

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

OneVA Pharmacy Project

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

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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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12/31/2015	2.1	Correct entries 2.5.2 & 2.5.3 (format only); Updated Appendix A Non-functional requirements	Kathy Coupland

Date	Version	Description	Author
03/01/2016	2.2	Modified to incorporate VA SharePoint links; updated references; updated rollout date; updated abbreviation table; modified the list of ProPath required deliverables; removed references to the VA ForumForUs/GitHub and replaced with the VA SharePoint; modified list of reviews; modify middleware components to include integration instead of development.	Kathy Coupland
03/02/2016	2.3	Applied Rob Silverman's tracked changes and feedback.	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 Business Information Technology Solutions (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 project is the high bar phase of the initiative. The OneVA Pharmacy 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 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 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 integrate with a middleware model that meets the One-VA Technical Reference Model (TRM) 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. ProPath 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 \(CPMP\)](#)
- [OneVA Pharmacy Systems Design Document \(SDD\)](#)

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
BITS	Business Information Technology Solutions, Inc.
CCOW	Clinical Context Object Workgroup
CDS	Clinical Data Services
CLIN	Contract Line Item Number
CPMP	Contractor Project Management Plan
DEA	Drug Enforcement Agency
DHCP	Dynamic Host Configuration Protocol
eMI	Enterprise Messaging Infrastructure
ESB	Enterprise Service Bus
GUI	Graphical User Interface
HDR	Health Data Repository
HL7	Health Level 7
ICN	Integration Control Number

Acronym/Abbreviation	Description
IOC	Initial Operating Capability
IPT	Integrated Project Team
IT	Information Technology
MLLP	Minimal Lower Layer Protocol
MUMPS	Massachusetts General Hospital Utility Multi Programming System
MVI	Master Veteran Index
OI&T	Office of Information and Technology
OIA	Office of Informatics and Analytics
PID	Patient Identification
PSO	Outpatient Prescription Pharmacy
PWS	Performance Work Statement
RTM	Requirements Traceability Matrix
Rx	Prescription
SDD	System Design Document
SLA	Service Level Agreement
SME	Subject Matter Expert
SOAP	Simple Object Access Protocol Service Oriented Architecture
SSL	Secure Sockets Layer
SSN	Social Security Number
TRM	Technical Reference Model
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 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 project are as follows:

2.2.1. A prescription will only have one of the following status values:

- a. Active
 - 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
 - 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 non-verified and cannot be printed, cancelled or edited except through the Verification menu.
- g. Pending Due to Drug Interactions
 - 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
 - A second or subsequent filling authorized by the provider.
- i. Suspended
 - 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 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.

2.5.1. Documentation for the OneVA Pharmacy project includes, but is not limited to the following:

- a) OneVA Pharmacy Installation Guide-VistA
- b) OneVA Pharmacy Production Operations Manual
- c) OneVA Pharmacy Installation/Back out/Rollback Plan
- d) OneVA Pharmacy User Guide
- e) OneVA Pharmacy Software Configuration Management Procedures
- f) OneVA Pharmacy Patch Description
- g) Section 508 Compliance Certification
- h) Section 508 Conformance Validation Statement
- i) Risk Issue Log
- j) Requirements Specification Document (RSD)
- k) System Design Document (SDD)
- l) Master Test Plan
- m) Test Evaluation Summary
- n) IOC Site Memorandum of Understanding
- o) Primary Developer Checklist
- p) Secondary Developer Checklist
- q) Requirements Traceability Matrix (RTM)
- r) Operational Acceptance Plan
- s) Sustainment Transition Plan
- t) IOC Entry Request and Exit Summary
- u) Lesson Learned
- v) Contractor Staff Roster
- w) Implementation Report

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 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 system 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. The 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
- j) Local Refill/Partial Cost

2.7. Graphical User Interface (GUI) Specifications

Not applicable.

2.8. Multi-divisional Specifications

Multi-divisional specifications will follow the existing VistA multi-divisional functionality that exists in the current application.

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

Not applicable.

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 Team.

Authentication and Authorization

The OneVA Pharmacy software will use the eMI middleware. The VAeMI 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 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 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.

Joshua Patterson	Date
Integrated Project Team (IPT) Chair	

Michael Valentino	Date
Business Sponsor	

Cecelia Wray	Date
Project Manager	

Appendix A: Non-Functional Requirements

Documentation Requirements

- The OneVA Pharmacy training curriculum shall be available for the IOC site users and placed on the VA OneVA Pharmacy SharePoint for other users in order to become proficient with the OneVA Pharmacy enhancement.
- All training curricula, user guide, and other training tools shall be developed by the OneVA Pharmacy team.
- The OneVA Pharmacy team shall provide operation and installation documentation required to support and maintain the OneVA Pharmacy enhancement. All documentation shall be made available on the VA SharePoint.

Conceptual Integrity

- OneVA Pharmacy shall incorporate standards based messaging and middleware needed to support both Legacy VistA and future VistA 4 deployments.

Interoperability

- OneVA Pharmacy shall utilize health system standards i.e., Health Level 7 (HL7).

Manageability

- A new file called the 'Remote Prescription Log (#52.09)' file shall be available to provide audit capabilities for system usage to support internal and external audits based on federal and VHA mandates.

Supportability

- The OneVA Pharmacy processing shall provide system messages for malfunctions and will time-out the processing, returning the user to the initial screen.
- The OneVA Pharmacy solution shall be designed to comply with the applicable approved Enterprise Service Level Agreements (SLAs).

Usability

- OneVA Pharmacy shall provide user prompts and screen help, embedded into the VistA system to guide users of the solution.