# Introduction

## Purpose

## Scope

# Overall Description

## 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.

## 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:

* + 1. A prescription will only have one of the following status values:

1. Active
   * A prescription with this status can be filled or refilled.
2. Discontinued
   * This status is used when a prescription was made inactive either by a new prescription or by the request of a physician.
3. 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.
4. 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.
5. Hold
   * A prescription that was placed on hold due to reasons determined by the pharmacist.
6. 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.
7. 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.
8. Refill
   * A second or subsequent filling authorized by the provider.
9. Suspended
   * A prescription which will be filled at some future date.
     1. A prescription will only be refilled when all the following events occur:
10. Status is active
11. One or more refills remain
12. Refill date and time considerations include:
    1. Date of the refill is no earlier than the scheduled next refill date for the prescription.
       1. 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.
    2. If the prescription refill request is suspended by the host VistA pharmacy system, it will not be available to the remote VA pharmacy.
13. Prescription is not for a controlled substance
14. Refilling drug matches VA product name and dosage
    * 1. A prescription will only be refilled when the patient is known and registered in one or more VistAs.
      2. The MVI creates and assigns an Integration Control Number (ICN) when a new patient registers.
      3. 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.

## 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 Implementationproject are as follows:

* + 1. The system shall use the VistA feature “Patient Prescription Processing [PSO LM BACKDOOR ORDERS]” to access local patient information.
    2. The system shall use data from Health Data Repository/Clinical Data Service (HDR/CDS) to display a medication profile.
    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.
    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.
    5. The prescription label generated for the dispensed product will always use the original label information from the host site.

## 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.

## 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).

* + 1. Product Documentation for the OneVA Pharmacy Implementation project includes, but is not limited to the following:

1. Installation Guide
2. Operations and Maintenance Plan
3. Technical Manual
4. User Guide
5. Training Manual
   * 1. PMAS Documentation for the One VA Pharmacy Implementation project includes, but is not limited to the following:
6. Risk Issue Log
7. Requirements Specification Document (RSD)
8. System Design Document (SDD)
9. Initial Operating Capability (IOC) Documentation
10. Master Test Plan
11. IOC Site Memorandum of Understanding
12. Primary Developer Checklist
13. Secondary Developer Checklist
14. Requirements Traceability Matrix (RTM)
15. Acceptance Criteria Plan
16. IOC Entry Request and Exit Summary
17. Lesson Learned
18. Contractor Staff Roster
19. Training Plan
    * 1. Reviews for the OneVA Pharmacy Implementation project includes, but it not limited to the following:
20. Operational Readiness Review
21. Initial Operating Capability Entry and Exit
22. National Deployment review

## 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:

* + 1. **Display Prescription Orders**
       1. The system shall provide the ability to display the entire Medication Profile for a patient from all other facilities.
       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.
       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:

1. Patient Name
2. Patient Address
3. Patient Social Security Number
4. Patient Prescriptions Listing
   * + 1. 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. 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.
       3. The system shall provide the ability to generate a header that separates the prescriptions by status.
       4. 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.
       5. The system shall provide the ability to display a message when a system on which a patient is registered has no prescriptions.
     1. **Local refills**
        1. The system shall provide the ability to dispense local refills as currently designed.
     2. **Remote refills**
        1. The system shall provide the ability to refill active-refillable prescriptions that originated from another VA pharmacy location.
        2. The system shall provide the ability to refill with a full or partial prescription.
        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.
5. 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.
6. If the prescription refill request is suspended by the host VistA pharmacy system, it will not be available to the remote VA pharmacy.
   * + 1. 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. The system shall provide the ability to display a drug for any selected active-refillable prescriptions refills.
       3. 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.
       4. The system shall provide the ability to generate the following information in the VistA action log:
7. Refill or Partial Date
8. Name of pharmacist
9. Name and Station Number of VA Site
10. Brief comment
11. Contact telephone number of originating pharmacy
12. Other
    * + 1. The system shall be free of defects.
      1. **Prescription Labels**
         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. **Remote Reports**
         1. The system shall provide the ability to generate and print a report to show all prescriptions filled for remote sites.
         2. The system shall provide the ability to generate and print a report to show local prescriptions filled by remote sites.
         3. The system shall provide the ability to limit the contents of a report in various ways. They are as follows:
13. Prescriptions filled within a date range
14. Prescriptions filled for a single patient, specifying the following search options:
15. Name
16. Social Security Number (SSN)
17. Last 4 SSN digits
18. First initial of last name with last 4 digits of SSN
19. Prescriptions filled for a single site, searching on Institution Name.
    * + 1. 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:
20. Patient Name
21. Drug Name
22. Type of refill
23. Quantity
24. Number of days supplied
    * + 1. The system shall provide the ability to view or print a report that displays the total cost.
        2. The system shall provide the ability to view the following data values for any prescription listed in a report:
25. Request Date/Time
26. Patient
27. Rx #
28. Site
29. Request Type
30. Requesting Pharmacist
31. Dispensed Date
32. Remote Drug Name
33. Local (matched) drug
34. Local Refill/Partial Cost
    * 1. **Files**
         1. The system shall add the following fields to Prescription (#52) REFILL sub file (#52.1):
35. Remote File Site (#91)
36. Remote Pharmacist (#92)
37. Remote Pharmacist Phone (#93
    * + 1. The system shall add the following fields to the Prescription (#52) PARTIAL DATE sub file (52.2):
38. Remote File Site (#91)
39. Remote Pharmacist (#92)
40. Remote Pharmacist Phone (#93)

## 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].

## Multi-divisional Specifications

Not applicable.

## Performance Specifications

* + 1. The system shall provide the ability to configure the connection and response timeouts.
    2. The system shall provide the ability to time out a query connection in five (5) seconds.
    3. The system shall provide the ability to time out the query response in ten (10) seconds.
    4. The system shall provide the ability to time out a ‘refill/partial fill’ connection in five (5) seconds.
    5. The system shall provide the ability to time out a ‘refill/partial fill’ response in sixty (60) seconds.

## Quality Attributes Specification

Not applicable.

## Reliability Specifications

Not applicable.

## 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.

## Security Specifications

* + 1. The system shall provide the ability to authenticate a username and password as an access and verify for the web service.
    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.

## System Features

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

## Usability Specifications

Not applicable.

# Purchased Components

Not Applicable.

# Estimation

Not Applicable.

# 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:

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Joshua Patterson Date

Integrated Project Team (IPT) Chair

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Michael Valentino Date

Business Sponsor

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Cecelia Wray Date

Project Manager

Appendix A: Non-Functional Requirements

Documentation Requirements

1. The training curriculum will be available for the IOC site users and placed on the VA ForumForUs OneVA Pharmacy community for other users in order to become proficient at understanding the OneVA Pharmacy enhancement.
2. All training curricula, user guide, and other training tools shall be developed by the OneVA Pharmacy team.
3. The OneVA Pharmacy team will provide documentation required to support and maintain the OneVA Pharmacy enhancement. All documentation shall be made available on the GitHub Innovations/One-VA-Pharmacy respository.

Conceptual Integrity

1. OneVA Pharmacy incorporates standards based messaging and middleware needed to support both Legacy VistA and future VistA 4 deployments.

Interoperability

1. OneVA Pharmacy utilizes health system standards i.e., Health Level 7 (HL7).

Manageability

1. A new file called the ‘Remote Prescription Log (#52.09)’ file will provide audit capabilities for system usage to support internal and external audits based on federal and VHA mandates.

Supportability

1. The OneVA Pharmacy processing provides system messages for malfunctions and will time-out the processing returning the user to the initial screen.
2. The IT solution shall be designed to comply with the applicable approved Enterprise SLAs.

Usability

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

Documentation

1. IOC sites - The training curriculum shall be provided in two hours or more of training time for IOC ……………..