

FDA Medication Guides Project INSTALLATION GUIDE

PSS*1*158 PSN*4*263 PSO*7*343

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Department of Veterans Affairs Product Development

Revision History

Date	Revision	Description	Author
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Purpose

The purpose of this Installation Guide is to provide an explanation of the installation and implementation process for the Food and Drug Administration (FDA) Medication Guides Increment 2 project.

The intended audience for this document is the Information Resources Management Service (IRMS) staff responsible for installing patches and Outpatient Pharmacy staff responsible for maintaining the pharmacy files.

Scope

The Outpatient Pharmacy application is being modified to allow pharmacists to manually display FDA Medication Guides for a specific prescription when one is available. The National Drug File application is also being modified to allow users to retrieve and print the FDA Medication Guides for specific VA Product entries when one is available. A Java software component is being created specifically for this project to allow the retrieval of the FDA Medication Guide from a web server repository via a web browser. This software must be installed in the user's computer for the functionality to work correctly.



Before You Begin

This document is organized into two major sections: "Pre-Installation" and "Installation of Patches and Java Component."

It is expected that most sites will install the software and not immediately implement the new interface. This approach is recommended.

Having the proper setup of parameters and settings is critical to the success of the implementation.

Section 1: Pre-Installation

This section provides information that helps you determine patch and system requirements before installing the patches that are included in this project. It also helps you understand the updates that the installation process makes. Additionally, descriptions are provided regarding the specific parameters that you must set up to implement the interface.

Documentation

Documentation distributed with the FDA Medication Guide project includes the following and may be retrieved from the VISTA Documentation Library (VDL) on the Internet at the following address: <u>http://www.va.gov/vdl</u>.

File Names	Description
PSO_7_PHAR_UM_R0411.pdf	Outpatient Pharmacy User Manual
PSO_7_P343_PHARM_UM_CP.pdf	Outpatient Pharmacy User Manual Change Pages
PSO_7_TM_R0411.pdf	Outpatient Pharmacy Technical Manual
PSO_7_P316_P343_TM_CP.pdf	Outpatient Pharmacy Technical Manual Change Pages
PSN_4_UM_R0411.pdf	National Drug File User Manual
PSN_4_P262_P263_UM_CP.pdf	National Drug File User Manual Change Pages
PHAR_FDA_MED_GUIDE_REL2_RN.pdf	FDA Medication Guides Project Release Notes
PHAR FDA MED GUIDE REL2 IG.pdf	FDA Medication Guides Project Installation Guide

System Requirements

The FDA Medication Guide project operates on standard hardware platforms used by the Veterans Health Administration (VHA) facilities and requires the following Department of Veterans Affairs (VA) software packages to support the enhancements in this project. The new interface requires that the Department of Veterans Affairs (VA) software packages and the latest version and most current released patches of the HL7, Inpatient Medications, Drug Accountability, Bar Code Medication Administration, and Controlled Substances applications must be running on the VistA server.

New functionality is being added to the Outpatient Pharmacy V.7.0, Pharmacy Data Management V.1.0 and National Drug File V.4.0 applications to allow users to manually display the associated FDA Medication Guide for a specific prescription or a VA Product, if one is available.

Package	Minimum Version Needed
VA FileMan	22.0
Kernel	8.0
MailMan	8.0
Health Level 7	1.6
Order Entry/Results Reporting	3.0
Inpatient Medications	5.0
Nursing	4.0
Outpatient	7.0
Pharmacy Data Management	1.0
Controlled Substances	3.0

Toolkit	7.3
Drug Accountability	3.0
BCMA	3.0

The above software is not included in the Master Build and must be installed before the build is completely functional.

User Interfaces

This software product will conform to the existing VistA conventions found in the Outpatient Pharmacy package. The reports, option and screen formats will conform to the existing VistA conventions. Report formats and option process steps, such as "roll & scroll" will be field tested for usability by test site personnel to ensure that all new functionality meets the needs of the VHA user.

Hardware Interfaces

The product will run on standard hardware platforms that Department of Veterans Affairs Healthcare facilities use. These systems consist of standard or upgraded Alpha AXP clusters and operate either VMS or NT and Open M products.

The primary hardware interface to consider in this enhancement is the software settings that will drive the printing of FDA Medication Guides.

Software Interfaces

An interface between Outpatient Pharmacy V.7.0 and NDF V.4.0 is required to manage the FDA Medication Guide output for this enhancement. Existing interfaces with other applications to support prescription processing will be maintained for this enhancement.

User Characteristics

The intended users of the FDA Medication Guide Project will include pharmacists, pharmacy technicians, and veteran patients and their families.

Acronyms

Term	Definition		
API	Application Programming Interface		
CFR	Code of Federal Regulations		
СМОР	Consolidated Mail Outpatient Pharmacy		
FDA	Food and Drug Administration		
NDC	National Drug Code		
NDF	National Drug File		
OPAI	Outpatient Pharmacy Automation Interface		
PDF	Portable Document Format		
PMI	Patient Medication Information		
PBM	Pharmacy Benefits Management		
PSN	National Drug File Application Namespace		
PSO	Outpatient Pharmacy Application Namespace		
URL	Uniform Resource Locator		
VistA	Veterans Health Information Systems and Technology Architecture		
SDD	Software Design Document		

Dependencies and Constraints

Pharmacy Benefits Management (PBM) policies and FDA regulations exist that define which prescriptions contain FDA Medication Guides. These should not be modified without guidance from PBM.

Data Dictionary Updates

For NDF

Modified Routines

The following routines were modified:

- PSNMEDG
- PSNFDAMG
- PSNAPIS

Modified Field

The following new field was added to the VA PRODUCT File (#50.68):

• FDA MED GUIDE field (#100)

Modified Menu Option

The following menu option was modified:

• Display FDA Medication Guide [PSN MED GUIDE]

For VA Medical Center

New Routine

The following new routine was added:

• PSOFDAMG

New Protocol

The following new protocol was added:

• PSO LM DISPLAY FDA MED GUIDE

Modified Protocol

The following protocol was modified:

• PSO LM HIDDEN OTHER #2

New Field

The following new field was added to the PHARMACY SYSTEM File (#59.7):

• FDA MED GUIDE SERVER URL (#100)

Section 2: Installation of Patches and Java Component

This installation is comprised of PSS*1*158, PSN*4*263, PSO*7*343 and a Java software component. Please read the following installation instructions carefully before beginning the installation.

Patches should be installed in the following order:

- 1) PSS*1*158
- 2) PSN*4*263
- 3) PSO*7*343

Installing PSS*1*158

Installation will take less than 2 minutes. It is recommended that installation be queued for off peak hours.

To install PSS*1*158

- 1. Use the INSTALL/CHECK MESSAGE option on the PackMan menu.
- 2. From the Kernel Installation & Distribution System (KIDS) menu, select the Installation menu
- 3. From this *menu*, *you may select to use the following* options (when *prompted for* INSTALL NAME, enter PSS*1.0*158).
 - a. Backup a Transport Global This option will create a backup message of any routines exported with the patch. It will NOT back up any other changes such as DDs or templates.
 - b. *Compare Transport Global to Current System* This option will allow you to view all changes that will be made when the patch is installed. It compares all components of the patch (routines, DDs, templates, etc.).
 - c. *Verify Checksums in Transport Global* This option will ensure the integrity of the routines that are in the transport global.
 - d. *Print Transport Global* This option will allow you to view the components of the KIDS build.
- 4. Use the Install Package(s) option and select the package PSS*1.0*158.
- 5. When prompted "Want *KIDS* to INHIBIT LOGONs during the install? NO//" respond NO.
- 6. When prompted "Want to DISABLE Scheduled Options, Menu Options, and Protocols? NO//" respond NO.

Example of PSS*1*158 Installation

Select Installation Option: INSTall Package(s) Select INSTALL NAME: PSS*1.0*158 Loaded from Distribution 9/14/10@16:36:43 => PSS*1*158 TEST v1 This Distribution was loaded on Sep 14, 2010@16:36:43 with header of PSS*1*158 TEST v1 It consisted of the following Install(s): PSS*1.0*158 Checking Install for Package PSS*1.0*158 Install Questions for PSS*1.0*158 Incoming Files: 59.7 PHARMACY SYSTEM (Partial Definition) Note: You already have the 'PHARMACY SYSTEM' File. Want KIDS to INHIBIT LOGONs during the install? NO// Want to DISABLE Scheduled Options, Menu Options, and Protocols? NO// Enter the Device you want to print the Install messages. You can queue the install by enter a 'Q' at the device prompt. Enter a '^' to abort the install. DEVICE: HOME// GENERIC INCOMING TELNET Install Started for PSS*1.0*158 : Sep 14, 2010@16:38:53 Build Distribution Date: Sep 14, 2010 PSS*1.0*158 Installing Routines: Sep 14, 2010@16:38:53 Installing Data Dictionaries: . Sep 14, 2010@16:38:54 Running Post-Install Routine: ^PSS158P Updating Routine file ... Updating KIDS files... PSS*1.0*158 Installed. Sep 14, 2010@16:38:54 Not a production UCI NO Install Message sent 100% 25 50 75 Complete Install Completed April 2011 FDA Medication Guides Project Installation Guide PSS*1*158, PSN*4*263, PSO*7*343

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Installing PSN*4*263

Installation will take less than 2 minutes. It is recommended that installation be queued for off peak hours.

To install PSN*4*263

- 1. Use the INSTALL/CHECK MESSAGE option on the PackMan menu.
- 2. From the Kernel Installation & Distribution System (KIDS) menu, select the Installation menu.
- 3. From this *menu*, *you may select to use the following* options (when *prompted for* INSTALL NAME, enter PSN*4.0*263).
 - a. *Backup a Transport Global* This option will create a backup message of any routines exported with the patch. It will NOT back up any other changes such as DDs or templates.
 - b. *Compare Transport Global to Current System* This option will allow you to view all changes that will be made when the patch is installed. It compares all components of the patch (routines, DDs, templates, etc.).
 - c. *Verify Checksums in Transport Global* This option will ensure the integrity of the routines that are in the transport global.
 - d. *Print Transport Global* This option will allow you to view the components of the KIDS build.
- 4. *Use the Install Package(s)* option and select the package PSN*4.0*263.
- 5. When prompted "Want KIDS to INHIBIT LOGONs during the install? NO//" respond NO.
- 6. When prompted "Want to DISABLE Scheduled Options, Menu Options, and
- 7. Protocols? NO//" respond NO.

Example of PSN*4*263 Installation

Select Installation Option: INStall Package(s) Select INSTALL NAME: PSN*4.0*263 Loaded from Distribution 9/14/10@16:37: 37 => PSN*4*263 TEST v1 This Distribution was loaded on Sep 14, 2010@16:37:37 with header of PSN*4*263 TEST v1 It consisted of the following Install(s): PSN*4.0*263 Checking Install for Package PSN*4.0*263 Install Questions for PSN*4.0*263 Want KIDS to INHIBIT LOGONs during the install? YES// NO Want to DISABLE Scheduled Options, Menu Options, and Protocols? NO// NO Enter the Device you want to print the Install messages. You can queue the install by enter a 'Q' at the device prompt. Enter a '^' to abort the install. DEVICE: HOME// GENERIC INCOMING TELNET PSN*4.0*263 Install Started for PSN*4.0*263 : Sep 14, 2010@16:40:55 Build Distribution Date: Sep 14, 2010 Installing Routines: Sep 14, 2010@16:40:56 Updating Routine file ... Updating KIDS files... PSN*4.0*263 Installed. Sep 14, 2010@16:40:56 Not a production UCI NO Install Message sent 100% 25 50 75 Complete Install Completed

Installing PSO*7*343

Installation will take less than 2 minutes. It is recommended that installation be queued for off peak hours.

To install PSO*7*343:

- 1. Use the *INSTALL/CHECK MESSAGE* option on the *PackMan* menu.
- 2. From the Kernel Installation & Distribution System (KIDS) menu, select the Installation menu.
- 3. From this *menu*, *you may select to use the following* options (when *prompted for* INSTALL NAME, enter PSO*7.0*343).
 - a. *Backup a Transport Global* This option will create a backup message of any routines exported with the patch. It will NOT back up any other changes such as DDs or templates.
 - b. *Compare Transport Global to Current System* This option will allow you to view all changes that will be made when the patch is installed. It compares all components of the patch (routines, DDs, templates, etc.).
 - c. *Verify Checksums in Transport Global* This option will ensure the integrity of the routines that are in the transport global.
 - *d. Print Transport Global* This option will allow you to view the components of the KIDS build.
- 4. Use the Install Package(s) option and select the package PSO*7.0*343.
- 5. When prompted "Want KIDS to INHIBIT LOGONs during the install? NO//" respond NO.
- 6. When prompted "Want to DISABLE Scheduled Options, Menu Options, and Protocols? NO//" respond NO.

Example of PSO*7*343 Installation

Select Installation Option: INStall Package(s) Select INSTALL NAME: PSO*7.0*343 Loaded from Distribution 9/14/10@16:37:2 4 => PSO*7*343 TEST v1 This Distribution was loaded on Sep 14, 2010@16:37:24 with header of PSO*7*343 TEST v1 It consisted of the following Install(s): PSO*7.0*343 Checking Install for Package PSO*7.0*343 Install Questions for PSO*7.0*343 Want KIDS to INHIBIT LOGONs during the install? NO// Want to DISABLE Scheduled Options, Menu Options, and Protocols? NO// Enter the Device you want to print the Install messages. You can queue the install by enter a 'Q' at the device prompt. Enter a '^' to abort the install. DEVICE: HOME// GENERIC INCOMING TELNET Install Started for PSO*7.0*343 : Sep 14, 2010@16:41:25 Build Distribution Date: Sep 14, 2010 Installing Routines: PSO*7.0*343 Sep 14, 2010@16:41:25 Installing PACKAGE COMPONENTS: Installing PROTOCOL Located in the PSO (OUTPATIENT PHARMACY) namespace. Sep 14, 2010@16:41:26 Updating Routine file... Updating KIDS files... PSO*7.0*343 Installed. Sep 14, 2010@16:41:26 Not a production UCI NO Install Message sent 100% 25 50 75 Complete Install Completed!

Installing the Java Software Component

Installation will take about 5 to 10 minutes and must be performed on every computer where the user needs to retrieve and display an FDA Medication Guide.

To install the Java Software Component:

To install and test the On-Demand Med Guide Viewer software, follow these instructions.

- 1. Installing the software.
 - a. Prepare the software
 - i. Since the On-Demand Med Guide Viewer software is a Java application, it requires that the Java SE Runtime Environment (JRE) be installed on your PC. The JRE is not distributed as part of this package and must be separately downloaded from the Oracle website (<u>http://www.java.com</u>.). Java Standard Edition (SE) 1.6, or newer, is required. If Java SE 1.6 is already installed on your PC, you may skip this step.
 - ii. The Java component is distributed as a ZIP-compressed file (PSN_4_P263.ZIP) containing a single EXE executable file.

The files listed below may be obtained via FTP. The preferred method is to FTP the files from: download.vista.med.va.gov

This transmits the files from the first available FTP server. Sites may also elect to retrieve software directly from a specific server as follows:

CIO FIELD OFFICE	FTP ADDRESS	DIRECTORY
Albany Hines	<u>ftp.fo-albany.med.va.gov</u> ftp.fo bines med va.gov	[anonymous.software]
Salt Lake City	ftp.fo-slc.med.va.gov	[anonymous.software]
File Name	Contents	Retrieval Format
PSN_4_P263.ZIP	File(s) indented below	BINARY

- On-Demand_Med_Guide_Viewer-1.0.0.11_setup.exe Install file for the Java Application component.

Unzip the file contents into a temporary folder of your choice. After successfully installed, the zip file and setup file may be deleted.

- b. Run the executable installer.
 - i. Locate the file named "On-Demand_Med_Guide_Viewer-1.0.0.11_setup.exe" (1.0.0.11 represents a four digit version number separated by dots.)
 - ii. Double-click on the file name to start/run the installer.

iii. The installer detects whether you already have a compatible version of Java installed on your PC. If not, the installer aborts and prompts you to download and install Java from the Oracle website.

Example of Java Software Installation

If JRE is not already installed, the following prompt will occur:



- iv. When JRE installation is complete, close the residual installer window.
- c. Reboot, when prompted to do so and continue.

If JRE is already installed, the prompt will not occur:



Example of Java Software Installation (continued)

File Download - Security Warning
The publisher could not be verified. Are you sure you want to run this software?
Name: On-Demand_Med_Guide_Viewer_setup.exe Publisher: Unknown Publisher Type: Application
Run Cancel
This file does not have a valid digital signature that verifies its publisher. You should only run software from publishers you trust. <u>How can I decide what software to run?</u>
🤔 On-Demand Med Guide Viewer Setup: Installing 💦 🔲 🗙
Created uninstaller: C:\Program Files\Vista\PSO\On-Demand_FDA_med_guin
On-Demand Med Guide Viewer Setup
Yes No
Cancel Nullsoft Install System v2.46 Close

- 2. Test the installation and the application software.
 - a. Logon to Vista using the roll-scroll interface.
 - b. Request display of a specific med guide document from Vista.
 - i. <u>Test for Outpatient Pharmacy Application users:</u>
 - 1. Logon to the Outpatient Pharmacy Application [PSO MANAGER]
 - Select the Patient Prescription Processing option [PSO LM BACKDOOR ORDERS], a.k.a. "Backdoor Pharmacy", which is located under the Rx (Prescriptions) menu [PSO RX].
 - 3. Select any Division.
 - 4. Select any Patient.

- 5. Select one of the patient's prescriptions with a dispense drug matched to a VA Product that contains an associated FDA Medication Guide.
- 6. Select hidden action OTH (Other OP Actions).
- 7. Select Item MG (Display FDA Medication Guide).
- ii. <u>Test for National Drug File Application users:</u>
 - 1. Logon to the National Drug File Application [PSNMGR].
 - 2. Select the Display FDA Medication Guide option [PSN MED GUIDE].
 - 3. When prompted for 'VA PRODUCT NAME', enter a VA Product that contains an associated FDA Medication Guide.
- c. After a few seconds, an FDA med guide should display within Adobe Acrobat Reader, embedded within the default Web Browser (Internet Explorer). This is the PDF file that you requested in the previous step. If step ii.3 is successful, the software is correctly installed and properly working.
- 3. Removing/uninstalling the software.
 - a. To remove the software from your PC, use the standard Add/Remove applet provided by Windows.
 - i. Click on the Start button.
 - ii. Select Control Panel.
 - iii. Select the Add or Remove Programs applet in the Control Panel.
 - iv. Scroll down to the listings in the applet starting with the letter "O".
 - v. Choose the On-demand Med Guide Viewer entry as shown below:

Example of Uninstalling Java Software



- vi. Click on the **Remove** button.
- vii. A removal tool appears on the screen indicating that the software has been removed.
- b. Reboot
- 4. Technical details:
 - a. The Java component software will automatically run in the background each time the PC is booted/rebooted. There is no visible evidence that it is running.
 - b. After the software is installed, there are no obvious signs of its presence other than the display of a med guide when requested. When not in use, the software remains silently in the background awaiting instructions. No GUI is associated with the application.

Example of Uninstalling Java Software (continued)

c. The software is (by default) typically installed in the folder shown below and contains the files listed in this folder.



d. Registry entries affected by this installation are shown below.

1 1 1 1			-	
	🖃 🧰 Windows	ab)OfflineFileSync	REG_SZ	"C:\Program Files\MSGArchive\EAS Client\OfflineFileSyn.exe" -silent
	🚊 🧰 CurrentVersion	On-Demand Med Guide Viewer	REG_SZ	"C:\Program Files\Vista\PSO\On-Demand_FDA_med_guides\fda_med_guides_on-demand-1.0.0.11.jar" "C:\Program
	😥 🧰 App Management	ag QuickTime Task	REG_SZ	"C:\Program Files\QuickTime\qttask.exe" -atboottime
	😥 🧰 App Paths	ab)rtnotify	REG_SZ	"C:\Program Files\Lumension Security\Sanctuary\Client\RTNotify.exe"
	Applets	ab)ShStatEXE	REG_SZ	"C:\Program Files\McAfee\VirusScan Enterprise\SHSTAT.EXE" /STANDALONE
	- BITS	ab SigmatelSysTrayApp	REG_SZ	stsystra.exe
	Communicator	ab Sun Java Update Sched	REG_SZ	C:\Program Files\Java\jre6\bin\jusched.exe
	🗉 🛄 Control Panel	ab UpdateManager	REG_SZ	"C:\Program Files\Common Files\Sonic\Update Manager\sgtray.exe" /r
	🗉 🛄 Controls Folder	ab VMware hotray	REG SZ	"C: \Program Files\VMware\VMware Player\hgtray.exe"
	CSCSettings		-	
	🗉 🛄 DateTime			
	III DIFx			
	DIFxApp			
	Dynamic Directory			
	EventForwarding	~		
IMV Compute	ervhket local machine/SOFTWARE/Microsoft/Wir	ndows/kurrentversion/kun		

Registry Editor File Edit View Favorites Help			
NLSDownlevelMapping NLSDownlevelMapping NLSD NVIDIA Drivers Orace Fusion Middleware 11.1.1.0. Orde Fusion Middleware 11.1.1.0.	Name (a) (Default) (a) DisplayName (b) NoModify (b) NoRepair (c) UninstallString	Type REG_SZ REG_SZ REG_DWORD REG_DWORD REG_SZ	Data (value not set) On-Demand Med Guide Viewer 1.0.0.11 Department of Veterans Affairs 0x00000001 (1) 0x00000001 (1) 0x00000001 (1) "C: \Program Files\Vista\PSO\On-Demand_FDA_med_guides\uninstaller.exe"
		>	

My Computer\HKEY_LOCAL_MACHINE\SOFTWARE\Microsoft\Windows\CurrentVersion\Uninstall\On-Demand Med Guide Viewer