4 Milestone 4: VLER Health Partner Integration Testing Completed

The VA VLER Health Exchange testing team presents partner testing results to the VA VLER Exchange business team.

5.5 Milestone 5: Partner Business Survey and Testing Results (if required) Reviewed by VLER Health Leadership for Approval.

If not Approved: Address the issues, Re-Test, Review the Results with VLER Health Leadership, and Return to Milestone 3.

The VA VLER Health On-boarding team presents the partner status to leadership and requests approval to confirm a production date.

5.6 Milestone 6: VA and Partner Move Software Capability to Production

The production date is a mutually agreed upon date. The VA requires 15 business days confirmation prior to the production date in order to submit the necessary production configuration requests.

5.7 Milestone 7: Partner and VLER Health Team Perform Production Software Validation

Production testing is short with a focus on ensuring that production works as consistently as in the testing phases.

VLER Health Exchange team will maintain a Dashboard to track issues and progress throughout the on boarding process and will use it to communicate with Partners.

5.8 Milestone 8: VLER Health Program Office and Partner Meet with Local VA Medical Center Leadership to Present VLER Health Exchange New Partner

The VA VLER Health Community Coordinator will serve as the liaison to the local VA medical centers and coordinate an introduction with the new partner.

5.9 Milestone 9: Partner and VA to Implement Training Education and Support Programs

The VA VLER Community Coordinator will ensure the VA medical centers have the needed training and support materials. They will also provide education about the Veteran Authorization requirements. During this milestone, we also like to confirm the partner is implementing any necessary training.

5.10 Milestone 10: Partner and VA Monitor Performance Sustain Operations and Maintenance

VLER Health Exchange team will monitor operations through several activities.

A VLER Health Exchange production dashboard will help monitor status of connections and any performance issue. In particular, VLER Health Exchange Partners are expected to initiate proper notifications (e.g., eHealth Exchange onboarding as per DURSA) when system is down, when end points change (update to UDDI necessary), and when content changes (retesting may be necessary).

One lesson learned from early pilots is that even after all of the eHealth Exchange and VLER partner testing that is done, once the exchange is live, there will be need for system and data modifications. It is important to plan on providing time and

resources to identifying and fixing issues that are discovered post production release.

In addition, on a periodic basis, VLER Health Exchange business team will inquire about clinician training activities, patient enrollment/recruiting activities, and any performance metrics, as needed. VLER Health Exchange team has access to and may share with Partners weekly reports from its VAP system including:

- Number of enrolled patients
- Number of unique provider users
- Number of transactions inbound and outbound
- And others.

APPENDIX A: GLOSSARY

TERM	DEFINITION
C32	Otherwise known as a "Component" document, a C32 is a Summary of Care document as defined by HITSP and was originally used to support an Emergency Room use case. The C32 conforms to the HL7 Continuity of Care Document (CCD) standard and contains 17 data "modules" or domains, which includes basic information such as patient demographics, medications, allergies, etc. Each data domain contains individual data elements. The data domains and elements are further simplified into those that are "required," "required if known," and "optional" to be HITSP compliant. According to the HITSP website, the C32 "defines content in order to promote Interoperability between participating systems such as Personal Health Record Systems (PHRs), Electronic Health Record Systems (EHRs), Practice Management Applications and others." (http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32)
C62	The HITSP Unstructured Document Component is provided for the capture and storage of patient identifiable, unstructured document content, such as text, PDF, and images rendered in PDF. It is based on the Cross-Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile from the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF).
CDA R2	HL7 Clinical Document Architecture, Revision 2 – an XML-based exchange model for clinical documents (such as discharge summaries and progress notes) that brings the healthcare industry closer to the realization of electronic medical record and to the standardized interchange of complex documents.
CONNECT Gateway	Software application providing interconnectivity for the exchange of information between providers.

TERM	DEFINITION
Data Use and Reciprocal Support Agreement (DURSA)	A comprehensive, multi-party trust agreement that will be signed by all eligible entities who wish to exchange data among Nationwide Health Information Network Participants. It requires signatories to abide by common set of terms and conditions that establish Participants' obligations and the trust fabric to support the privacy, confidentiality and security of health data that is exchanged.
Electronic Health Record (EHR)	An electronic health record (EHR) is a longitudinal electronic medical record of patient health information generated by one or more encounters in any care delivery setting. The EHR contain of patient demographics, progress notes, problems, medications, allergies, vital signs, past medical history, immunizations, laboratory data, and radiology reports.
Health Level Seven (HL7)	HL7 is an ANSI accredited standards development organization for health data interchange standards designed to facilitate the transfer of health data resident on different and disparate computer systems in a healthcare setting environment.
HL7 Unstructured Document	Describes the constraints on the Clinical Document Architecture (CDA) header and body elements for an Unstructured Document
HIPAA	The HHS Office for Civil Rights enforces the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The HIPAA Privacy Rule protects the privacy of individually identifiable health information. The HIPAA Security Rule sets national standards for the security of electronic protected health information.
HITSP	Healthcare Information Technology Standards Panel - Cooperative partnership between public and private sectors for the purpose of achieving a widely accepted and useful set of standards specifically to enable and support widespread interoperability among healthcare software applications, as they will interact in a local, regional, and national health information network for the United States.
Identity Management	Overarching term encompassing processes used to uniquely identify an individual for the purposes of data sharing and benefits delivery. Identity Management enables the ability to draw information and data from disparate systems or sources to create a single view of an individual throughout their lifetime.
VA Business and Technical Requirements Document (VBTR) – VLER Health Exchange Exchange	The VLER Health Exchange VBTR supports the collective identification, review and approval of the VA requirements, architecture/design and development artifacts which support the delivery of the VLER Health Exchange Project scope. The VBTR is intended to serve as the authoritative project document for this information. The VBTR is not intended to replace each VLER partner's requirement, architecture/design and/or development related documentation but rather supplement them from a VA perspective.

TERM	DEFINITION
Metadata	Information describing the characteristics of data, data or information about data; or descriptive information about an entity's data, data activities, systems, and holdings. For example, discovery metadata is a type of metadata that allows data assets to be found using enterprise search capabilities.
Registry Services	Registry services provide federated access to UDDI and metadata information about data/services.
Retrieval Services	Data retrieval services provide uniform platform independent access to data stored in disparate databases.
Web Services	A standardized way of integrating web-based applications using open standards over an Internet Protocol backbone. Web services allow applications developed in various programming languages and running on various platforms to exchange data without intimate knowledge of each application's underlying IT systems.

APPENDIX B: ACRONYMS

Acronym	Definition
AES	Advanced Encryption Standard
ATO	Authority To Operate
BHIE	Bidirectional Health Information Exchange
C&A	Certification and Accreditation
CA	Certifying Authority
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
CDR	Clinical Data Repository
DAA	Designated Accrediting Authority
DEWG	Data Exchange Work Group
DISA	Defense Information Systems Agency
DoD	Department of Defense
EDI PI	Electronic Data Interchange Personal Identifier
EMR	Electronic Medical Record
HC IdM	Healthcare Identity Management
HIE	Health Information Exchange
HIT	Health Information Technology
HL7 UD	Health Level Seven 7 Unstructured Document
HTTP	Hyper Text Transfer Protocol
IA	Information Assurance
ICN	Integration Control Number
IPO	Interagency Program Office
VBTR	VA Business and Technical Requirements
MHS	Military Health System
MPI	Master Patient Index
MTOM	Message Transmission Optimization Mechanism
MVI	Master Veteran Index
NIST	National Institute of Standards and Technology
NwHIN	Nationwide Health Information Network
ONC	Office of the National Coordinator for Health Information Technology
PHI	Protected Health Information
RM	Reliable Messaging
SAML	Security Assertion Markup Language
SMC	Senior Management Committee
SNOMED	Systematized Nomenclature of Medicine
SOAP	Simple Object Access Protocol
UDDI	Universal Discovery and Description Interface
UTC	Coordinated Universal Time
VA	Veterans Affairs
VLER	Virtual Lifetime Electronic Record

Acronym	Definition
WS	Web Service
WS-I	Web Services Interoperability Organization
WSDL	Web Service Description Language
XCA	Cross Community Access
XCPD	Cross Community Patient Discovery
XML	Extensible Markup Language
XSPA	Cross-Enterprise Security and Privacy Authorization