**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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**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 location 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. 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 host pharmacy and manages controlled substances by displaying a message that a controlled substance cannot be refilled outside of the host 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:

o OneVA Pharmacy Performance Work Statement (PWS)

o Contractor Project Management Plan (CPMP)

o Essential Medication Directive Publication

o 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 |
| **CHDR** | Clinical Data Health Care Repository |
| **CLIN** | Contract Line Item Number |
| **CPMP** | Contractor Project Management Plan |
| **DEA** | Drug Enforcement Agency |
| **DHCP** | Dynamic Host Configuration Protocol |
| **DoD** | Department of Defense |
| **eMI** | Enterprise Messaging Infrastructure |
| **ESB** | Enterprise Service Bus |
| **GUI** | Graphical User Interface |
| **HDR** | Health Data Repository |

|  |  |  |
| --- | --- | --- |
| **Acronym/Abbreviation** |  | **Description** |
| **HL7** | Health Level 7 |  |
| **ICN** | Integration Control Number | |
| **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 | |

|  |  |
| --- | --- |
| **Acronym/Abbreviation** | **Description** |
| **VistA** | Veterans Health Information Systems and Technology  Architecture |

**2. Overall Description**

**2.1. Accessibility Specifications**

The OneVA Pharmacy project artifacts and the OneVA Pharmacy software 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 may have one of the following status values:

 '0' FOR ACTIVE

 1' FOR NON-VERIFIED

 2' FOR REFILL

 3' FOR HOLD

 4' FOR DRUG INTERACTIONS

 5' FOR SUSPENDED

 10' FOR DONE

 11' FOR EXPIRED

 12' FOR DISCONTINUED

 13' FOR DELETED

 14' FOR DISCONTINUED BY PROVIDER

 15' FOR DISCONTINUED (EDIT)

 16' FOR PROVIDER HOLD

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 for action by the dispensing VA Pharmacy. (Note: Because it would still be part of the active profile and therefore viewable.)

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.

2.3.6. The system shall filter out Clinical Data Health Care Repository/Department of Defense (CHDR/DoD) prescriptions that are available in the HDR/CDS repository for active dual patients.

**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 Conformance Validation Statement h) Risk Issue Log

i) Requirements Specification Document (RSD)

j) System Design Document (SDD)

k) Master Test Plan

l) Test Evaluation Summary

m) IOC Site Memorandum of Understanding n) Primary Developer Checklist

o) Secondary Developer Checklist

p) Requirements Traceability Matrix (RTM)

q) Operational Acceptance Plan r) Sustainment Transition Plan

s) IOC Entry Request and Exit Summary t) Lesson Learned

u) Contractor Staff Roster v) 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 screen from all VA Pharmacy locations at which the patient is registered with prescriptions and the prescription status contains a value of “Active”, “Hold”, “Suspended”, “Discontinued (within the past 120 days)” or “Expired (within the past 120 days)”.

(NOTE: Pending prescriptions are part of the Essential Medication Directive but will not be available to OneVA Pharmacy because they are not “Pharmacist-verified” or “Finished” yet.)

2.6.1.2. The system shall provide the ability to display the system response message: “Please wait. Checking for prescriptions at other VA pharmacy locations. 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 the same display elements as the local prescription.

2.6.1.4. The system shall provide the ability to display the prescription information from another VA Pharmacy location grouped under a divider header line showing the site name, number, and status.

2.6.1.5. The system shall provide the ability to generate a header that separates the prescriptions by status.

2.6.1.6. The system shall provide the ability to display the system response message: “The system is down or not responding. Could not query other VA Pharmacy locations. Press RETURN to continue” when the system (on which a patient is registered) does not respond.

**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. Dispensing Refills for Prescriptions from another VA Pharmacy**

**Location**

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 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 another VA Pharmacy location.

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 dispensing 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, at the dispensing site, a partial refill prescription label or a full refill prescription label for all prescriptions dispensed; similarly, to how this is done for local prescriptions.

**2.6.5. Other VA Pharmacy Locations Prescription Reports**

2.6.5.1. The system shall provide the ability to generate and print a report to show all prescriptions filled from all other VA Pharmacy locations.

(NOTE: Report should not include local prescriptions.)

2.6.5.2. The system shall provide the ability to generate and print a report to show prescriptions filled by other VA Pharmacy locations via the OneVA Pharmacy process.

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 prescriptions refilled or partially refilled sorted by date from all other VA Pharmacy locations. 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) Host Drug Name

i) Dispensing (matched) drug

j) Dispensing Refill/Partial Cost

**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] roll and scroll user interface.

**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 prescriptions from other VA Pharmacy locations. 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 VA Pharmacy 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 VAeMI 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.