

# **Department of Veterans Affairs**

## **Multiple Sclerosis Surveillance Registry (MSSR)**

### **Requirements Specification Document**



**December 2013**

**Version 1.0**

## Revision History

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

Date	Version	Description	Author
12/10/2013	1.0	<ul style="list-style-type: none"><li>Removed comments and accepted approved changes only.</li></ul>	
11/26/2013	0.4	<ul style="list-style-type: none"><li>Corrected version numbering to reflect draft versioning.</li><li>Updated section 2.2 Business Rules based on PWS and BRD business requirements.</li><li>Updated section 2.3 Design Constraints to include more design constraints.</li><li>Updated section 2.4 to reflect no applicable Disaster Recovery requirements.</li><li>Per Stakeholders and PMO, updated section 2.5 with a list of the applicable CLIN deliverables.</li><li>Updated sections 2.6.1.1-2.6.1.4, 2.13 per Stakeholders input.</li></ul>	
11/25/2013	0.3	Business Stakeholder input	
11/8/2013	0.2	Re-formatted to current VA PMAS/ProPath template.	
10/31/2013	0.1	Initial Baseline Draft submitted for CLIN 0002AA acceptance on W	

## Artifact Rationale

The Requirements Specification Document (RSD) records the results of the specification gathering processes carried out during the Requirements phase. The RSD is generally written by the functional analyst(s) and should provide the bulk of the information used to create the test plan and test scripts. It should be updated for each increment.

The level of detail contained in this RSD should be consistent with the size and scope of the project. It is not necessary to fill out any sections of this document that do not apply to the project. The resources necessary to create and maintain this document during the life cycle of a large project should be acknowledged and clearly reflected in project schedules. Do not duplicate data that is already defined in another document or a section in this document; note in the section where the information can be found.

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# 1. Introduction

In response to Congressional legislation, the VHA established two Multiple Sclerosis Centers of Excellence (MSCoE) in 2003. These Centers (East and West) were subsequently made permanent by “The Veteran’s Benefits, Healthcare and Information Technology Act of 2006”. The MSCoEs were mandated to report on the epidemiology, healthcare use, and costs of the Veteran Multiple Sclerosis (MS) population. Current tools to date have failed to fulfill this mandate that is critical to all MSCoE functions. A VHA Handbook entitled Multiple Sclerosis System of Care Procedures 1011.06, was released to the field on December 7, 2009. This approved Handbook (which includes reference to the Congressional Mandate for the MSCoE) established policy and procedure for healthcare services for patients with MS and requires ongoing surveillance of this patient population.

The goal of this procurement is to create a surveillance system for the entire MS patient population within VHA. This objective will be met through the collection of clinical utilization, demographic, and epidemiologic data. The scope entails the creation of a front end portal within the Computerized Patient Record System (CPRS) for the entry of data by clinicians, as well as a back end data storage capability. The portal tool will be triggered annually for any patient with an MS diagnosis and will provide a user interface for data entry into the database. The tool will prompt providers to enter standard demographic and clinical variables important for clinical, quality improvement, and research activities mandated by VHA (which can be found in Appendix C of the VHA Handbook, Multiple Sclerosis System of Care Procedures 1011.06). Data shall be stored centrally at the enterprise level.

VA also requires development of a new registry system leveraging VA’s existing Converged Registries Solution (CRS) to provide clinical data surveillance tools and a back end registry database for surveillance of the entire MS population within VHA, along with software enhancements to the following existing systems: Converged Registries Solution, Traumatic Brain Injury Registry, Oncology Registry, and Clinical Case Registry. Both MSCoE (East and West) require real-time access to this data, so to provide up-to-date surveillance data on the MS patient population. Relevant clinical and administrative data from other VHA databases, such as VistA, (made available to the MS Registry) shall be aggregated and reported as required to allow for systematic evaluation and analysis. This effort is intended to provide VHA with a population- focused perspective for the MS patient population.

## 1.1. Purpose

The purpose of this Requirements Specification Document (RSD) is to present decomposed requirements from the Multiple Sclerosis Surveillance Registry (MSSR) Business Requirements Document (BRD) and requirements gathering sessions for MSSR development. The decomposed requirements consist of the functional, non-functional, and technical specifications described in Section 3 Overall Specifications.

This RSD enlists all necessary requirements that are required for project development. To derive the requirements, we need to have a clear and thorough understanding of the products to be developed, which is determined after detailed communications with key stakeholders from the Multiple Sclerosis Center of Excellence (MSCoE) and the Northwest Innovation Center.

This document is directed at a broad audience of stakeholders external and internal to the project team. These stakeholders include, but are not limited to, the Multiple Sclerosis Center of Excellence (MSCoE) and Northwest Innovation Center, Business Owners, Architect, and the Project Team (see Table 1 below).



**Table 1. Key Stakeholders for MSSR RSD**

Key Stakeholder	Purpose
Multiple Sclerosis Center of Excellence (MSCoE) and Northwest Innovation Center	Key stakeholders who provide guidance relative to the development of the MSSR.
Business Owners	Provide oversight for and business knowledge to the project team.
Architect	Design and implement registry architecture.
Project Team	Design, build, implement, integrate and deploy the registry.

## 1.2. Scope

The MS Registry will provide the Program Office with the ability to create new policies, programs, and plans and support the needs of the Department of Veterans Affairs (VA) MS population. The mission of the MSCoEs is to support and maintain the health, independence, quality of life, and productivity of Veterans with MS through clinical care, education, and research. The MS Regional Programs are responsible for ensuring the MS patients in their region are evaluated at least annually either at MS support programs (spoke facilities) or at the Regional Center site. This request directly supports the mission of the MSCoEs as well as meeting the intent of the legislation: ‘Veterans Benefits, Healthcare, and Information Technology Act of 2006’. S.3421, Title II, Sec 209, ‘(G).

The goal of this effort is to create a surveillance system for the entire MS patient population within VHA. This objective will be met through the collection of clinical utilization, demographic, and epidemiologic data.

The scope of this RSD is specific to the MSSR development project, and involves the creation of a front end portal within the Computerized Patient Record System (CPRS) for the entry of data by clinicians, as well as a back end data storage capability. The portal tool will be triggered annually for any patient with an MS diagnosis. This portal tool will provide a user interface for data entry into the database. The tool will prompt providers to enter standard demographic and clinical variables important for clinical, quality improvement, and research activities mandated by VHA, which can be found in Appendix C of the VHA Handbook, MULTIPLE SCLEROSIS SYSTEM OF CARE PROCEDURES 1011.06.

## 1.3. References

- Multiple Sclerosis Surveillance Business Requirements Document (BRD), Work Effort Unique Identifying Number 20100105; March 2010, Attachment 001  
[REDACTED]
- Multiple Sclerosis Surveillance Registry T4 Performance Work Statement, 8/28/2013  
[REDACTED]
- VHA Handbook, Multiple Sclerosis System Of Care Procedures 1011.06,  
[REDACTED]
- VA Information And Information System Security/Privacy Language VA Handbook 6500.6, Appendix C, March 12, 2010, Attachment 002  
[REDACTED]

## 2. Overall Description

Data would be stored centrally at the enterprise level. MSCoE business owners require real-time access to these data. The MSCoE data store will provide up-to-date surveillance data for the MS patient population.

Relevant clinical and administrative data from other VHA databases, such as VistA, would also be made available to the MS Registry. Data will be aggregated and reported as required to allow for systematic evaluation and analysis. This effort is not intended to replicate individual patient records, but to provide VHA with a population-focused perspective for the MS patient population.

The new MS Surveillance Registry shall be developed by leveraging VA's existing Converged Registries Solution (CRS) to provide clinical data surveillance tools and back end registry database for surveillance of the entire MS population within VHA. In accordance with the Multiple Sclerosis Surveillance BRD, the MS Surveillance Registry shall include a front end portal within the Computerized Patient Record System (CPRS) that supports entry of data by Providers, as well as a back end data storage capability.

## **2.1. Accessibility Specifications**

This MS registry shall be developed in compliance with the VA requirements for Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d). Section 508 requirements are listed on the VA Section 508 Office website at [REDACTED]

## **2.2. Business Rules Specification**

Per the MSSR Performance Work Statement (PWS) and Business Requirements Document (BRD), the Business Rules are described as follows:

### **INCREMENT 1:**

**Business Need 1: Ability, within VHA, to track and monitor the MS patient population by creating a national software system wherein all clinicians can enter MS data for their patients.**

- The MS Registry will incorporate data from the CDS Tool, along with other relevant clinical databases for clinical monitoring.
- The MS Registry will provide data for longitudinal analyses of the MS population.
- The CDS tool MSAT is the portal for entry of data into the MSSR Registry by clinicians at the point of care.
- The MSSR Registry will securely receive data from source databases and provide time relevant and data indicators of how current the data is – e.g., date/time stamps.

### **INCREMENT 2:**

**Business Need 2: Provide tools and utilities to retrieve, extract, analyze, and report data from the MS Registry**

- Tools will be provided to retrieve, analyze, and display data within a user interface.
- The reporting tools will provide capability to generate standard and ad hoc individual and aggregated reports.

**Business Need 3: The MS system must be able to display data from VistA.**

- The MS Registry must be able to display clinical and administrative data.
- The MS Registry will have storage capacity from other relevant VHA data sources.

## **2.3. Design Constraints Specification**

Design constraints for this development effort are as follows:

- SQL Server 2008R2 (v10.5) for back end development
- Visual Studio 2008 for RTC compatibility and 2010 for code development
- .Net programming language and framework for front end development
- Any other design constraints directly or indirectly imposed by the following:
  - Existing or enhanced Converged Registries Solution (CRS) architectural framework
  - Future bug fixes or defects resolved by the Registries Support team
  - Austin Information Technology Center (AITC), due to capacity or access limitations

## **2.4. Disaster Recovery Specification**

There are currently no applicable Disaster Recovery specifications identified for MSSR.

## **2.5. Documentation Specifications**

Per the VA PMAS/ProPath methodology, the documentation specifications are as follows:

- Contractor Project Management Plan (CPMP) (CLIN 0001AA), which includes the Communication Plan (CLIN 0001AD), Risk Management Plan (CLIN 0001AK), and Configuration Management Plan (CLIN 0002AF) – Per the Project Management Body of Knowledge (PMBOK), the CPMP or PMP is "a formal, approved document used to guide both project execution and project control. The primary uses of the project plan are to document planning assumptions and decisions, facilitate communication among stakeholders, and document approved scope, cost, and schedule baselines. A project plan may be summarized or detailed.
- Project Risk Registry (CLIN 0001AL) – a Risk Management tool commonly used in Project Management and organisational risk assessments. It acts as a central repository for all risks identified by the project or organisation and, for each risk, includes information such as risk probability, impact, counter-measures, risk owner and so on. It can sometimes be referred to as a Risk Log.
- Integrated Master Schedule (IMS) (CLIN 0001AJ) – a Program Management tool that provides assistance in the planning and scheduling of work efforts and accomplishments necessary to complete the work and tie each accomplishment to a key program event. It is time-based to produce a networked and multi-layered schedule showing all detailed tasks required to accomplish the work effort contained in the CPMP.
- Requirements Specification Document (RSD) (CLIN 0002AA) – a complete description of the behavior of the system to be developed, and may include a set of use cases that describe interactions the users will have with the software. In addition, it contains the business requirements and technical requirements (functional and non-functional), and enlists all necessary requirements that are required for successful project development. Requirements are derived and prepared, after detailed communications with the business stakeholder and project team.
- Requirements Traceability Matrix (RTM) (CLIN 0002AB) – a document, usually in the form of a table, that correlates any two baselined documents that require a many-to-many relationship to determine the completeness of the relationship. It aligns the business requirements, technical requirements (functional and non-functional) with the correlating test cases. It will be generated in using Rational Team Concert (RTM).
- Software/System Design Document (SDD) (CLIN 0002AC) - a written description of a system to provide overall architectural guidance. An SDD usually accompanies an architecture diagram with pointers to detailed feature specifications of smaller pieces of the design.

- Interface Control Document (ICD) (CLIN 0002AD) - describes the interface or interfaces between subsystems or to a system or subsystem.
- Operations Acceptance Plan (OAP) (CLIN 0002AE) – a plan used to conduct operational readiness (pre-release) of a system as part of a quality management system. The plan focuses on the operational readiness of the system to be supported, or which is to become the production environment.
- MSSR Release Package (CLIN 0002AG) – per the Austin Information Technology Center (AITC), a software release package includes the software code, a detailed Installation Guide, detailed and tested Back-Out Plan, Installation files and/or scripts staged in an agreed to location, updated and current requirements and design documentation (e.g., RSD and SDD).
- Test Readiness Review (TRR) Package (CLIN 0002AM) - a review of the plan and procedures status, procedure deviations, known problems, requirements and performance metrics, test schedule, and other information relevant to beginning of testing phase
- Master Test Plan (MTP) (CLIN 0002AN) - a document detailing a systematic approach to testing the system. It documents items to be tested, test strategy, test criteria, test deliverables, test schedule, test environments and locations, test data, staffing needs, risks and constraints, and test metrics .
- Software Code (CLIN 0002BT) –a single, comprehensive “product” which shall include the final tested code, free of all application defects, and a final comprehensive set of documentation that addresses all application capabilities
- Defect Resolution Plan (CLIN 0002BY) – a plan detailing how defects are prioritized, scheduled, fixed, and reported. It also includes a timeline for resolution and impacts to both the Software Code and documentation.
- Defect/Fix Status Report (CLIN 0002BZ) – a report detailing the status of any defects found and fixed
- Implementation and Operations Plan (CLIN 0002CC) – a plan that defines: all technical and physical requirements for hosting, housing, operating and maintaining the Registry hardware and software, all requirements associated with initial installation/implementation, any security processes and procedures to ensure compliance with security requirements defined herein, and maintenance and upgrade timelines.
- Knowledge Transfer Materials (CLIN 0002CD) – material and a 4-hour knowledge transfer virtual session to familiarize the project team with the Registry’s functional and technical features, and maintenance considerations so to minimize VA missteps in the management, administration and operational support of the MS Surveillance Registry and all Registry enhancements.

## 2.6. Functional Specifications

### 2.6.1. Increment 1

**Business Need 1: Ability, within VHA, to track and monitor the MS patient population by creating a national software system wherein all clinicians can enter MS data for their patients.**

#### **2.6.1.1 The MS Registry will incorporate data from the CDS Tool, along with other relevant clinical databases for clinical monitoring.**

- The CDS Tool is now called the MS Assessment tool(MSAT).
- The national MSSR should allow for input and display of MS unique health factors, and gather demographic and clinical data, such as race, sex, dates of MS onset/diagnosis, disability, and medication. The data to be included are itemized below. Based on discussion



at the most recent MSSR stakeholder meeting on 11/21/13, it appears that all of these data sources are now available from CDW.

- Inpatient Utilization
  - Outpatient Utilization
  - Health Economics Resource Center (HERC) Cost - generated annually following final adjudication of utilization files
  - Decision Support System (DSS) Pharmacy
  - Decision Support System (DSS) Laboratory
  - Decision Support System (DSS) Radiographic
  - Decision Support System (DSS) Costs
  - Vital Status
  - Vital Signs
  - Prosthetics
  - Veterans Benefits Administration (VBA) Enrollment
  - Veterans Benefits Administration (VBA) VetsNet
  - Veterans Benefits Administration (VBA) CnP mini
  - Multiple Sclerosis Assessment Tool (MSAT)
- The MSAT is a web-based application developed by the Northwest Innovation Center, who will provide the Test Patient Data.
  - A true functional surveillance relational database is desired out of the national MSSR. The data that should be incorporated and collected include healthcare utilization/encounter data, DSS pharmacy, DSS laboratory data, healthcare costs, in home modifications, prosthetics, walkers, canes, etc.
  - The data sources consist of CDW and Medical Domain Web Services (MDWS).
  - Relevant clinical databases include pharmacy, costs, inpatient/outpatient care from New Patient Treatment File (NPTF), and new interfaces to various databases in the VA network (networks to be defined). See above for specification of data sources to be included in the MSSR.
  - Clinical monitoring is required “once a year.” This low-level monitoring should note the patient's point of entry for the initial visit, any updates to medications, other medications in use, ER visits, and treatments. System use, patient status, disability status, and medication purposes and interactions may change. This functionality is currently built into the MS Assessment Tool.
  - Data entry functionality for patient related notes is necessary.
  - Editable Query capabilities should be developed or enhanced, based on existing reports.

- The local MS registry data is not associated with any other applications in the current version. However, in the future, the web-based Care Management tool may be integrated with the local MS registry to help facilitate task management, but it does not use CPRS, as it is free-standing.
- 7-Delta will research and explore a means for entry of the MSAT data through a web-based form (e.g. TBI Registry) to populate the MSSR with patients from across VISN lines or in remote areas of United States far away from a MSCoE Regional Center. For example, when a patient visits two different VISNs, their entry needs to be accounted, so perhaps a note may be entered from one VISN be pushed to a VistA instance into a different VISN.

#### **2.6.1.2 The MS Registry will provide data for longitudinal analyses of the MS population.**

- The national MSSR should provide the following types of data: Utilization, Cost, Pharmacy, Prosthetics, Historical Data, Treatment Pattern changes, Drug Usage changes, number of annual visits, and the number of admissions. It should track the trends at a national level.
- For the purpose of this project, longitudinal analysis means simply a study of variables impacting MS patients over time, and should provide the ability to track trends regarding the data types noted above. Analysis can vary.
- The data sources consist of CDW.
- The data is not associated with any other applications and/or Registries. Data is transferred uni-directionally, and no MS data is pulled into any other registry. No real-time data is retrieved, and all data is moved between systems during a nightly batch process; therefore, all data is only as current as the previous day.
- Expectations of real-time data integration are to be determined. A quarterly or annual collection for some databases may be feasible.

#### **2.6.1.3 The MSAT is the portal for entry of data into the MSSR by clinicians at the point of care.**

- Security Permissions are required, but it is access-level dependent. Clinicians may see data from their local area, but not necessarily regional or national data.
- The local MS registry is the point of entry for the clinicians that should feed into the national MSSR. Clinicians and CO enter data into the CPRS template and currently, 25,000-30,000 patients are estimated at the national level albeit less than 1,000 patients are currently registered in the local MS registry.
- The national MSSR should allow some data to the clinicians, as they should have access to their local facility and data related to their patients' data. This functionality is essentially already built into the MSAT.
  - However, should a local provider require access to national data via the MSSR, those requests should be made through the MSCoE-East business owners.
  - A formal request process will need to be developed. For those clinicians in the field who are not part of MSCoE, their access should be limited to only their patients.
  - Requests for access to national data to be routed to Joel and Mitch.

- The backend and Administrative features should only be available to highest level of authority i.e., Directors of MSCoE and Northwest Innovation Team.
- Leveraging the existing Registries security protocols, the appropriate access will be permitted to various clinicians.
- The local MS registry should feed into the national MSSR, similar to TBI and TBI Instruments.
- The national MSSR should be enhanced to allow each location to view data by location. Currently, only 4 locations have this ability, so a list of all possible locations is still to be identified. This information will need to be integrated into the framework to bring those sites online. Their users and access levels will need to be defined, as well. Local clinicians can view their facility and VISN patients via functionality within the MSAT. Independent access to national data (MSSR) shall not be granted. All such requests should be process through the MSCoE-East business owners.
- The collected data is gathered through the CPRS template and displayed at the local level in the local MS Registry.

#### **2.6.1.4 The MSSR will securely receive data from source databases and provide time relevant data indicators – e.g., date/time stamps.**

- The security measures required include clinicians having local patient access, CPRS template information, but national data should be restricted to higher permission levels.
- MSCoE requires aggregated national data to be pulled with only full access granted to the MSCoE Directors and key members of the Northwest Innovation Center.
- Regarding User Permissions, clinicians like Neurologists and Nurse Practitioners should have local data access, but administrative/clerical staff should not have access.
- Possible User Roles are to be defined once the Active Directory Groups are determined.
- Current data is retrieved from CDW, MDWS, Decision Support System (DSS) for Cost data, and Health Econ.
- The national MSSR should allow manual entry of Fee Based data, which are private sector clinical visits, medications purchased outside of the VA, etc.
- With regard to real-time data, other data that is required includes encounter and pharmacy data changes over the year, and updates that occur within VA impact the data on file. After adjudication, data is reviewed and confirmed on site annually.
- Frequency of updates and currency of data is still to be determined, whether monthly, quarterly, or annually.
- The current paradigm for other registries associates patient records by 'Update By,' 'Create Date,' and 'Update Date.' The report should include the following: CDW (patient, pharmacy data), "Update Date" (currently not pulled), the data pull date from CDW, and "Updated By" (Role/User ID or Name).
- The national MSSR is not responsible for determining most recent data, as it should be evaluated and confirmed before acceptance.

- The national MSSR should provide a series of historic records by date e.g., Type of Exam: Initial, Annual, Follow up, Relapse. A Longitudinal DB is in progress.
- The Clinicians should always see the most recent data, but the higher levels of access should have the ability to see all parameters of the national data.

## **2.6.2. INCREMENT 2 (to be fully vetted at a later date)**

**Business Need 2: Provide tools and utilities to retrieve, extract, analyze, and report data from the MS Registry**

**2.6.1.5 Tools will be provided to retrieve, analyze, and display data within a user interface.**

**2.6.1.6 The reporting tools will provide capability to generate standard and ad hoc individual and aggregated reports.**

**Business Need 3: The MS system must be able to display data from VistA.**

**2.6.1.7 The MS Registry must be able to display clinical and administrative data.**

**2.6.1.8 The MS Registry will have storage capacity from other relevant VHA data sources.**

## **2.7. Graphical User Interface (GUI) Specifications**

The graphical user interface (GUI) shall meet the national registry requirements for aesthetics in “form, fit, and function”.

## **2.8. Multi-divisional Specifications**

Multi-divisional Specifications are described in the Converged Registries Solution (CRS) Requirements Specification Document (RSD).

## **2.9. Performance Specifications**

The performance measures for the national MSSR are as follows:

<b>Success Factors</b>	<b>Measurement</b>
A national Multiple Sclerosis data store is created.	The MSCoE staff will work with MS Regional Centers to maintain a national data store of MS patients. 100% of VA patients diagnosed with MS will be tracked through the new Multiple Sclerosis software system.
Clinicians are able to enter a patient’s data into the MS Registry.	Clinicians at all facilities can access the MS tool and enter their patients’ data into the software application.
Users can track and monitor the population of Veterans with MS.	The MS source data is available 100% of the time, it is available real-time and available for report generation.

## 2.10. Quality Attributes Specification

Quality Attributes specifications are described in the Master Test Plan.

## 2.11. Reliability Specifications

Reliability Specifications are described in the MSSR Performance Work Statement (PWS).

## 2.12. Scope Integration

Scope Integration are described in the Software Design Document (SDD) and Interface Control Document (ICD) for MSSR.

## 2.13. Security Specifications

Security will be provided for the national MSSR through access control. Three layers of access will be administered including the following:

**Enterprise Access:** To be granted to users requiring reports and information on an enterprise level. Enterprise access will also include access to VISN level and Local level functionalities.

**VISN Access:** To be granted to users requiring reports and information on a VISN specific level. The access will be restricted to reports and information from that user's assigned VISN. VISN level access will also include Local level functionality for sites within the VISN.

**Local Level:** To be granted to users requiring reports and information on a Local level. Users with Local Access will be restricted to reports and information for their assigned location. Local users will not have access to VISN or Enterprise reports or information. Local level will be the most restrictive level of access.

The three levels of access will be maintained as part of the national MSSR. Access will be granted and controlled by the MSCoE Business Owners, consisting of Dr. Mitch Wallin, Dr. Joel Culpepper, the Northwest Innovation Center team, and Shan Jin (Programmer for Dr. Culpepper). Users will be required to enter a user ID and password to access the MSSR interface. Users entering incorrect user ID or password will be presented a pop-up notification. After three attempts, the user will be locked out of the system. Passwords will be reset by Remedy Help Desk.

The entire MSSR interface will reside within the VA Firewall.

Access to the MSSR components will be controlled through the use of a user security key. The user security key will be created by the MSSR team and released with the MSSR components.

In addition to the specified access controls, MSSR will conform to all enterprise security requirements and Certification and Accreditation (C&A) requirements.

The registry shall comply with all Enterprise requirements:

- The System shall accomplish User authentication through Microsoft Active Directory (AD) Services.
  - Access to VA information systems shall be controlled and limited based on positive identification and authentication mechanisms when possible.
- The System shall be compliant with the Health Insurance Portability Accountability Act (HIPAA).
- The System shall be compliant with the Privacy Act of 1974.
- All communications will be protected in accordance VA Information Security standards.



- The System shall inform users concerning authorized or appropriate use, either through a logon banner or a notification.
- The System shall limit access to Protected Health Information (PHI) based on the functional role of the user.

## **2.14. System Features**

System Features include utilization data and data useful for research studies and reporting at the Central Office (CO) level.

## **2.15. Usability Specifications**

See section 2.9 Performance Specifications.

## **3. Applicable Standards**

The applicable standards are as follows:

- VHA Handbook, Multiple Sclerosis System Of Care Procedures 1011.06,  
[REDACTED]
- VA Information And Information System Security/Privacy Language VA Handbook 6500.6,  
Appendix C, March 12, 2010, Attachment 002  
[REDACTED]

## **4. Interfaces**

### **4.1. Communications Interfaces**

There are no Communication Interfaces.

### **4.2. Hardware Interfaces**

There are no Hardware Interfaces.

### **4.3. Software Interfaces**

The Software Interfaces include the following:

- Interface with relevant existing VHA clinical & administrative databases, for clinical and demographic information.
- Consider leveraging the existing Office of Information and Technology (OI&T) Registries Convergence project, which provides a common registries platform/architecture on the front and back ends, along with common tools for retrieving, analyzing, and reporting registry data.
- Consider identification of patient with MS diagnosis from the CPRS Problem List, VistA (such as Patient Treatment File – PTF and Patient Care Encounter File – PCE).

## 4.4. User Interfaces

The user interfaces consist of the Computerized Patient Record System (CPRS) and the local MS registry.

## 5. Legal, Copyright, and Other Notices

Legal, Copyright, and Other Notices are described in the MSSR Performance Work Statement (PWS).

## 6. Purchased Components

There are no purchased components.

### 6.1. Defect Source (TOP 5)

The Defect Source (TOP 5) is described in the MSSR Defect/Fix Status Report.

## 7. User Class Characteristics

The intended users of the MSSR are described in Table 2 below.

**Table 2. Intended User General Characteristics**

Intended User	Educational Level	Experience	Technical Expertise	MSSR Level of Access
MSSCoE Directors	High	High	High	Full
NW Innovation Center	High	High	High	Full
Clinicians	Varies	Varies	Low	Local VISN
Administrative / Clerical Staff	Varies	Varies	Low	None

## 8. Estimation

Estimation is described in the MSSR Integrated Master Schedule (IMS).

## 9. Approval Signatures


REVIEW DATE: 11 December 2013


SCRIBE: N/A


Signed:


	, Business Sponsor	Date
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	Business Sponsor	Date
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	IT Program Manager/IPT Chair (VA)	Date
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	Project Manager (VA)	Date
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	Program Manager (7Delta)	Date
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	Project Manager (7Delta)	Date
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