Veterans Health Administration Office of Informatics and Analytics (OIA) Innovation Program

OneVA Pharmacy Implementation Project

Requirements Specification Document (RSD) (CLIN #0002AA)

Business Information Technology Solutions, Inc. 3190 Fairview Park Drive, Suite 315 Falls Church, VA 22042

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Revision History

Note: The revision history cycle begins once changes or enhancements are requested after the Requirements Specification Document has been baselined.

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11/23/2015	1.4	Updated for the VAeMI-Middleware components, Scope Integration, Secure Sockets Layer, and Authentication and Authorization.	Kathy Coupland
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12/29/2015	1.6	Modify requirements to include Rob Silverman's feedback on drug matching logic and Pharmacist drug selection constraints.	Kathy Coupland
12/30/2015	2.0	Apply Rob Silverman's feedback and include Abbreviations and Acronyms table.	Kathy Coupland

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1. Introduction

Leadership at the VAs Grassroots Innovations Program, a cooperative effort between the Chief Technology Officer, the Health and Medical Informatics Office, and the VAs Office of Information and Technology (OI&T) provided innovators (VA employees) with a forum to propose new opportunities and to develop new ideas into functional prototypes.

There are two (2) separate phases to the Innovations Program. The low bar phase is a proof-of-concept phase where all work is accomplished outside of the VAs network in a VA virtual testing environment (Innovations Sandbox). The high bar phase occurs when a concept is moved to a developmental/production environment after the proof of concept has been developed, tested, and approved for full scale deployment.

In 2014, the VA engaged The BITS Group to execute the low bar phase for the development of a proof of concept/prototype known as OneVA Pharmacy. OneVA Pharmacy provides the Department of Veterans Health Administration (VHA) the capability to allow Veterans travelling across the United States to refill active VA prescriptions at any VA pharmacy regardless of where the prescription originated.

The OneVA Pharmacy Implementation project is the high bar phase of the initiative. The OneVA Pharmacy Implementation project modifies the existing proof-of-concept software's capability by including the requirements contained within its Project Work Statement (PWS), includes integration into Veterans Health Information Systems and Technology Architecture (VistA), development of documentation, and training to support a national rollout in March 2016.

OneVA Pharmacy provides a foundation to build and extend new capabilities to the Veteran, who are better served by integrating virtual care into pharmacies, using technology to close the gap between the previous quality of information, and the Veteran's level of engagement. A well-designed OneVA Pharmacy builds upon the history of the VHA and advances in modern technology, to allow Veterans to take a more active role in their own health care.

1.1. Purpose

The purpose of the Requirement Specification Document (RSD) is to document the business rules and requirements for the implementation of the OneVA Pharmacy proof-of-concept into the production VistA environment.

Intended audiences for the RSD are the OneVA Pharmacy project stakeholders, Veterans Health Administration (VHA) Pharmacy subject matter experts (SMEs), and VA Office of Information & Technology (OI&T).

1.2. Scope

The scope of the RSD is to document the "as-is" requirements contained in the OneVA Pharmacy proof-of-concept module and the modifications being applied to expand the software's functionality, based on the requirements documented in the OneVA Pharmacy Implementation PWS.

OneVA Pharmacy provides VistA the functionality to allow pharmacists to refill a prescription at any VA pharmacy location. It decrements the patients number of remaining refills' balance at the

originating pharmacy and manages controlled substances by displaying a message that a controlled substance cannot be refilled outside of the originating pharmacy. The proof-of-concept software will be modified to utilize a middleware model that meets One-VA Technical Reference Model list of approved technologies.

Project and training documentation will be developed and testing best practices will be executed. Training will be conducted for the product in accordance with an Initial Operating Capability (IOC) delivery. Project Management Accountability System (PMAS) documents consistent with the identified approach will be delivered to the VA.

1.3. References

Reference material includes the following:

- OneVA Pharmacy Performance Work Statement (PWS)
- Contractor Project Management Plan (PMP)
- WorldVistA Prescription Status

1.4. Acronyms and Abbreviations

The following table provides the list of acronyms used throughout the document along with their descriptions.

Table 1: Acronym & Abbreviation Table

Acronym/Abbreviation	Description
[PSO LM BACKDOOR ORDERS]	Patient Prescription Processing
ANR	Automated Notification Reporting
BITS	Business Information Technology Solutions, Inc.
CCOW	Clinical Context Object Workgroup
CDS	Clinical Data Services
CLIN	Contract Line Item Number
СООР	Continuity of Operations Plan
CSV	Comma Separated Value
DEA	Drug Enforcement Agency
DHCP	Dynamic Host Configuration Protocol
DRP	Disaster Recovery Plan
eMI	Enterprise Messaging Infrastructure
ESB	Enterprise Service Bus

Acronym/Abbreviation	Description	
GUI	Graphical User Interface	
HDR	Health Data Repository	
HL7	Health Level 7	
ICN	Integration Control Number	
IOC	Initial Operating Capability	
IPT	Integrated Project Team	
IT	Information Technology	
MLLP	Minimal Lower Layer Protocol	
MTD	Maximum Tolerable Downtime	
MUMPS	Massachusetts General Hospital Utility Multi Programming System	
MVI	Master Veteran Index	
NSPD	National Security and Homeland Security Presidential Directive	
OI&T	Office of Information and Technology	
OIA	Office of Informatics and Analytics	
OIT	Office of Information and Technology	
PDF	Portable Document File	
PID	Patient Identification	
PMAS	Project Management Accountability System	
PMP	Project Management Plan	
POC	Point-of-Contact	
PSO	Outpatient Prescription Pharmacy	
PWS	Performance Work Statement	
RCS	Record Control Schedule	
REST	Representational State Transfer	
RPO	Recovery Point Objective	
RPT	Reports	

Acronym/Abbreviation	Description	
RSD	Requirements Specification Document	
RTM	Requirements Traceability Matrix	
RTO	Recovery Time Objective	
Rx	Prescription	
SDD	System Design Document	
SLA	Service Level Agreement	
SME	Subject Matter Expert	
SOA	Service Oriented Architecture	
SQA	Software Quality Assurance	
SSL	Secure Sockets Layer	
SSN	Social Security Number	
TBD	To be determined	
TRM	Technical Reference Model	
UI/OCD	User Interface/User Centered Design	
VA	Department of Veterans Affairs	
VAeMI-Middleware	The middleware components being implemented within the OneVA Pharmacy software development.	
VHA	Department of Veterans Health Administration	
VistA	Veterans Health Information Systems and Technology Architecture	

2. Overall Description

2.1. Accessibility Specifications

The OneVA Pharmacy Implementation project documents and the OneVA Pharmacy module will follow the Section 508 and Clinical Context Object Workgroup (CCOW) standards required for accessibility to the software product involved.

2.2. Business Rules Specification

Business rules are a high-level functionality condition that the system must support in order to complete the business of the organization. Business rules describe the operations, definitions, and constraints that apply to an organization. The business rules for OneVA Pharmacy Implementation project are as follows:

- 2.2.1. A prescription will only have one of the following status values:
 - a. Active
 - o A prescription with this status can be filled or refilled.
 - b. Discontinued
 - This status is used when a prescription was made inactive either by a new prescription or by the request of a physician.
 - c. Deleted
 - This status is used when a prescription is deleted. Prescriptions are no longer physically deleted from the system, but marked as deleted. Once a prescription is marked deleted no access is allowed other than view.
 - d. Expired
 - This status indicates the expiration date has passed. Note: A prescription which was cancelled or has expired more recently than the date specified by the cutoff date, typically 45 days in the past, can still be acted upon.
 - e. Hold
 - o A prescription that was placed on hold due to reasons determined by the pharmacist.
 - f. Non-verified
 - Depending on a site parameter, prescriptions entered by a technician do not become active until they are reviewed by a pharmacist. Until such review, remain nonverified and cannot be printed, cancelled or edited except through the Verification menu.
 - g. Pending Due to Drug Interactions
 - o This status is given to prescriptions when a drug/drug interaction is encountered during the new order entry or editing of a prescription.
 - h. Refill
 - o A second or subsequent filling authorized by the provider.
 - i. Suspended
 - o A prescription which will be filled at some future date.
- 2.2.2. A prescription will only be refilled when all the following events occur:
 - a. Status is active
 - b. One or more refills remain
 - c. Refill date and time considerations include:
 - a. Date of the refill is no earlier than the scheduled next refill date for the prescription.
 - i. This value is calculated at the host VistA system and is equal to the original ISSUE DATE + (DAYS SUPPLY * # OF FILLS TAKEN TO DATE) – 10 DAYS.

- b. If the prescription refill request is suspended by the host VistA pharmacy system, it will not be available to the remote VA pharmacy.
- d. Prescription is not for a controlled substance
- e. Refilling drug matches VA product name and dosage
- 2.2.3. A prescription will only be refilled when the patient is known and registered in one or more VistAs.
- 2.2.4. The MVI creates and assigns an Integration Control Number (ICN) when a new patient registers.
- 2.2.5. A drug is considered a controlled substance if the first character of the 'Drug Enforcement Agency (DEA), Special Hdlg' field #3 on the Drug File is less than 6.

2.3. Design Constraints Specification

Design constraints specifications mandate design decisions that the system must support in order to complete the business of the organization. The design constraints for the OneVA Pharmacy Implementation project are as follows:

- 2.3.1. The system shall use the VistA feature "Patient Prescription Processing [PSO LM BACKDOOR ORDERS]" to access local patient information.
- 2.3.2. The system shall use data from Health Data Repository/Clinical Data Service (HDR/CDS) to display a medication profile.
- 2.3.3. The system shall use the Enterprise Messaging Infrastructure (eMI) and the VistA Dynamic Host Configuration Protocol (DHCP) Health Level 7 (HL7) interface for information exchange between VistA systems.
- 2.3.4. If there is not a one to one match within the drug matching logic, the multiple matching drugs should be displayed on a screen to the Pharmacist to select the dispensing site drug file entry corresponding to the drug to be dispensed.
- 2.3.5. The prescription label generated for the dispensed product will always use the original label information from the host site.

2.4. Disaster Recovery Specification

The OneVA Pharmacy code base will be integrated into the VA VistA environment and Disaster Recovery requirements will follow the VistA structure that is currently in place within the VA environment.

2.5. Documentation Specifications

The goal of the 'Documentation Specifications' section is to ensure necessary documentation is developed according to standard, including the VA Certification and Accreditation process (when applicable).

- 2.5.1. Product Documentation for the OneVA Pharmacy Implementation project includes, but is not limited to the following:
 - a) Installation Guide
 - b) Operations and Maintenance Plan

- c) Technical Manual
- d) User Guide
- e) Training Manual
- 2.5.2. PMAS Documentation for the One VA Pharmacy Implementation project includes, but is not limited to the following:
- 2.5.3. Risk Issue Log
 - a) Requirements Specification Document (RSD)
 - b) System Design Document (SDD)
 - c) Initial Operating Capability (IOC) Documentation
 - d) Master Test Plan
 - e) IOC Site Memorandum of Understanding
 - f) Primary Developer Checklist
 - g) Secondary Developer Checklist
 - h) Requirements Traceability Matrix (RTM)
 - i) Acceptance Criteria Plan
 - j) IOC Entry Request and Exit Summary
 - k) Lesson Learned
 - 1) Contractor Staff Roster
 - m) Training Plan
- 2.5.4. Reviews for the OneVA Pharmacy Implementation project includes, but it not limited to the following:
 - a) Operational Readiness Review
 - b) Initial Operating Capability Entry and Exit
 - c) National Deployment review

2.6. Functional Specifications

A requirement specifies functions that the application should be able to perform and constraints on application performance. The functional specifications for OneVA Pharmacy Implementation project are as follows:

2.6.1. Display Prescription Orders

- 2.6.1.1. The system shall provide the ability to display the entire Medication Profile for a patient from all other facilities.
- 2.6.1.2. The system shall provide the ability to display the system response message: "Please wait. Checking for remote prescriptions. This may take a moment..." while the system is processing.
- 2.6.1.3. The system shall provide the ability to display on the Medication Profile screen all prescriptions from other VA facilities (local and remote) at which a patient is registered. The fields should include the same display elements as the local prescription. Some are as follows:
 - a) Patient Name
 - b) Patient Address

- c) Patient Social Security Number
- d) Patient Prescriptions Listing
- 2.6.1.4. The system shall provide the ability to display all prescriptions from other VA facilities (local and remote) at which the patient is registered on for prescriptions with a status value of "Active", "Suspended", or "Hold".
- 2.6.1.5. The system shall provide the ability to display the prescription information from a remote site grouped under a divider header line showing the site name, number, and status.
- 2.6.1.6. The system shall provide the ability to generate a header that separates the prescriptions by status.
- 2.6.1.7. The systems shall provide the ability to display the system response message: "The pharmacy manger is down or not responding. Could not query remote prescriptions. Press RETURN to continue" when the system (on which a patient is registered) does not respond.
- 2.6.1.8. The system shall provide the ability to display a message when a system on which a patient is registered has no prescriptions.

2.6.2. Local refills

2.6.2.1. The system shall provide the ability to dispense local refills as currently designed.

2.6.3. Remote refills

- 2.6.3.1. The system shall provide the ability to refill active-refillable prescriptions that originated from another VA pharmacy location.
- 2.6.3.2. The system shall provide the ability to refill with a full or partial prescription.
- 2.6.3.3. They system shall provide the ability to refill a full or partial prescription if the date of the refill is no earlier than the scheduled next refill date for the prescription.
 - a) This value is calculated at the host VistA system and is equal to the original ISSUE DATE + (DAYS SUPPLY * # OF FILLS TAKEN TO DATE) 10 DAYS.
 - b) If the prescription refill request is suspended by the host VistA pharmacy system, it will not be available to the remote VA pharmacy.
- 2.6.3.4. The system shall provide the ability to determine if a prescription is a controlled substance and display a message to inform the pharmacist that the prescription selected cannot be refilled because it is a controlled substance.
- 2.6.3.5. The system shall provide the ability to display a drug for any selected active-refillable prescriptions refills.
- 2.6.3.6. The system shall provide the ability to log actions taken by the local site pharmacy user on any particular prescription with annotation of the site the action was taken by, in real time; in under one minute.
- 2.6.3.7. The system shall provide the ability to generate the following information in the VistA action log:
 - a) Refill or Partial Date

- b) Name of pharmacist
- c) Name and Station Number of VA Site
- d) Brief comment
- e) Contact telephone number of originating pharmacy
- f) Other
- 2.6.3.8. The system shall be free of defects.

2.6.4. Prescription Labels

2.6.4.1. The system shall provide the ability to generate and print a partial refill Rx label or a full refill Rx label on accessed remote prescriptions similarly to how this is done for local prescriptions.

2.6.5. Remote Reports

- 2.6.5.1. The system shall provide the ability to generate and print a report to show all prescriptions filled for remote sites.
- 2.6.5.2. The system shall provide the ability to generate and print a report to show local prescriptions filled by remote sites.
- 2.6.5.3. The system shall provide the ability to limit the contents of a report in various ways. They are as follows:
 - a) Prescriptions filled within a date range
 - b) Prescriptions filled for a single patient, specifying the following search options:
 - 1) Name
 - 2) Social Security Number (SSN)
 - 3) Last 4 SSN digits
 - 4) First initial of last name with last 4 digits of SSN
 - c) Prescriptions filled for a single site, searching on Institution Name.
- 2.6.5.4. The system shall provide the ability to view or print a report of all remote prescriptions refilled or partially refilled sorted by date. The following shall be displayed:
 - a. Patient Name
 - b. Drug Name
 - c. Type of refill
 - d. Quantity
 - e. Number of days supplied
- 2.6.5.5. The system shall provide the ability to view or print a report that displays the total cost.
- 2.6.5.6. The system shall provide the ability to view the following data values for any prescription listed in a report:
 - a) Request Date/Time
 - b) Patient
 - c) Rx #
 - d) Site
 - e) Request Type
 - f) Requesting Pharmacist
 - g) Dispensed Date

- h) Remote Drug Name
- i) Local (matched) drug
- i) Local Refill/Partial Cost

2.6.6. Files

- 2.6.6.1. The system shall add the following fields to Prescription (#52) REFILL sub file (#52.1):
 - a) Remote File Site (#91)
 - b) Remote Pharmacist (#92)
 - a) Remote Pharmacist Phone (#93
- 2.6.6.2. The system shall add the following fields to the Prescription (#52) PARTIAL DATE sub file (52.2):
 - a) Remote File Site (#91)
 - b) Remote Pharmacist (#92)
 - c) Remote Pharmacist Phone (#93)

2.7. Graphical User Interface (GUI) Specifications

The graphical user interface portion of this application will be the current VistA Patient Prescription Processing [PSO LM BACKDOOR ORDERS].

2.8. Multi-divisional Specifications

N/A

2.9. Performance Specifications

- 2.9.1. The system shall provide the ability to configure the connection and response timeouts.
- 2.9.2. The system shall provide the ability to time out a query connection in five (5) seconds.
- 2.9.3. The system shall provide the ability to time out the query response in ten (10) seconds.
- 2.9.4. The system shall provide the ability to time out a 'refill/partial fill' connection in five (5) seconds.
- 2.9.5. The system shall provide the ability to time out a 'refill/partial fill' response in sixty (60) seconds.

2.10. Quality Attributes Specification

Not applicable.

2.11. Reliability Specifications

Not applicable.

2.12. Scope Integration

OneVA Pharmacy will use Health Level (HL7) logical links, HL7 application protocols, and SOAP web services to send and receive messages related to remote prescriptions. Once a user enters the option [PSO LM BACKDOOR ORDERS], an HL7 QBP^Q13 message is sent to the Health Data Repository/Clinical Data Services (HDR/CDS) via the Enterprise Messaging Infrastructure (eMI) for the selected patient (i.e. a populated Patient Identification (PID) segment). The HDR/CDS will return a list of active prescriptions for the patient at each location. The VistA active prescriptions lists are aggregated together and sent back in the HL7 response.

2.13. Security Specifications

- 2.13.1. The system shall provide the ability to authenticate a username and password as an access and verify for the web service.
- 2.13.2. The system shall provide the ability to demonstrate the exchange of patient sensitive information between systems in a secure manner in accordance with VA regulations for Privacy and Security.

Secure Sockets Layer (SSL)

The 'Secure Sockets Layer (SSL)' will be handled within the VAeMI and is therefore out of scope for the OneVA Pharmacy Implementation Team.

Authentication and Authorization

The OneVA Pharmacy software will use the eMI middleware. The VA eMI uses the Minimal Lower Layer Protocol (MLLP) protocol which does not require authentication but performs file transfer therefore the 'Authentication and Authorization' is out of scope for the OneVA Pharmacy Implementation Team.

2.14. System Features

The systems features can be found in the OneVA Pharmacy Systems Design Document (SDD).

2.15. Usability Specifications

Not applicable.

3. Purchased Components

Not Applicable.

4. Estimation

Not Applicable.

5. Approval Signatures

This section is used to document the approval of the OneVA Pharmacy *Implementation* RSD during the Formal Review. The review should be ideally conducted face to face where signatures can be obtained 'live' during the review however the following forms of approval are acceptable:

- 1. Physical signatures obtained face to face or via fax
- 2. Digital signatures tied cryptographically to the signer
- 3. /es/ in the signature block provided that a separate digitally signed e-mail indicating the signer's approval is provided and kept with the document

The following members of the governing Integrated Project Team (IPT) are required to sign. Please annotate signature blocks accordingly.

REVIEW DATE: 10/29/2015	
SCRIBE: Cecelia Wray	
Signed:	
Joshua Patterson	Date
Integrated Project Team (IPT) Chair	
Michael Valentino	Date
Business Sponsor	
Cecelia Wray	Date
Project Manager	

Appendix A: Non-Functional Requirements

The following non-functional requirements should be reviewed and accessed while developing the requirements for the project.

System Performance Reporting Requirements

(Note: Each system developed by the Department of Veterans Affairs (VA) Office of Information and Technology (OI&T) must comply with the following mandatory requirements.)

- 1. Include instrumentation to measure all performance metrics specified in the Non-Functional Requirements section of the Requirements Traceability Matrix (RTM). At a minimum, systems will have the ability to measure reporting requirements for Responsiveness, Capacity, and Availability as defined in the non-functional requirements section of the RTM.
- 2. Make the performance measurements available to the Information Technology (IT) Performance Dashboard to enable display of "actual" system metrics to customers and IT staff.

Operational Environment Requirements

- 1. System response times and page load times shall be consistent with _____ standards (for example, My HealtheVet or HealtheVet). (Comment: There may be different expectations for an external display vs. a query. Need to address these different uses. Also indicate if this information is unknown).
- 2. Maintenance, including maintenance of externally developed software incorporated into the _____application(s), shall be scheduled during off peak hours or in conjunction with relevant maintenance schedules. The business owner should provide specific requirements for establishing system maintenance windows when planned service disruptions can occur in support of periodic maintenance.
- 3. Information about response time degradation resulting from unscheduled system outages and other events that degrade system functionality and/or performance shall be disseminated to the user community within 30 minutes of the occurrence. The notification shall include the information described in the current Automated Notification Reporting (ANR) template maintained by the VA Service Desk. The specific business impact must be noted in order for OIT to provide accurate data in the service impact notice of the ANR.
- 4. Provide a real-time monitoring solution to report agreed/identified critical system performance parameters.
- 5. Critical business performance parameters shall be identified e.g., transaction speed, response time for screen display/refresh, data retrieval, etc. in a manner that data capture can occur to support metric reporting and support the OI&T performance dashboard display. If no such performance metrics are required or provided there will be no program specific Service Level Agreements (SLA) created, nor shall there be any active/real time monitoring through OI&T Performance Dashboard to provide the business owners any performance metrics.

6. Notification of scheduled maintenance periods that require the service to be offline or that may degrade system performance shall be disseminated to the business user community a minimum of 48 hours prior to the scheduled event.

1. The training curriculum shall state the expected training time for primary users and

Documentation Requirements

	secondary users to become proficient at using the OneVA Pharmacy application(s).
2.	All training curricula, user manuals and other training tools shall be developed/updated
	by < <i name="" of="" office="" program="">> and delivered to all levels of users</i>
	If known, insert how much time in advance the training tools will be
	delivered and via what mechanism(s); for example, 2-4 weeks in advance of the release
	of the enhancement through nationwide conference calls and PowerPoint presentations).
	The curricula shall include all aspects of the enhanced application(s) and all
	changes to processes and procedures.
3.	The training curriculum developed by the Program Office shall state the expected task

- The training curriculum developed by the Program Office shall state the expected task completion time for primary and secondary users.
- 4. User manuals and training tools shall be developed. If they already exist, updates shall be made, as necessary, to them and they shall be delivered to all levels of users.
- 5. IT will provide the level of documentation required to support the system and maintain operations and continuity. Documentation shall represent minimal programmatic and lifecycle operations support documentation artifacts as defined by VA standards in ProPath and as required by the VA Enterprise System Engineering Lifecycle and Release Management office for sustained operations, maintenance, and support (http://vaww.eie.va.gov/lifecycle/default.aspx) prior to approval by any VA change control board and release into production.

Implementation Requirements

Technical Help Desk support for the application shall be provided for users to obtain
assistance with
The IT solution shall be designed to comply with the applicable approved Enterprise
SLA.
The implementation must be complete by (Enter date - dd-mm-yyyy)

Data Protection/Back-up/Archive Requirements

- 1. Based upon the criticality of the system, provide a back-up and data recovery process for when the system is brought off-line for maintenance or technical issues/problems.
- 2. Data protection measures, such as back-up intervals and redundancy shall be consistent with systems categorized as routine (30-day restoration), mission essential (72-hour restoration), or mission critical (12-hour restoration).

Business owners are required to state the mission criticality of the IT services required in order to assist the planners and developers in determining best strategies for engineering an IT solution to meet their business objectives/needs. The business owner needs to state the criticality of the data and the impact to the business during a service disruption so appropriate technologies can be considered.

Levels for Disaster Recovery

Classification Recovery Time Objective Recovery Point

Objective Routine 30-day restoration TBD

Mission Essential 72-hour restoration 24 hours

Mission Critical 12-hour restoration 2 hours

Recovery Time Objective (RTO) – RTO defines the maximum amount of time that a system resource can remain unavailable before there is an unacceptable impact on other system resources, supported mission/business processes, and the MTD.

Maximum Tolerable Downtime (MTD) - The MTD represents the total amount of time the system owner/authorizing official is willing to accept for a mission/business process outage or disruption and includes all impact considerations.

Recovery Point Objective (RPO) - The RPO represents the point in time, prior to a disruption or system outage, to which mission/business process data can be recovered (given the most recent backup copy of the data) after an outage.

Data Quality/Assurance Requirements

A monitoring process shall be provided to ensure that data is accurate and up-to-date and provides accurate alerts for malfunctions while minimizing false alarms.

User Access/Security Requirements

Ensure the proposed solution meets all Veterans Health Administration (VHA) Security, Privacy, and Identity Management requirements including VA Handbook 6500 (see the Enterprise Requirements section of the RTM).

Usability/User Interface Requirements

Adhere to good User Interface/User Centered Design (UI/UCD) principles as outlined in the Usability Appendix of the BRD.

Conceptual Integrity

Provide standards based messaging and middleware infrastructure needed to support both Legacy Veterans Health Information Systems Technology Architecture (VistA) and future VistA 4 deployments.

Availability

 Maintenance window, including maintenance of externally developed software incorporated into the VistA 4 application(s), will be by mutual agreement between OI&T and the VHA Point of Contact (POC) for the affected facility (ies). VHA will provide POCs for each facility.

- 2. VistA application unavailability due to an unplanned outage or planned outages that exceed the defined maintenance window will not exceed 8.76 hours per year and will not exceed 43.8 minutes per month (99.9% availability).
- 3. The application shall be available 24 hours a day, seven days a week, with an uptime of 99.9%.
- 4. All system updates and scheduled maintenance should occur between the hours of 1800 and 0600 (per local time zone), when clinical usage would be lightest.

Interoperability

- 1. The system shall support all recognized health system standards i.e., Health Level 7 (HL7).
- 2. Systems must be heterogeneous and agnostic for operating systems and code bases.
- 3. Provide the ability to securely transfer large files (of 4-8 gigabyte) from an external source to VA systems.
- 4. Provide access to the system over a remote access solution.

Manageability

- 1. Provide Service Desk/Incident and Problem Management tracking related to maintenance events of patient care systems with priority over non-patient care systems.
- 2. Provide data related to maintenance events, both routine and exceptional, including key metadata:
 - Predicted routine work
 - Occurrences where maintenance is completed, including restart from down time
 - Identity of the organization performing maintenance
 - User performing maintenance (if available)
 - Identity of the system
 - Date/time, physical location
 - Systems impacted
 - Does it affect patient care?
 - Non-urgent or emergent
- 3. Provide audit capabilities for system access and usage with settings that are configurable to support internal and external audits based on federal and VHA mandates.
- 4. The system must comply with VA Directive 6300 Records and Information Management and with VHA Records Control Schedule (RCS) 10-1, in general and specifically with Electronic Final Version of Health Record: Destroy/Delete 75 years after last episode of patient care, or longer (if specified).

Performance

1. Provide an Infobutton Query Responder on all platforms with a response time of less than .5 seconds.

- 2. The system shall recognize, report, and retransmit data lost, with less than 0-1% chance of incomplete patient records.
- 3. Provide patient data (for data within the system) transactions (e.g., capture, search, request for data) within .5 seconds.
- 4. Mouse or key-based UI controls, e.g., menus, checkboxes shall provide instantaneous responsiveness (<90ms).
- 5. Part-screen refreshes after user action shall complete within a pro-rated interval between 200 ms and 1200 ms times a percentage of the screen area being refreshed. For example, a component 10% of the screen area would refresh in (1200 200) * 0.10 + 200 = 300 ms.

Reliability

- 1. Provide system reliability:
 - Threshold = 99.9%
 - Objective = 99.99% system and application
- 2. Provide system reliability:
 - Level 1 severity =<1 failure per month
 - Level 2 severity =<2 failures per month
 - Level 3 severity =<3 failures per month

Security

Provide management of electronic attestation of information including the retention of the signature of attestation (or certificate of authenticity) associated with incoming or outgoing information.

Supportability

- 1. Provide alerts (that extend beyond system messages to external systems like mobile devices) for malfunctions, while preventing false alarms for local, regional, and national evaluations in real time.
- 2. Provide reports on performance metrics as specified in the VistA 4 Effectiveness and Value / Benefits Framework on a bi-weekly basis.
- 3. Provide national, regional, and local reports on performance metrics as specified in the VistA 4 Effectiveness and Value / Benefits Framework.
- 4. Provide performance metrics (from request for information to receipt of information on the screen) monitored by the system and system administrators so they know what the user experience is like without users having to call them and tell them the system is running very slow.
- 5. Provide the ability for VHA and IT staff to create standard and ad-hoc reports of usage, bandwidth, response time, login time, and other variables with a verification process for measuring the capabilities of the system.

- 6. Provide end-user training on how to generate the various system performance reports (e.g., in standard file formats such as Comma Separated Values [CSV], Portable Document Format [PDF], or Excel) depending on the user's needs.
- 7. Provide the ability to view system statistics (e.g., information on the specific network environment) and identify areas that are having issues or are beyond capacity, in near-real-time (to be quantified at a later time).
- 8. Technical Help Desk support for the application via instant message, on-line, phone, and remote desktop access support, shall be provided for users to obtain assistance 24/7.
- 9. The IT solution shall be designed to comply with the applicable approved Enterprise SLAs.
- 10. Data protection measures, such as back-up intervals and redundancy shall be consistent with systems categorized as mission critical (1hr restoration, 2hrs backup recovery). Impact of system failure must be monitored on a near real time basis.
- 11. Provide the ability to set thresholds and notification type (e.g., email or text alerts) when alerting the user about response time degradation and unscheduled outages.
- 12. Disaster Recovery Plans (DRP) and Continuity of Operations Plan (COOP) will be updated and tested semi-annually to address the VistA 4 product (see National Security and Homeland Security Presidential Directive: National Continuity Policy. NSPD-51/HSPD-20, May 9, 2007 http://www.fas.org/irp/offdocs/nspd/nspd-51.htm)

Usability

- 1. Provide view ability/usability of VistA 4 applications on mobile devices.
- 2. User prompts and screen help shall be embedded into the system to guide use of the solution

Documentation

- 1. The training curriculum shall be provided in two hours or more of training time for primary users and secondary users to become proficient at using the VistA 4 application(s).
- 2. All training curricula, user manuals and other training tools shall be developed/updated by the VE Program Office and delivered to all levels of users 4 weeks in advance of the release of the enhancement through mediums that will best support the sharing of information to all affected staff.
- 3. Provide follow-up training classes tailored to VHA workflow 4 weeks after the users have begun to use the system.