

Medical Care Collection Fund (MCCF) ePharmacy Compliance Phase 3

New Service Request #20140411

Business Requirements Document



August 2014

Revision History

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

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8/29/14	Approved version	[REDACTED] (9/3/14) [REDACTED] (9/3/14)
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1. Purpose

The Business Requirements Document (BRD) is authored by the business community for the purpose of capturing and describing the business needs of the customer/business owner identified within the New Service Request (NSR) #20140411 – Medical Care Collection Fund (MCCF) ePharmacy Compliance Phase 3¹. The BRD provides insight into the AS-IS and TO-BE business area, identifying stakeholders and profiling primary and secondary user communities. It identifies what capabilities the stakeholders and the target users need and why these needs exist, providing a focused overview of the request requirements, constraints, and other considerations identified. This document does not state the development methodology. The intended audience for this document is the Office of Information and Technology (OI&T).

2. Overview

Changes to Veterans Health Information Systems and Technology Architecture (VistA) Electronic Claims Management Engine (ECME), Integrated Billing (IB), Accounts Receivables (AR), Pharmacy Data Management, Outpatient Pharmacy and Consolidated Mail Outpatient Pharmacy (CMOP) software applications are being requested by the Veterans Health Administration (VHA) Chief Business Office (CBO) eBusiness Solutions to comply with legislative changes mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by Public Law (P.L.) 111-148, the Patient Protection and Affordable Care Act (PPACA).

Currently, VHA uses the National Council for Prescription Drug Programs (NCPDP) Pharmacy Electronic Data Interchange (EDI) transactions in support of its third-party pharmacy revenue and collections operation.

VHA has updated its current HIPAA NCPDP pharmacy transaction standards to the current D.0 version as required by a previous HIPAA mandate. To maintain HIPAA compliance, VHA must implement periodic subsequent NCPDP releases to the D.0 standard and implement new data fields and data field values that continue to be updated in support of the External Code Lists (ECL) as established by the American National Standards Institute (ANSI) for NCPDP standards. VHA must address business changes and software system impacts that will result from final rules published by the Department of Health and Human Services (HHS) to meet PPACA legislative requirements.

In general, transaction standards adopted under HIPAA enable electronic data interchange through a common interchange structure, thus minimizing the industry's reliance on multiple formats. If the needs outlined in this document are not implemented, VHA will not only miss meeting the compliance standards, but will also be incapable of meeting subsequent mandates for future compliance that rely on current development.

¹ [REDACTED]

3. Customer and Primary Stakeholders

██████████ (Director, eBusiness Solutions), representing the Chief Business Office, is the primary stakeholder for this request. Review [Appendix C](#) for the complete list of primary and secondary stakeholders.

4. Scope

Changes to VistA's Outpatient Pharmacy, ECME, CMOP, Pharmacy Data Management, Accounts Receivables and IB software applications are being requested by the VHA CBO eBusiness Solutions Department to comply with the legislative changes mandated by HIPAA as amended by PPACA, P.L. 111-148, Section 1104 and to ensure VHA follows established policies, procedures and Directives.

The following eBusiness program area needs must be addressed:

- Update VistA to utilize the most current version of ECL data fields to ensure compliance with NCPDP standards.
- Update VistA to utilize the most current version of NCPDP standard data field values to ensure continued revenue from pharmacy claims.
- Increase system efficiencies with ePharmacy options to improve reject resolution and direct patient care.
- Further define ePharmacy functionality to ensure continued compliance with VHA policies, procedures and Directives.

5. Goals, Objectives and Outcome Measures

Goal/Objective and Desired Outcome	Impact/Benefit	Measurement
Update VistA to utilize the most current version of ECL data values to ensure compliance with NCPDP standards.	This will continue to minimize manual intervention of pharmacy claim processing to Pharmacy Benefit Management (PBM)/payers.	NCPDP rejects received due to NCPDP data values will decrease by 1%.
Update VistA to utilize the most current version of NCPDP standard data fields to ensure continued revenue from pharmacy claims.	This will allow VHA to continue sending required NCPDP data fields specified by the PBM/payers on electronic pharmacy claims to third party payers.	NCPDP rejects received due to inability to submit required NCPDP data fields will decrease by 1%.
Improve system efficiencies within ePharmacy options and the NCPDP transactions to improve reject resolution and direct patient care.	Improves efficiency in processing electronic pharmacy claims while upholding patient safety.	Reduce the amount of time spent on reject resolution and troubleshooting transaction issues by 2%.
Further define ePharmacy	Will ensure compliance	Improve system functionality to

functionality to ensure continued compliance with VHA policies, procedures and Directives.	with VHA policies, procedures and Directives.	reduce the number of electronically submitted pharmacy claims needing manual follow-up by 1%.
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6. Enterprise Need/Justification

The PPACA was passed in March 2010 with the intent of implementing standardized operating rules and processes to increase the portability, efficiency and quality of health care services. As a federal entity and the nation's largest integrated health care provider, VHA is required to comply with all mandates. This legislation requires that health care providers structure health care operating information in a way that is universal amongst entities across the country. Refer to [Appendix A](#) for additional information.

Penalties for Non-Compliance

Non-compliance penalties are stated in the HIPAA regulations for non-compliance.

“Under the statute, failure to comply with standards may result in monetary penalties. The Secretary is required by statute to impose penalties of not more than \$100 per violation on any person who fails to comply with a standard, except that the total amount imposed on any one person in each calendar year may not exceed \$25,000 for violations of a single standard for a calendar year.”

Essentially, there is a cap of \$25,000 per year per violation. If it is taken as per transaction, VA could be penalized \$150,000 per year. However, there are some interpretations of the penalties which also include the lack of use of standard code sets which are defined. This interpretation could approach \$1,000,000 in penalties.

7. Requirements

7.1. Business Needs/Owner Requirements

Identifier BN/OWNER Number	Business Need (BN)/Owner (OWNER) Requirement	OWNER Priority*
Business Need 1	Adhere to the Enterprise Level requirements as specifically addressed in Appendix E of this document.	
Business Need 2	Utilize nationally standardized terminology for all use of trademark names.	
Requirement 2.1	Provide the ability to express all content using nationally recognized reference and authoritative terminology standards.	High
Business Need 3	Update VistA to utilize the most current version of NCPDP ECL data values.	High/ Required
Requirement 3.1	Update VistA to utilize the most current NCPDP ECL data values.	High
Business Need 4	Update VistA to utilize the most current version of NCPDP standard data fields.	High/ Required

Identifier BN/OWNER Number	Business Need (BN)/Owner (OWNER) Requirement	OWNER Priority*
Requirement 4.1	Remove NCPDP version 5.1 residual code.	High
Requirement 4.2	Provide the ability to utilize the most current NCPDP standard data fields.	High
Business Need 5	Improve system efficiencies with Pharmacy options and the NCPDP transactions to improve reject resolution and direct patient care.	High
Requirement 5.1	Provide the ability to automatically update DEA, Special HDLG fields in facility Drug files via a central process.	High
Requirement 5.2	Provide the ability to automatically update the NCPDP Quantity Multiplier in facility Drug files via a central process.	High
Requirement 5.3	Provide the ability to automatically update the NCPDP Dispense Unit in facility Drug files via a central process.	
Requirement 5.4	Provide the ability to allow a separate NCPDP Quantity Multiplier and NCPDP Dispense Unit for each entry in the Synonym File.	High
Requirement 5.5	Modify ¾ days' supply functionality to include new prescriptions.	High
Requirement 5.6	Modify Suspense Date Calculator functionality to check new prescriptions. (Note: This will require checking the prescription status.)	High
Requirement 5.7	Provide the ability to improve the resolution for Reject Resolution Required (RRR) rejects.	High
Requirement 5.7.1	Add the Total Amount Paid to display on the screen after resolving a Reject Resolution Required (RRR) reject.	High
Requirement 5.7.2	Add the View ePharmacy Rx action as a hidden action on the Third Party Payer Rejects – Worklist, Insurance Rejects-Worklist screen.	High
Requirement 5.7.3	Develop a report that will provide the amount of revenue generated within a specified time frame as a result of Reject Resolution Required (RRR) rejects resolved to payable claims.	High
Requirement 5.8	Add the Outpatient Pharmacy Electronic Claims Coordinator (OPECC) comments to the Reject Information screen.	High
Requirement 5.9	Provide the ability to allow non-billable TRICARE claims to be resubmitted from the Reject Information screen.	High
Requirement 5.10	Provide the ability to allow non-billable Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) claims to be resubmitted from the Reject Information screen.	High
Requirement 5.11	Add the Reverse Claim action to the Outpatient Medications (Active) screen.	High

Identifier BN/OWNR Number	Business Need (BN)/Owner (OWNR) Requirement	OWNR Priority*
Requirement 5.12	Add the heading of 'Veteran' to the Reject Information screen when the reject is for a Veteran patient.	High
Requirement 5.13	Modify the default action in the Reject Notification screen for the non-billable Release of Information related rejects.	High
Requirement 5.14	Modify the Third Party Payer Rejects – Worklist and Third Party Payer Rejects - View/Process screens to remove a reject for a Veteran claim from the Worklist when a reject is resolved to payable by the OPECC.	High
Business Need 6	Further define the ePharmacy functionality to ensure continued compliance with VHA policies, procedures and Directives.	High
Requirement 6.1	Create a report for OPECCs to proactively identify when Release of Information forms will expire.	High
Requirement 6.2	Add a DEA, Special HDLG code facilities can use to prevent claims transmission for products that should not be billed through Outpatient Pharmacy.	High
Requirement 6.3	Modify functionality to ensure duplicate TRICARE copays are not created.	High
Requirement 6.4	Modify billing determination hierarchy to check for patient insurance before checking for billable product.	High
Requirement 6.4.1	Modify software to use appropriate comment for activity log.	High
Requirement 6.5	Modify functionality to ensure prescriptions related to Camp Lejeune are not submitted to third party payers.	High
Business Need 7	Improve system efficiencies with OPECC options and the NCPDP transactions to improve reject resolution.	High
Requirement 7.1	Add an action to the ECME User Screen that provides all information needed by an OPECC when contacting a third party about a reject.	High
Requirement 7.2	Provide the ability (within ECME) to allow a user to resubmit a payable claim without first submitting a reversal.	High
Requirement 7.3	Remove action 'Display Update' from the ECME User Screen.	High
Requirement 7.4	Remove action 'Continuous Update' from ECME User Screen.	High
Requirement 7.5	Modify the functionality for the Billed Amount in Integrated Billing to pull from the Gross Amount Due field in ECME.	High
Requirement 7.6	Provide the ability to allow non-billable TRICARE claims to display on the ECME User Screen.	High
Requirement 7.7	Provide the ability to allow non-billable CHAMPVA claims to display on the ECME User Screen.	

Identifier BN/OWNER Number	Business Need (BN)/Owner (OWNER) Requirement	OWNER Priority*
Requirement 7.8	Provide the ability to allow non-billable TRICARE claims to be resubmitted from the ECME User Screen.	High
Requirement 7.9	Provide the ability to allow non-billable CHAMPVA claims to be resubmitted from the ECME User Screen.	High
Requirement 7.10	Provide the ability to use the release date in ECME as the default date of service for back-billing.	High
Requirement 7.11	Add the new indicator for resubmitted claims to the ECME User Screen.	High
Business Need 8	Increase use and efficiency of ePharmacy reports.	High
Requirement 8.1	Provide the ability to capture the user's name when the claim is resubmitted.	High
Requirement 8.2	Provide the ability to capture the user's name when the claim is submitted through Claims Tracking.	High
Requirement 8.3	Provide the ability to create a report to capture pharmacists' Pharmacy workload.	High
Requirement 8.4	Provide the ability to display the VA Plan ID on the Group Plan Worksheet Report.	High
Requirement 8.5	Modify Match Multiple Group Plans to a Pharmacy Plan to display the VA Plan ID.	High
Requirement 8.6	Modify Match Group Plan to a Pharmacy Plan to display the VA Plan ID.	High
Requirement 8.7	Add the billed amount to the Closed Claims Report.	High
Requirement 8.8	Add the billed amount to the Ignored Rejects report.	High
Requirement 8.9	Modify current Potential TRICARE Claims Report to allow users to select eligibilities, e.g., TRICARE/CHAMPVA Employee etc.	High
Requirement 8.10	Create a new indicator to reflect when claims are resubmitted.	High
Requirement 8.11	Add the new indicator for resubmitted claims to the Reject Information Screen.	High
Business Need 9	Improve System Efficiency to Increase Revenue.	
Requirement 9.1	Modify functionality to store original manufacturers National Drug Code (NDC) from CMOP in the prescription file.	High
Requirement 9.2	Maintain functionality to store CMOP repackaged NDC in the prescription file.	High
Requirement 9.3	Provide the ability to transmit the original manufacturers NDC from CMOP.	High

Identifier BN/OWNER Number	Business Need (BN)/Owner (OWNER) Requirement	OWNER Priority*
Requirement 9.4	Provide the ability to not assign a Reason Not Billable (RNB) for sensitive diagnosis drugs.	High
Requirement 9.5	Create a separate Health Level Seven (HL7) Logical Link for ePharmacy to remove the dependency on the Electronic Insurance Verification (eIV) HL7.	High
Requirement 9.6	Enhance functionality to optimize the use of Health Plan Identifier (HPID) in order to address CMS Requirements.	High

*All listed requirements are needed by the business community. The Priority is merely a mechanism to suggest a sense of urgency and order to the technical community if the requirements are to be parsed into phases. The order of importance begins with those that are designated as High priority.

7.2. Non-Functional Requirements

Functional requirements describe what a system must be able to perform—that is, the system behavior. All other requirements are non-functional. This section describes the non-functional requirements from a business need perspective.

ReqPro Tag	Non-Functional Requirements (NONF) Category <i>(Note: Each system developed by VA OI&T <u>must</u> comply with the following mandatory System Performance Requirements. This excludes class III software.)</i>
	System Performance Reporting Requirements
NONF2811	Include instrumentation to measure all performance metrics specified in the Non-Functional Requirements section of the BRD. 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 this document.
NONF2812	Make the performance measurements available to the IT Performance Dashboard to enable display of “actual” system metrics to customers and IT staff.
	Operational Environment Requirements
	System response times and page load times shall be consistent with ePharmacy standards (for example, My HealtheVet or HealtheVet).
	Maintenance, including maintenance of externally developed software incorporated into the impacted VistA applications 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.
NONF1608	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 OI&T to provide accurate data in the service impact notice of the ANR.

ReqPro Tag	Non-Functional Requirements (NONF) Category <i>(Note: Each system developed by VA OI&T <u>must</u> comply with the following mandatory System Performance Requirements. This excludes class III software.)</i>
NONF1609	Provide a real-time monitoring solution to report agreed/identified critical system performance parameters.
NONF2820	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 the OI&T Performance Dashboard to provide the business owners any performance metrics.
NONF1610	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.
	When/if lapses in system/update availability occur, users would follow the usual procedures of contacting the IT Departments to enter a remedy ticket.
	Documentation Requirements
NONF2228	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.
	Information Technology (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 ([REDACTED]) prior to approval by any VA change control board and release into production.
	Implementation Requirements
	An implementation plan shall be developed for all aspects of the NCPDP EDI process.
	Technical Help Desk support for the application shall be provided for users to obtain assistance with processing NCPDP EDI transactions.
NONF1614	The IT solution shall be designed to comply with the applicable approved Enterprise SLA.
	The update will be implemented in the following manner: single switchover during non-peak operation hours. The switch over to the NCPDP EDI enhancements shall be implemented to minimize impact on Veterans and VA staff.
	Implementation will require a system downtime of equivalent to the time typically allocated for patches to these applications.
	The implementation must be complete by October 1 st of the current year.
	Data Protection/Back-up/Archive Requirements

ReqPro Tag	Non-Functional Requirements (NONF) Category <i>(Note: Each system developed by VA Ol&T <u>must</u> comply with the following mandatory System Performance Requirements. This excludes class III software.)</i>
NONF1615	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.
	Data Quality/Assurance Requirements
NONF2229	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
	Due to patient safety considerations, data protection measures such as backup intervals and/or redundancy shall be consistent with systems categorized as mission critical.
NONF1617	Ensure the proposed solution meets all VHA Security, Privacy, and Identity Management requirements including VA Handbook 6500 (see Appendix E).
	User Interface/User Centered Design
NONF3141	Adhere to good User Interface/User Centered Design (UI/UCD) principles as outlined in the Usability Appendix of the BRD.
	Additional Non-Functional Requirements
	Verify all software enhancement releases are installed and working properly in the VistA system.
	Documentation of detailed system design and process mapping will be provided to CBO in the appropriate technical document.
	The implementation timeline will be provided to CBO on or before the kick-off of the project.
	Monthly progress reports will be provided to CBO.
	Extensive testing in VistA to ensure the software functions as expected.
	Creation of required development, testing and implementation documentation.

7.2.1. User Access Levels

The table below defines the different levels of user access to the VistA ePharmacy (ECME) application:

Name	Description	VistA ePharmacy (ECME) Access	VistA ePharmacy (ECME) Access
Primary Users	Outpatient Pharmacy Electronic Coordinator (OPECC)	Full Control	Full Control
Primary Users	Pharmacists	Full Control	Full Control
Secondary Users	Accounts Receivable	Read Only	View access only

Name	Description	VistA ePharmacy (ECME) Access	VistA ePharmacy (ECME) Access
	Users		
Secondary Users	System Administration	Full Control	Full Control

7.2.2. Performance, Capacity, and Availability Requirements

7.2.2.1. Performance

If this is a system modification, how many users does the current system support?
This is a system modification. The exact number of users of the current system is unknown. It is estimated there are +/- 2500 end users. End users span the entire VHA electronic pharmacy claims revenue process including, but not limited to, pharmacists, OPECCs, as well as system support staff.
How many users will the new system (or system modification) support?
The new system modifications will support the entire VHA electronic pharmacy claims revenue process including pharmacists and OPECCs. It is estimated there are +/- 2500 users.
What is the predicted annual growth in the number of system users?
Although there is no way to predict the increase in staff, it has been determined that additional users would not have a negative impact on the system.

7.2.2.2. Capacity

What is the predicted size (average) of a typical business transaction?
The predicted size of a typical business transaction is unknown by business subject matter experts. This estimate can more appropriately be made by IT staff.
What is the predicted number of transactions per hour (day, or other time period)?
Daily ePharmacy requests are approximately 55,000 to 60,000.
Is the transaction profile expected to change (grow) over time?
Yes, the transaction profile is expected to change over time as use of NCPDP EDI transactions increases. It is estimated the transaction profile increase will not exceed 5%.
What is the process for planning/adjusting capacity?
There are no plans to adjust the capacity due to the stability of the system.
Does the update require a surge capacity that would be different from the base application?
This is a stable system, so there should not be any surge in capacity. Thus, no additional planning or design is needed. The Program Office is not aware of any large spikes in systems use due to epidemics, news stories, Congressional rulings, drug recalls, etc.

7.2.2.3. Availability

Describe when the envisioned system will need to be available (business hours only, weekends, holidays, etc.) to support the business.

The envisioned systems would be available 24 hours per day/7 days per week to support the unrestricted patient activity taking place at VHA facilities.

ReqPro Tag NONF1571: The application must be available 24 hours a day, 7 days a week, consistent with VistA uptime at 99.99%.

7.3. Known Interfaces

This is the business community's best understanding of known interfaces and may not be a comprehensive listing.

This operation has multiple internal and external interfaces. To implement the requirement modifications, changes to Pharmacy and ECME modules and/or applications and interfaces of the VistA system will be required. External interfaces include, but are not limited to, the following:

Name of Application	Description-of current application	Interface Type	Existing Functionality	Deliverables
Financial Management System (FMS)	System supports the collection, processing, and dissemination of several billion dollars of financial information and transactions each fiscal year.	Automated	Yes	NA
Austin Information Technology Center (AITC)	Provides the connectivity between the Financial Services Center (FSC) and the Clearinghouse.	Automated	Yes	NA
Clearinghouse	Used by VHA as a provider and as a payer community to ensure that payer transaction requirements, both HIPAA and contractual, are maintained in EDI transactions initiated by VHA	Automated	Yes	NA

7.4. Related Projects or Work Efforts

There are no active projects or other related work efforts to this request.

8. Other Considerations

8.1. Alternatives

Compliance with HIPAA as amended by the PPACA is mandatory and there are no alternatives.

8.2. Assumptions

- Modifications to the ePharmacy processes and to VistA will adhere to all HIPAA standards.
- All PBMs/payers maintain accurate and consistent data according to the HIPAA and NCPDP standards and guidelines.

8.3. Dependencies

The success of this project is dependent upon the approval of funding and resources to develop the project as well as the timely acquisition of developers and building of the development team with the appropriate equipment and security access to computer accounts.

This implementation is dependent upon the successful implementation of prior NCPDP standards.

This work is dependent upon the PBMs/payers adopting and meeting the yearly NCPDP update deadline of October 15th of each year. If PBMs/payers do not meet this deadline, then VA cannot implement the updated ECLs/field definitions as specified; thus making this project unable to meet the Business Owners' needs.

This project is dependent upon VA being able to accept/transmit a defined set of data in the NCPDP standard format with our PBMs/payers. If our PBMs/payers do not send data as expected per the standards (even if VA is positioned through this project to capture and file that data), then the system will not produce the expected outcome (increased efficiency in pharmacy third party billing).

8.4. Constraints

The ECL updates are continuous maintenance standards. Prior versions of standards must be implemented prior to applying the current version. The technological advancements incorporated must be implemented and tested prior to all training is rolled out. All activities must be completed prior to the compliance deadline enforced by the PPACA legislation

8.5. Business Risks and Mitigation

Business Risks	Mitigation
If funding is delayed, then an inability to release timely acquisitions, an unrealistic vendor Periods of Performance, and overall timely delivery will occur.	The Business Owners and OIT organization will monitor funding cycle events closely for potential risks to timely funds commitment, certification, and obligation. As risks are discovered, plans for addressing those risks through the Integrated Product Team (IPT) structure will be analyzed and implemented.

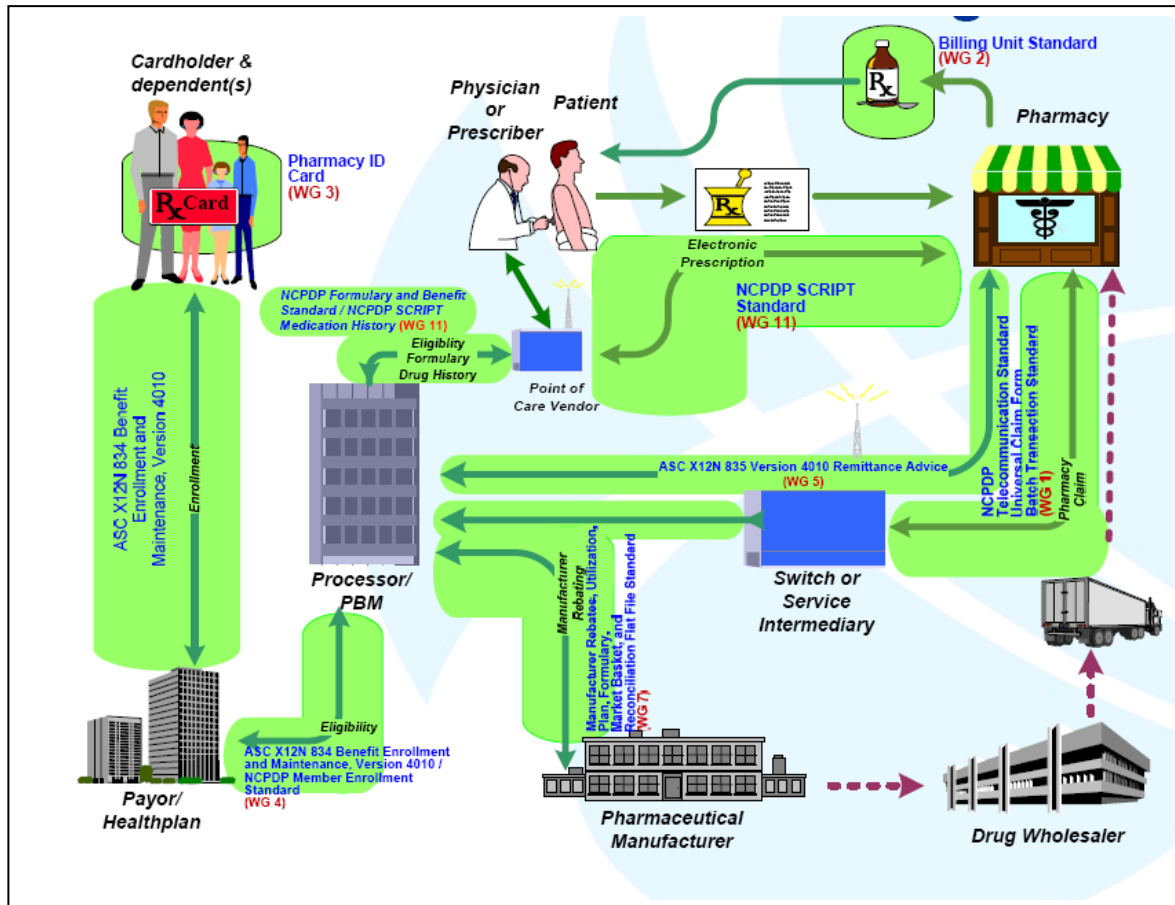
Business Risks	Mitigation
If PBMs/payers do not meet the October 15 deadline each year, then VA cannot implement the updated ECLs/field definitions as specified, thus making this project unable to meet the Business Owners' needs.	The Business Owner will periodically reach out to their payer partners to determine readiness and as necessary implement a phased schedule for testing based on payer readiness.
This project is dependent upon VA being able to accept/transmit a defined set of data in the NCPDP standard format with our PBMs/payers. If our PBMs/payers do not send data as expected according to the standards, the system will not produce the expected outcome (increased efficiency in pharmacy third party billing).	The Business Owners will periodically reach out to their payer partners to determine readiness and as necessary implement a phased schedule for testing based on payer readiness.

Appendix A References

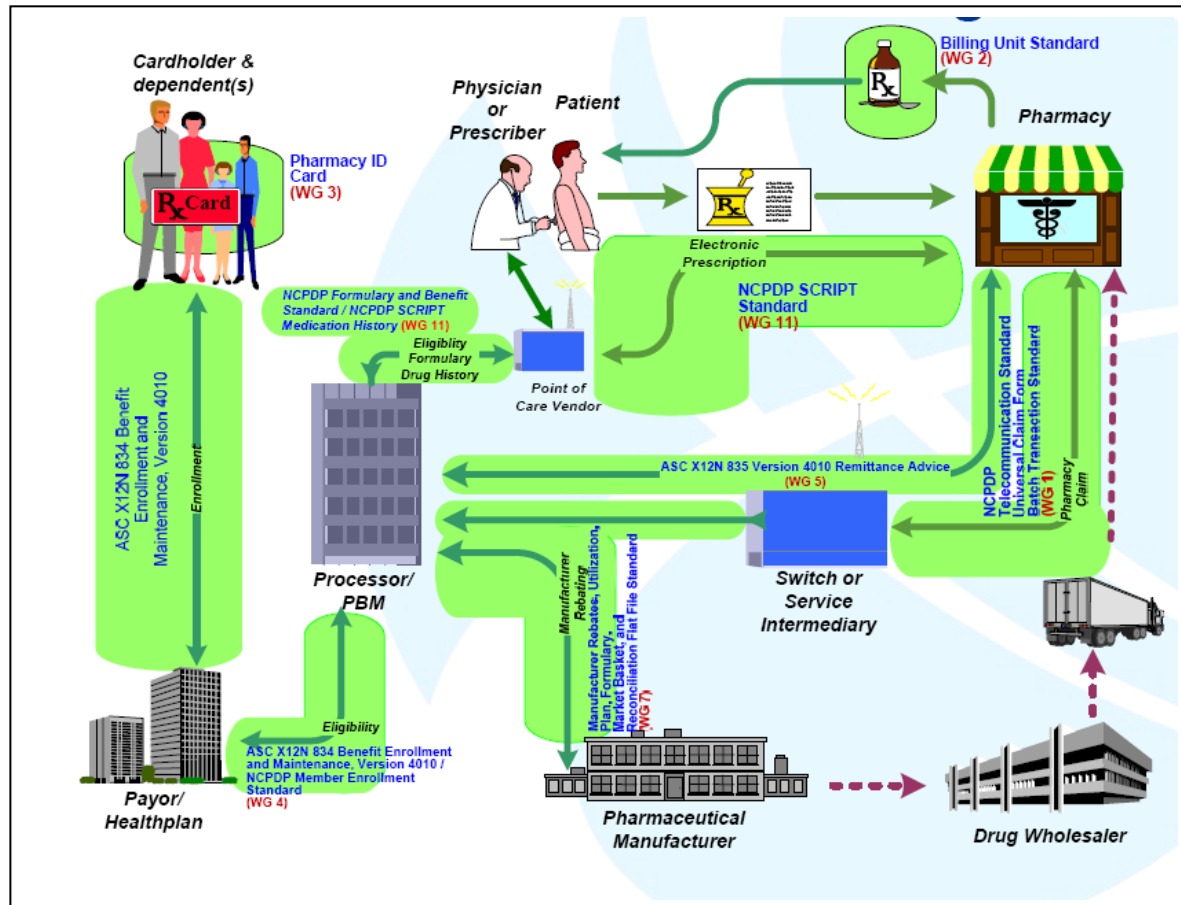
- Healthcare Insurance Portability and Accountability Act of 1996 (HIPAA)
<http://aspe.hhs.gov/admsimp/pl104191.htm>
- NSR #20140411 MCCF ePharmacy Compliance Phase 3
[REDACTED]
- Patient Protection & Affordable Care Act of 2010 (PPACA), Section 1104,
Administrative Simplification provisions
<http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>
- VA Handbook 6500 – Information Security Program
[REDACTED]

Appendix B Models

ePharmacy Process Flow: NCPDP Standards in the Information Exchange Process (As Is Model)



ePharmacy Process Flow: NCPDP Standards in the Information Exchange Process (To Be Model)



Appendix C Stakeholders, Users, and Workgroups

Stakeholders

Type of Stakeholder	Description	Responsibilities
Requester	██████████ EDI Transactions, eBusiness Solutions, CBO	Submitted request. Submits business requirements. Monitors progress of request. Contributes to BRD development.
Endorser	██████████, Deputy Chief Business Officer, CBO Revenue Operations	Endorsed this request. Provides strategic direction to the program. Elicits executive support and funding. Monitors the progress and time lines.
Business Owner/Program Office	██████████ Director, eBusiness Solutions, CBO	Provide final approval of BRD with sign-off authority. Provide strategic direction to the program. Elicits executive support and funding. Monitors the progress and time lines.
Business Subject Matter Experts (SMEs)	<ul style="list-style-type: none"> • ██████████ ██████████ ██████████ ██████████ ██████████ ██████████ ██████████ ██████████ ██████████ ██████████ 	Provide background on current system and processes. Describe features of current systems, including known problems. Identify features of enhancement.
Technical SMEs	<ul style="list-style-type: none"> ██████████ ██████████ ██████████ ██████████ ██████████ 	Provide technical background information about the current software and requested enhancements.

Type of Stakeholder	Description	Responsibilities
	Manager, ePharmacy • [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
User SME	[REDACTED]	Ensures that the enhancements will account for current business processes and existing software capabilities.

Stakeholder Support Team (BRD Development)

Type of Stakeholder	Description	Responsibilities
Health Care Security Requirements SME	[REDACTED]	Responsible for determining and providing guidance on compliance with the Health Information Portability and Accountability Act.
Service Coordination SME	[REDACTED]	Responsible for ensuring all aspects of non-functional requirements have been accurately recorded for this request.
Applied Informatics Management (AIM) Health Enterprise Systems Manager (ESM) and Staff	[REDACTED]	Serve as the liaison between the Program Office (Business Owner) and Product Development throughout the lifecycle.
Strategic Investment Management (SIM), Requirements Development and Management (RDM)	[REDACTED]	Responsible for working with all stakeholders to ensure this externally generated BRD have been accurately documented for this request.

Primary and Secondary Users

Type of User	Description	Responsibilities
Primary Users	OPECCs	Ensure electronic pharmacy claims are appropriately adjudicated by third party payers and resubmit rejected claims once reject issues are resolved.
Primary Users	Pharmacists	Processes all prescription related activities
Secondary Users	Veterans Integrated Service Network (VISN) Business	Oversee billing and collection activities at the VISN, VAMC and CPAC levels.

	Implementation Managers, VA Medical Center (VAMC)/Consolidated Patient Account Center (CPAC) Revenue Coordinators	
Secondary Users	CBO	Oversee revenue cycle operations, national payer relations and collections.
Secondary Users	VAMC Information Resource Managers (IRMs)	Provide on-site support for VistA system at each medical center.
Secondary Users	Product Support (PS)	Provide national user support.
Secondary Users	Veterans	Receive timely first party statements on recently dispersed prescriptions and medical care.
Secondary Users	ePharmacy Users	Process all prescription related activities.

Appendix D Usability

User Experience encompasses the entire interaction between the user and the system. This includes direct interaction with the system as well as other interactions, understanding, awareness, perceptions, beliefs, feelings, and actions that result from that interaction. One key component of the user experience is the usability of the system. Improving usability over the prior version is a key requirement for this application. The International Organization for Standardization (ISO) defines usability as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” (1998).

In order for this application to achieve a good user experience for users who interact with it, the system must meet the requirements outlined in this section. These involve attributes of the application as well as the process that is required to achieve them.

In order to improve usability of VA-developed or purchased applications, the following action are required:

- In accordance with the Office of the National Coordinator for Health Information Technology’s (ONCHIT) Meaningful Use (MU) Stage 2 final ruling, employ an industry recognized User Centered Design (UCD) process. The methods for UCD are well defined in documents and requirements such as ISO 9241–11, ISO 13407, ISO 16982, National Institute of Standards and Technology Interagency Report (NISTIR) 7741, ISO/International Electrochemical Commission (IEC) 62366, and ISO 9241-210. Developers will choose their UCD approach; one or more specific UCD processes will not be prescribed.
- Adhere to an industry recognized User Interface (UI) Best Practices Guideline or Style Guide. For example, first follow UI guidelines for the development platform. In instances where platform guidelines are not available, adhere to VA’s Best Practices Guidelines/Style Guide.
- Inform requirements and designs with detailed human factors work products that have been/will be completed for the specific project. Examples of specific human factors activities might include heuristic evaluations, site visits, interviews, application-specific design guides, and usability testing on existing systems or prototypes.

A sound UCD and development process based on human factors should include the following activities:

- Understanding of the users, the users’ tasks, and the users’ environments
- Review of similar or competitive systems to inform requirements and design
- Heuristic evaluation of prior versions, prototypes, or baseline applications, if applicable
- Iterative design and formative usability testing (formative usability testing is used to discover usability problems during the design and development process)
- User risk analysis
- Summative validation usability testing (summative usability testing is used to quantify and validate usability of a product with measures of effectiveness, efficiency, user perceptions, etc.)

To demonstrate high usability, the application should be:

- Intuitive and easy to learn with minimal training
- Effective by allowing users to successfully complete tasks
- Efficient by allowing users to complete their work in a manner consistent with clinical practice and workflow
- Perceived to have high usability, as demonstrated by appropriate survey measures
- Designed to aid users in meeting task goals without being an additional burden

The system must be reliable and enable user trust by providing:

- Stable and reliable performance
- Accurate data
- Display of all data that is available in native or interfaced systems and intended to be available in the application
- Accessible information related to the source of data

The application should include a modern Graphical User Interface (GUI) that allows the user to view data from multiple sources and include:

- Integrated display of structured and unstructured data
- Rich data visualization and graphical display of data
- Ability to switch between tabular and graphical data views
- Ability to interact with displayed data to obtain additional details related to the data and source of the data
- User customizable components and settings

The application must provide for advanced and up-to-date searching, to include:

- Fast, Google-like, Lucene search functionality with auto-complete and real-time display of matched results during typing
- Search history

The application must provide for advanced filtering capabilities, to include:

- Filtering of data tables, lists, and grids
- Filtering of search results

The application design should be modified to:

- Address the specific findings from a human factors heuristic evaluation conducted on the prior version of the application
- Address the specific findings reported from field use of the prior version
- Address the specific findings reported from usability testing of the prior version or relevant prototypes

ReqPro Tag	Usability/User Interface Requirements
NONF2661	Left align content in table cells to facilitate quick visual scan.
NONF2662	Left align text for column headers to facilitate visual scan and make columns and content appear more organized.
NONF2663	Use mixed case instead of all caps whenever possible (e.g., dropdown list items, table data, table headers, hyperlinks, tab names). Limit the use of “all caps” throughout the application.
NONF2664	Simplify button labels. Re-label buttons to reflect standard terminology that is common in web interfaces and other applications (e.g., “Cancel”). Emphasize the action being performed in the most succinct way possible. Minimize redundancy in text/terminology that is used to convey the same action.
NONF2665	Left align page/section titles to anchor titles in consistent locations regardless of window sizing.
NONF2666	Labels for fields should be left aligned to facilitate quick visual scan and make forms and field groupings appear more organized.
NONF2667	Avoid using acronyms or abbreviations unless (a) they are widely understood/well known or (b) there is very limited space to display the full meaning. This supports naïve user understanding. If limited space results in using a non-common acronym/abbreviation, ensure it is specified within “Help” and/or as a tooltip.
NONF2668	Use colors such as red and green only for status driven content. Avoid using red for text/content, links, button labels, etc. This will reduce risk for user error, improve link discoverability, and facilitate understanding of differences in navigation/actions/content. It will also help users to isolate important status information (using red, green, etc.) from other less important information when viewing and processing information provided to them on a page.
NONF2669	Provide visual separation between the navigation space and the main content area.
NONF2670	Add field level validation and notification of missing information on the same page without launching a new window or navigating to another page.
NONF2671	Make all text hyperlinks appear consistent in style.
NONF2672	Make drop-down selection box widths appropriate for content and visual appeal.
NONF2673	Use standard and always visible radio buttons for “Yes/No” options instead of requiring the user to click in a drop down box and then click to select the “Yes” or “No” option.
NONF2674	Use standard date and time selection widgets. Where date and time are selected/picked from a standard widget, also provide direct data entry to support keyboard navigation. Enable field level validation immediately upon entry. Include instructional format text within the field entry box.
NONF2675	Provide standard sort behavior and visual indications on columns in all tables.
NONF2676	Define and adhere to a standard model for use and design of controls, buttons, hyperlinks, and navigation elements.
NONF2677	Ensure that text is sized to be readable (for example, by using the 007 Rule to assure text size is readable for users with 20/40 vision. The formula: Text height = .007 * distance between eyes and screen).
NONF2678	Place common navigation elements in consistent locations.

ReqPro Tag	Usability/User Interface Requirements
NONF2679	Place critical information “above the fold” (i.e., in the top portion of the screen that is immediately viewable).
NONF2680	Use consistent screen flow models, elements, and terms to support similar workflows.
NONF2681	Use consistently named buttons when actions are the same (e.g., Add vs. Save vs. Submit).
NONF2682	Enable users to print views from where they are in the interface. Avoid requiring the user to “run a report” in order to print something that is viewable on the screen.
NONF2683	Provide field entry tool tips at the field location. Ensure consistency across the application in field labels, formats, location of tooltips, and tool tip text.
NONF2684	Provide visual indication of required fields.
NONF2685	Display field labels in close proximity to entry elements.
NONF2686	Use consistent elements to filter data.
NONF2687	Use consistent elements to sort data.
NONF2688	Use a consistent model for display, layout, and grouping of data entry fields.
NONF2689	Provide alternate row shading in lengthy tables of data, form elements, etc.
NONF2690	Ensure that icons are recognized by users.
NONF2691	Provide some “white space” between status icons in report views, white board views, etc.
NONF2692	Auto-populate default values in entry/selection fields when possible and appropriate.
NONF2693	Visually differentiate status icons from clickable icons, when appropriate.
NONF2694	Define and support the appropriate user tab sequence through fields in forms in order to support keyboard navigation when entering data in forms.
NONF2695	Define and adhere to standard action button placement on screens, forms, etc.
NONF2696	Visually distinguish the primary action button on a page.
NONF2697	Consistently use screen elements, action elements, workflow sequences within/across screens, language, etc.
NONF2698	Provide error messages in user-centric language with specific instructions on the meaning of the error and how to recover from it. Use error messages and method of display consistently across the interface.
NONF2699	Provide context-specific Help.
NONF2700	Do not use the term “sex” or any like abbreviations of that to represent gender.

Appendix E Enterprise Requirements

Below is a subset of Enterprise-level Requirements that are of particular interest to the business community. These requirements **MUST** be addressed within each project resulting from this work effort. If OI&T cannot address these Enterprise-level requirements, the Business Owners responsible for each area **MUST** be engaged in any waiver discussions prior to any decisions being made. This section is not meant to be a comprehensive list of all Enterprise-level requirements that may apply to this work effort and should not preclude the technical community from reviewing all Enterprise-level requirements and identifying others that should apply to this work effort as well.

Enterprise-level requirements are contained in the VA Requirements Management Repository (RMR). Contact the RMR Team to gain access to the RMR and to obtain the comprehensive allocation of Enterprise-level requirements for the project development iteration at VAOITOESEEnterpriseRequirementsManagement@va.gov.

Identifier	Requirement Type	Description
ENTR25	Security	<p>All VA security requirements will be adhered to. Based on Federal Information Processing Standard (FIPS) 199 and National Institute of Standards and Technology (NIST) SP 800-60, recommended Security Categorization is Moderate.</p> <p>The Security Categorization will drive the initial set of minimal security controls required for the information system. Minimum security control requirements are addressed in NIST SP 800-53 and VA Handbook 6500, Appendix D.</p>
ENTR10	Privacy	All VA Privacy requirements will be adhered to. Efforts that involve the collection and maintenance of individually identifiable information must be covered by a Privacy Act system of records notice.
ENTR95	508 Compliance	All Section 508 requirements will be adhered to. Compliance with Section 508 will be determined by fully meeting the applicable requirements as set forth in the VHA Section 508 checklists (1194.21, 1194.22, 1194.24, 1194.31 and 1194.41) located at: http://www.ehealth.va.gov/508/resources_508.html or as otherwise specified. Checkpoints will be established to ensure that accessibility is incorporated from the earliest possible design or acquisition phase and successfully implemented throughout the project.
ENTR7	Executive Order	All executive order requirements will be adhered to.
ENTR8	Identity Management	All Enterprise Identity Management requirements will be adhered to. These requirements are applicable to any application that adds, updates, or performs lookups on persons.
ENTR103	Terminology Services	Application/services shall reference the Standard Data Services (SDS) as the authoritative source to access non-clinical reference terminology.

Identifier	Requirement Type	Description
ENTR104	Terminology Services	Application/Services shall use the VA Enterprise Terminology Services (VETS) as the authoritative source to access clinical reference terminology.
ENTR105	Terminology Services	Applications recording the assessments and care delivered in response to an Emergency Department visit shall conform to standards defined by the VHA-endorsed version of C 28 – Health Information Technology Standards Panel (HITSP) Emergency Care Summary Document Using Integrating the Healthcare Enterprise (IHE) Emergency Department Encounter Summary (EDES) Component.
ENTR106	Terminology Services	Applications exchanging data summarizing a patient's medical status shall conform to standards defined by the VHA-endorsed version of C 32 – HITSP Summary Documents Using Health Level Seven (HL7) Continuity of Care Document (CCD) Component.
	AITC	Provides the connectivity between FSC and the Clearinghouse and must be consulted prior to testing.
	EDI Clearinghouse	The clearinghouse provides connectivity and communications with the PBMs/payers and must be consulted prior to testing.

Appendix F Acronyms and Abbreviations

OI&T Master Glossary:

Term	Definition
AIM	Applied Informatics Management
AITC	Austin Information Technology Center
ANR	Automated Notification Reporting
ANSI	American National Standards Institute
AR	Accounts Receivable
BN	Business Need
BRD	Business Requirements Document
CBO	Chief Business Office
CCD	Continuity of Care Document
CHAMPVA	Civilian Health and Medical Program of the Department of Veterans Affairs
CMOP	Consolidated Mail Outpatient Pharmacy
CPAC	Consolidated Patient Account Center
ECL	External Code Lists
ECME	Electronic Claims Management Engine
EDES	Emergency Department Encounter Summary
EDI	Electronic Data Interchange
eIV	Electronic Insurance Verification
ESM	Enterprise Systems Manager
FIPS	Federal Information Processing Standard
FMS	Financial Management System
FSC	Financial Services Center
GUI	Graphical User Interface
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HPID	Health Plan Identifier
IB	Integrated Billing
IEC	International Electrochemical Commission
IHE	Integrating the Healthcare Enterprise

Term	Definition
IPT	Integrated Product Team
IRM	Information Resource Managers
ISO	International Organization for Standardization
IT	Information Technology
MCCF	Medical Care Collection Fund
MU	Meaningful Use
NCPDP	National Council for Prescription Drug Programs
NDC	National Drug Code
NIST	National Institute of Standards and Technology
NISTIR	National Institute of Standards and Technology Interagency Report
NONF	Non-Functional Requirement
NSR	New Service Request
OI&T	Office of Information and Technology
ONCHIT	Office of the National Coordinator for Health Information Technology
OPECC	Outpatient Electronic Claims Coordinator
OWNR	Owner Requirement
PBM	Pharmacy Benefit Management
P.L.	Public Law
PPACA	Patient Protection and Affordable Care Act
PS	Product Support
RDM	Requirements Development and Management
RMR	Requirements Management Repository
RNB	Reason Not Billable
RRR	Reject Resolution Required
SDS	Standard Data Services
SIM	Strategic Investment Management
SLA	Service Level Agreement
SME	Subject Matter Expert
UCD	User Centered Design
UI	User Interface
VA	Department of Veterans Affairs
VAMC	Veterans Affairs Medical Center
VETS	VA Enterprise Terminology Services

Term	Definition
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture

Appendix G Approval Signatures

The requirements defined in this document are the high level business requirements necessary to meet the strategic goals and operational plans of the Chief Business Office. Further elaboration to these requirements will be done in more detailed artifacts.


Business Owner

Signifies that the customer approves the documented requirements, that they adequately represent the customers desired needs, and that the customer agrees with the defined scope.

Signed:

[REDACTED], Director for CBO eBusiness Solutions Date

/es/ [REDACTED] (9/3/14)


[REDACTED]


Business Liaison

Signifies appropriate identification and engagement of necessary stakeholders and the confirmation and commitment to quality assurance and communication of business requirements to meet stakeholder expectations.

Signed:

[REDACTED] ESM, Business Informatics Date

/es/ [REDACTED] (9/3/14)


20 [REDACTED] al

Office of Information and Technology

Indicates agreement that the requirements have been received, are clear, understandable, and are documented sufficiently to facilitate project planning when the project is approved and funded. It is understood that negotiations may need to occur with the business during project planning as a result of technical reviews and feasibility.

Signed:

[REDACTED], Supervisory Program Analyst, OIT, VHA

Date



FW Acceptance of
NSR Requirements an