

Pharmacy Enterprise Customization System (PECS)

System Design Document



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Version 6.0

**Department of Veterans Affairs
Office of Information and Technology (OIT)
Product Development**

Revision History

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| 12/30/2014 | 2.23 | Minor updates. | |
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Artifact Rationale

The System Design Document (SDD) is a dual-use document that provides the conceptual design as well as the as-built design. This document will be updated as the product is built, to reflect the as-built product. Per the Project Management Accountability System (PMAS) Guide, the SDD with conceptual design is required prior to the Milestone 1 Review. The as-built for each delivery must be incorporated prior to the Milestone 2 Review.

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1 Introduction

The Pharmacy Enterprise Customization System (PECS) is a JEE application used to research, review, report, and manage customized drug information from First Databank (FDB) used in the enhanced order checking. Through a web-based GUI, it allows users to request custom changes to Drug-Drug Interaction, Drug Pairs, Dose Range, Duplicate Therapy, and Drug-Drug Interaction Professional Monograph, controlling access through a role based system. The File Transfer Protocol (FTP) is used to disseminate updates from a national database to all local/regional instances of FDB standard and custom tables.

1.1 Purpose of the SDD

The purpose of this System Design Document (SDD) is to describe in sufficient detail how the PECS Application is to be constructed. This document translates the Requirement Specifications into a document from which the developers can create the PECS application. It identifies the top-level system architecture, as well as hardware, software, communication, and interface components.

The intended audience of this System Design Document (SDD) is the Pharmacy Reengineering (PRE) project team, SQA, and other teams or departments that may be interested parties to the development of this application.

1.2 Identification

This document describes version 6.0 of PECS.

1.3 Scope

The Pharmacy Enterprise Customization System (PECS) provides VA Pharmacists the ability to receive and store descriptive and clinical drug information from a COTS product and customize that data as needed per VA business procedures and disperse that customized data across the VA Medical Center. PECS utilizes First Databank's National Drug Data File as COTS drug information.

The scope of this document includes the functionality applicable to the PECS application, including design and implementation details on the significant or important logical parts of the application. The run-time use for order checks, through the Medication Order Check Healthcare Application (MOCHA) system, of the customizations created in PECS is outside the scope of this document.

Table 1: Scope Inclusions

| Includes |
|--------------------------------|
| Querying Drug Information |
| Drug Information customization |
| Custom Data Export |
| Easy Search |
| FDB Comparison Report |

Table 2: Scope Exclusion

| Excludes |
|-------------------------------------|
| Run-time use of customization files |

1.4 Constraining Policies, Directives, and Procedures

Various VA policies, directives, and procedures are used as guidelines/recommendations for the PECS Application design.

Note: Due to policy constraints, active links cannot be included in this document. Please copy and paste the URLs into your browser.

- Section 508 Checklist for Web-based Internet Information and Applications
http://www.ehealth.va.gov/508/terms/web_508_checklist.doc
- One-ONE-VA TRM Approved Technologies/Standards List
[REDACTED] T [REDACTED]
- Java Coding Standards v2.0
[REDACTED] V [REDACTED]
- VA Web Operations Developer's Guide, as mandated by SEI Requirement ENTR882
- OIT Release Architecture
[REDACTED] V [REDACTED]

1.5 Constraints

Various VA policies, directives, and procedures specify constraints that the PECS Application design must conform to. There are three basic constraints, detailed in the sections below:

- The FDB DIF database technical specification.
- KAAJEE Security for Authentication and Authorization.
- ONE-VA TRM (Technical Reference Model) approved methodologies and tools

1.5.1 FDB DIF Database Technical Specification

PECS uses a COTS Drug Database from FDB. This product is designed for use for medication checks through an API and the technical specification for the database schema is not available for reference. Aside from the DIF tables, other database objects such as foreign keys, indexes, sequences, etc., are not known. This has potential constraints on the design and implementation of the PECS application as the application needs to access the FDB DIF tables.

1.5.2 KAAJEE Security for Authentication and Authorization

The VA mandates implementing JEE application security through the use of the KAAJEE framework. This constraint has to be taken into account when designing the technical solution.

1.5.3 ONE-VA TRM Approved Methodologies and Tools

Specific tools and methodologies used in the implementation of the proposed solution must adhere to the VA Technical Reference Model (One-ONE-VA TRM). Specifically, any technologies used must be on the TRM Approved Product List.

1.6 Design Trade-offs

PECS application changes/customizes drug information related to 5 Drug Concepts – Dose Range, Duplicate Therapy, Drug-Drug Interaction, Drug Pairs, and Drug-Drug Interaction Professional Monograph. This information change is critical and relates to patient safety. To achieve Reliability, a

scheme has been implemented where each change must be approved by two users. That obviously comes at a cost in terms of efficiency of use, but the benefits outweigh the inconvenience.

The application's user interface is highly configurable. A user in an administrator role can tailor the fields that can be included on the various screens. While in some situations, like displaying query results, this is a desirable feature; in other instances this has an impact on the application's usability. Another drawback is the increased technical difficulty of implementation.

1.7 User Characteristics

The system's user community is primarily comprised of the Pharmacy Benefits Management (PBM) group, ADPAC users, and a National Drug File (NDF) manager or designee. PECS application is a role based Web-based applications. The role designates the functionality the user is able to perform. User introduction and training is needed prior to using the application. Once training is completed the user can perform the functionality needed to research or complete the task they are assigned to do.

1.8 User Problem Statement

Pharmacy applications and systems are some of the oldest technologies in VistA. Systems limitations and cumbersome non-consistent pharmacy processes have long been identified as a weakness in VA's ability to provide efficient pharmacy service, driven by patient safety protocols, across the VA continuum. In 2001, a functionality assessment of pharmacy applications and operations was conducted by an external contractor, First Consulting Group, to determine the viability of maintaining the status quo of current technology supporting VA Pharmacy operations, taking into account agency goals and priorities. This analysis identified several fundamental problems with the current system, and recommended that VA pharmacy systems technology and operational processes change from dispensing and labeling focus to patient centric care focus.

A Graphical User Interface (GUI) Pharmacy Enterprise Customization System (PECS) application has been developed to allow for customization of FDB standard reference tables used in the enhanced order checking by MOCHA and to do Easy Search for Drugs.

1.9 Relationship to Other Documents and Plans

This SDD relies on the following documents, which can be found here:

[REDACTED]

Note: Due to policy constraints, active links cannot be included in this document. Please copy and paste the URLs into your browser.

- PECS Requirements Specification Document (RSD)
- Pharmacy Reengineering (PRE) Configuration Management Plan (CMP)
- PECS Database Design Document
- PEPS Style Guide
- PECS Project Architecture Document
- PECS Interface Control Document
- PECS Product Operational Manual (POM)

This document also relies on the following documents maintained by SDE:

- AITC Disaster Recovery Services
- "High Availability" reference document
- PECS Application Contingency Plan (5/10/2012)

- Virtual Environment Continuity of Operations (COOP) Design Document Plan (the file name for the document is “VMW Shared Infrastructure COOP.docx”)

1.10 Methodology, Tools, and Techniques

The Unified Modeling Language (UML) will be used for modeling. Diagrams and models will be created using, Rational Software Architect and Visio. Change management will be performed through Rational Team Concert (RTC).

1.11 References

- PECS Requirements Specification Document (RSD)
- Pharmacy Reengineering (PRE) Configuration Management Plan (CMP)
- PECS Database Design Document
- PEPS Style Guide
- PECS Project Architecture Document
- PECS Interface Control Document
- PECS Product Operational Manual (POM)

2 Background

PECS was born out of the need to support enhanced order checks. A decision was made to replace the home-grown order checking process, implemented in M (short for MUMPS, Massachusetts University Medical Programming System), with a Commercial off-the-Shelf (COTS) product. However, the VA desired to be able to customize the drug information (such as drug interaction severity, monographs etc.) existing in FDB. PECS will satisfy this need, while adhering to stringent requirements intended to ensure patient safety.

The PECS application has following functionality, to:

- Allow for customization of FDB data used in the enhanced order checking by National NDF Manager
- Provide access to GUI customization application by facility users to request custom changes
- Provide role based system accessibility
- Provide a report to list all customizations created to date compared against corresponding FDB standard reference data
- Provide a process to allow drug interaction information in VistA to be transferred to the custom tables
- Provide a process via FTP to update from a national database to all local/regional instances of FDB standard and custom tables

A Graphical User Interface (GUI) Pharmacy Enterprise Customization System (PECS) application has been developed to allow for customization of FDB standard reference tables such as Duplicate Therapy, Dose Range, Drug-Drug Interaction, and Drug-Drug Interaction Professional Monograph, which are used in the enhanced order checking by MOCHA.

2.1 Overview of the System

The PECS application:

- Provides a web based UI to allow for customization of FDB standard reference tables used in the enhanced order checking that will be used by the PBM group, ADPAC user, NDF manager or designee to enter/update the custom table values
- Provides the following customization capabilities:
 - Add or remove/inactivate a custom drug-drug interaction.
 - Add or remove/inactivate drug pairs associated with a custom drug-drug interaction.
 - Add, update and/or remove attributes associated with a custom drug-drug interaction (i.e. interaction description (custom message), interaction severity code, clinical effect codes, and the custom monograph ID).
 - Add or remove/inactivate a custom professional monograph for a drug-drug interaction.
 - Add, update and/or remove attributes associated with a custom, professional monograph (i.e. a version code, a section code, a format code, and line text).
 - Add, update and/or remove a custom duplication allowance value for a duplicate therapy class.
 - Add, update and remove custom values for attributes associated with a custom dose range check table.

- Provides for Searching capability - for a user to see Drug-Drug Interaction, Duplicate Therapy or Professional Monograph information separately or together, for chosen drugs.
- Provides the following reports:
 - Custom table application maintains history of custom changes for each of the five tables. The information is reportable by performing a query of the information that is needed.
 - Exportable FDB or Custom Data - Individual query data can be exported from the five FDB DIF or Custom tables. The available format is Excel.
 - FDB Comparison Reports to compare incoming updated FDB data against VA customized data to help determine if the VA customized data needs to be modified.
- Provides process via FTP to transfer Custom data from a national server to all local/regional instances server.
- Leverages the existing FDB data loader utility at each site that is used to update the FDB DIF databases.
- Custom table content distribution involves using automated DATUP application.
 - Distribution method supports the following data content scenarios
 - Only FDB standard reference table data.
 - FDB standard reference table data and Custom table data.
 - Only Custom table data.
 - Custom table content distribution shall support both periodic and as-needed releases.

The major users of the Web application are PBM and ADPAC that will research, and request customization of FDB data. Once approved by the NDF committee members the changes made will affect all of the VA sites throughout the country to where the data is sent and used in the enhanced order check. The order check is used by Doctors and pharmacist to see if any serious drug conflicts occur with the patients existing medication. It will also check for duplication of therapy of other prescribed drugs also taken by the VA patient.

2.2 Overview of the Business Process

The table below provides an overview of the business processes that PECS application will support.

Table 3: Business Processes

| Business Process ID | Business Process Name | Type – Existing or Modernized | Owner – Organization Performing the Process | Description |
|---------------------|--|-------------------------------|---|---|
| 1 | PECS approval process | Modernized | PBM – ADPAC Users | The customization process from entry to being approved. |
| 2 | PECS deletion process | Modernized | PBM – NDF Committee users | The process of deleting a customized record |
| 3 | PECS Customization Process Update Flow | Modernized | The owners are the doctors and pharmacists at the regional or local site where the data is loaded | This high level diagram below shows the process after the customization is approved and released within the PECS application. |

The business processes implemented within PECS include searching of existing FDB or VA Custom record, modifying it and taking the customization request for modification thru the approval process, and disseminating the customized Drug Information to local VAMC's.

2.2.1 Query Process

Query Process includes the functionality for creating, executing, viewing, and exporting the two categories of queries (MyQueries and OtherUsers) by business concept. MyQueries are those queries which were created and saved by the user who is signed-in. OtherUsers is a query web page section that lists queries that were developed by other users. User can execute a query against FDB, VA Customized or both. Results are presented in separate sections for FDB and VA Customized records, a user can open the detail page by clicking on the hyperlink or can also export the results in an Excel worksheet.

2.2.2 Customization Process

The customization process demonstrates the steps that the user will perform when creating a new customization request in the PECS application via the GUI. It includes the interaction between the user with the application, as well as the application's interface with the FDB database.

This includes the process of querying for existing FDB of VA records, customization request, modification of customization request, and review and approval processes.

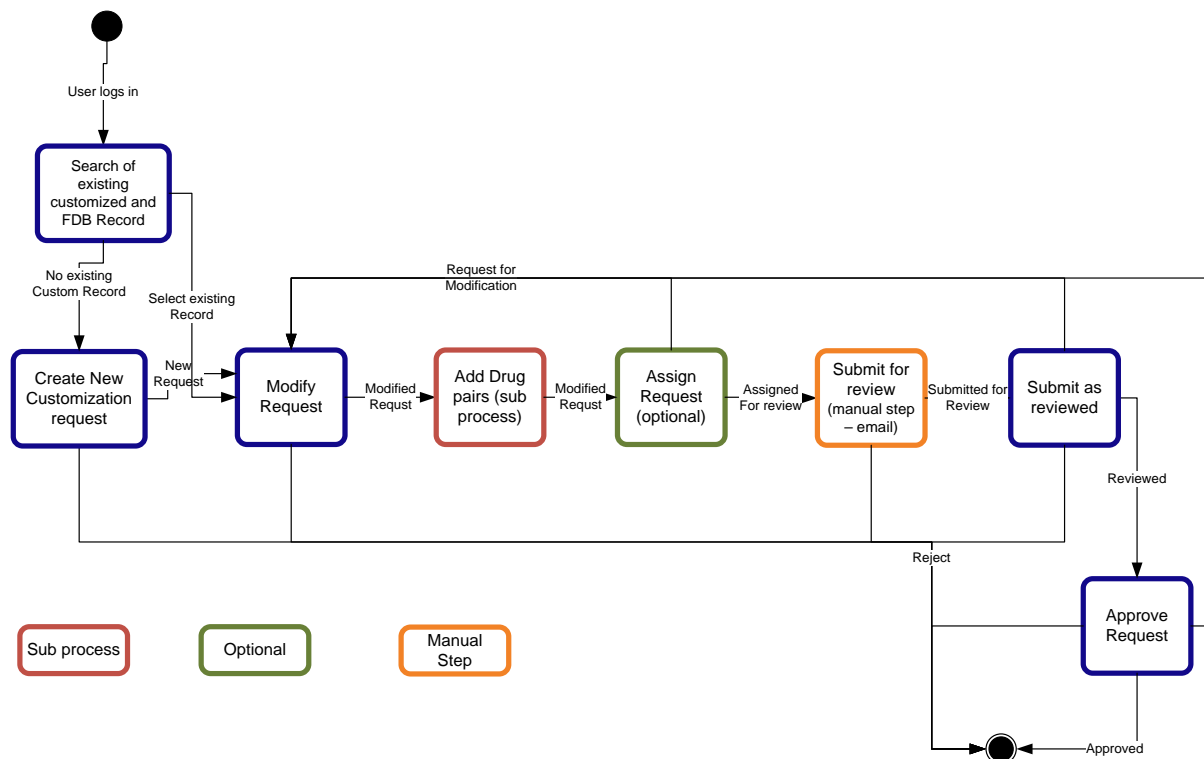


Figure 1: PECS Customization Business Processes

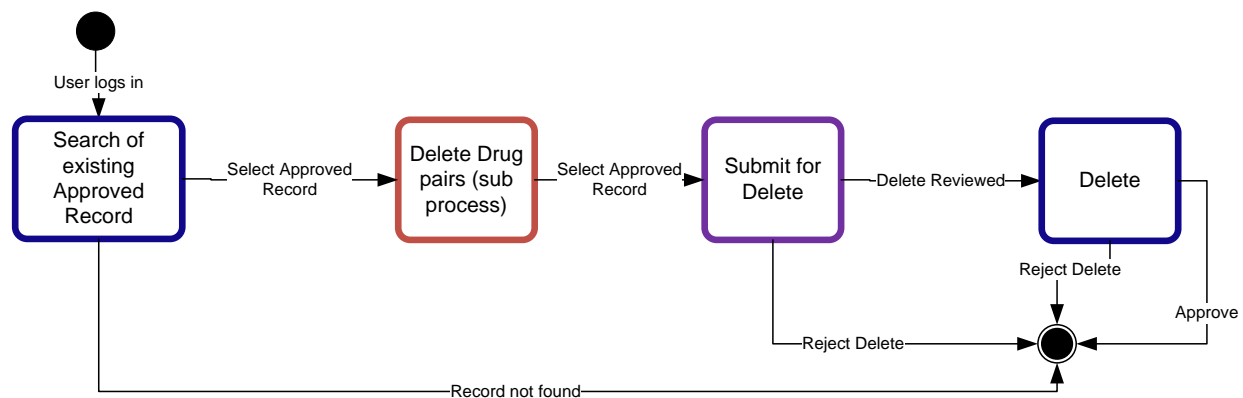


Figure 2: PECS Delete Sub-Process

2.2.3 Customization – Without FDB DIF Record Override

The new customization without FDB DIF override demonstrates the process that a new request for customization record goes through, without customizing an existing FDB DIF record. This is a valid process for the Dosing, Monograph, and Drug-Drug Interaction Order Checks. A request for customization can be placed into the system that is not based on an existing FDB DIF record. Duplicate Therapy order check customizations must always be based on existing FDB DIF records.

2.2.4 Customization – with FDB DIF Record Override

The new customization with FDB DIF override includes first selecting an existing FDB record and then making required changes and submitting records for customization. The system will check to make sure that a user cannot submit a duplicate request.

2.2.5 Modification of Customization

A user is allowed to make as many changes as needed before assigning the request to an approver for review. Changes to the non-FDB fields will not impact the Action Status.

2.2.6 Approval of Customization

The Approval of customization request is a two-step process, first step is for an approver to review the request and if agrees then submit as reviewed. Second step is for a different approver to approve the request.

2.2.7 Deletion of Customization

Only a record with action status of 'approved' can be delete. Similar to approval, delete is also a two-step process. Once an approver identifies an approved VA customization record, the record will be submitted for delete, the second approver then approves the deletion request.

2.2.8 State Transition

Following state machine diagram steps thru the process starting from a new customization request until the request is approved or deleted.

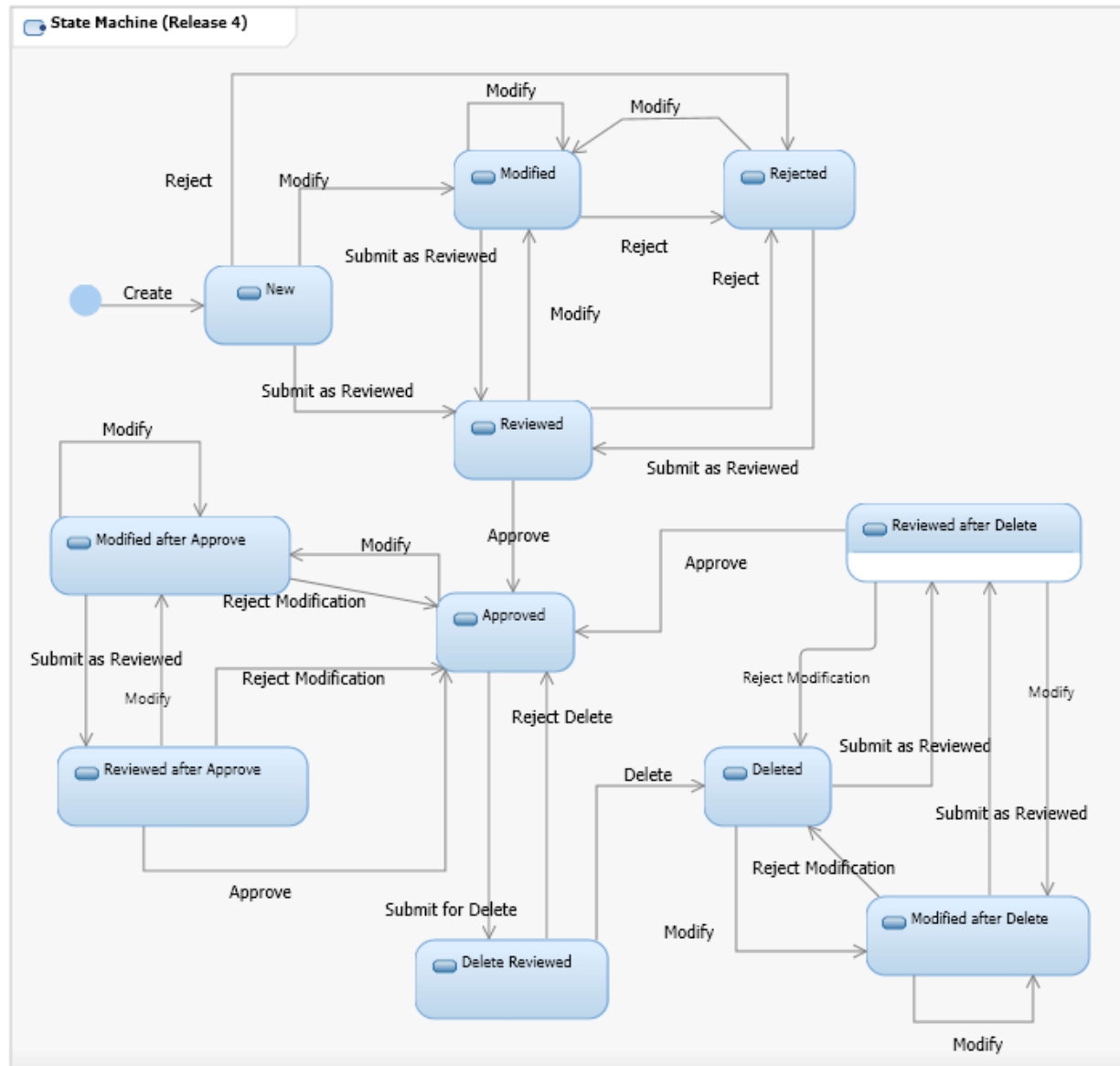


Figure 3: PECS State Transition Business Processes

2.2.9 Easy Search

Easy Search provides capability for a user to see Drug-Drug Interaction, Duplicate Therapy or Professional Monograph information separately or together, for chosen drugs. In addition, the user can also enter patient and dose particulars for the routed generic drug and retrieve dose related information so that user can ensure the amount being prescribed is in an acceptable amount.

2.2.10 FDB Update Pre-Processing

Since Pharmacy is now using the First Databank Drug Information Framework APIs and database, PBM wanted a way to determine what updates the VA is receiving from FDB.

2.3 Business Benefits

PECS provides a business benefit by allowing PBM to customize the data from a COTS database to better meet the needs of the pharmacists who support the VA and the veterans it serves. The software is being continually enhanced to provide increased benefit and meet changing business requirements/

2.4 Assumptions

The following section describes the assumptions and constraints that impacted the design of the PECS system.

2.4.1 Design Assumptions

The System design assumptions are that the application:

- Must be Web based
- Must be able to access the COTS data and query records for the user
- Must be Section 508 compliant
- Must be compliant with framework/tools/library as recommended by ONE-ONE-VA TRM.
- Shall easily allow the administrator to turn on or off fields without development code changes
- Shall provide a role based security
- Shall provide as much wizard flow action for ease of use for the end-user

2.4.2 Design Constraints

This section lists the design constraints specifications:

- SPEC844: The system shall follow the Section 508 compliance standards for the GUI. (3.6.1.5)
- SPEC845: The system shall support TRM-approved browsers that are part of the standard client system configuration and are supported through configuration and patching maintenance on an enterprise level. (CR 4573)
- SPEC846: The system shall follow VA's authentication/authorization standard. (3.6.3.9)
- SPEC847: The system shall display time in standard VA format (MMDDYYYY:HHMMSS) based on the time set on the server. (3.6.1.12)
- SPEC848: The system shall display entered text as English. (3.6.1.13)

2.4.3 Design Trade-offs

None identified.

2.5 Overview of the Significant Requirements

2.5.1 Overview of Significant Functional Requirements

The PECS application has been developed as a web based application with adherence to the 508 compliance standards.

The VA selection of the third party drug data vendor of First Databank influenced the database schemas and tables.

The need for query results and report data to be exportable to excel introduced the use of Apache Poor Obfuscation Implementation (POI) open source software.

Some of the significant functional requirements include:

- PECS architectural changes needed when MOCHA Server is transitioned from Cache to Oracle database (Depends on MOCHA's direction)
- Automate the lookup table synchronization process so that PECS lookup and terminology tables will stay in sync with the First Data Bank (FDB) tables
- Analysis of solutions for archiving data
- Merge functionality between PECS and Pharmacy Product System-National (PPS-N)
- Inclusion of additional FDB order checks
- Analysis of use of Public Key Infrastructure (PKI)-based Personal Identity Verification (PIV) cards to access PECS
- Implementing Secure File Transfer Protocol (sFtp) for PECS/DATUP
- Setting up Virtual DEV/SQA environment for PECS/DATUP
- WebLogic version Upgrade for PECS per TRM recommendation
- Mitigate Security Vulnerability(s) reported in AITC Security Scan for PECS
- Implement design solution Comparison Report- redesigns PECS.
- Implementing PIV/IAM.
- Implementing Enterprise Service Bus (ESB) for PECS/DATUP (as required by VA).

Table 4: Functional Requirements

| ID | Requirement |
|----------|---|
| SPEC844: | The system shall follow the Section 508 compliance standards for the GUI. (3.6.1.5) |
| SPEC845: | The system shall support TRM-approved browsers that are part of the standard client system configuration and are supported through configuration and patching maintenance on an enterprise level. |
| SPEC846: | The system shall follow VA's authentication/authorization standard. (3.6.3.9) |
| SPEC977: | The system shall provide the capability for the user to export any query results to Microsoft Excel. (3.6.6.8) |

2.5.2 Overview of Functional Workload / Performance Requirements

| ID | Requirement |
|----|-------------|
|----|-------------|

| ID | Requirement |
|---|---|
| SPEC838: Total Number of Users by Role | Administrator: Five Approver: Twenty Requestor: 10 per medical center (1280) (or potentially all VA clinical employees) Release Manager: Five |
| SPEC839: Number of Concurrent Users by Role | Administrator: One Approver: Five Requestor: Three per medical center (384) Release Manager: One |
| SPEC840: Response Time: | Submitting / approving request: Five seconds Running queries: Five seconds or less Creating custom file: Five minutes or less |
| SPEC841: | Usage peak times: Monday through Friday, 7:00 a.m. Eastern Time – 7:00 p.m. Eastern Time |
| SPEC842: Maximum number of customization request (estimated): | Daily: 3 Weekly: 15 |
| SPEC1120: Number of users, worst case scenario | 128 VMS facilities (defined as VistA instance) 10 users / facility 5 concurrent / facility Facilities are open from 7:00 am eastern to 7:00 pm eastern |

Table 3: Workload and Performance Requirements

2.5.3 Overview of Operational Requirements

This section is not applicable to the project. There are not any special operational requirements that are unique to this project.

2.5.4 Overview of the Technical Requirements

PECS does not have any additional technical requirement beyond those dictated by the constraints listed previously.

2.5.5 Overview of the Security or Privacy Requirements

The PECS application has role based logins. Functional requirements vary for the approver, requestor, administrator, and release manager roles.

PECS 6.0 will introduce PIV card authentication for the PECS application. Design specifications will take into account the user's functional requirement for role based workflows.

SPEC924: The system shall allow a user to have multiple roles.

2.5.6 Overview of System Criticality and High Availability Requirements

SPEC1021: The system shall be available 24/7, with exception made for required system maintenance activities. Required maintenance activities shall be scheduled for known periods of decreased system utilization. (3.6.1.15)

SPEC1124 In the event of a disaster taking the data center hosting PECS off-line, the business customer expects PECS to be restored within three days.

2.5.7 Single Sign-on Requirement

PECS uses KAAJEE authentication.

During the process of developing PECS 6.0, the feasibility of using PIV-based logon is being explored.

2.5.8 Requirement for Use of Enterprise Portals

The PECS application requirements do not describe any use of the Enterprise Portals.

2.5.9 Special Device Requirements

The PECS application requirements do not describe need for Special Devices.

2.6 Legacy System Retirement

The PECS application does not directly impact or retire any mainframe applications.

3 Conceptual Design

This section addresses the conceptual design of PECS.

3.1 Conceptual Application Design

The conceptual application design is covered in two parts. Section 3.1.1 is the application context, which covers the relationship of PECS to the external systems it touches, and its internal and external interfaces to OIT. Section 3.1.2 covers the high-level application design and its objects.

3.1.1 Application Context

The following figure depicts the PECS application and the external system(s) that it interacts with.

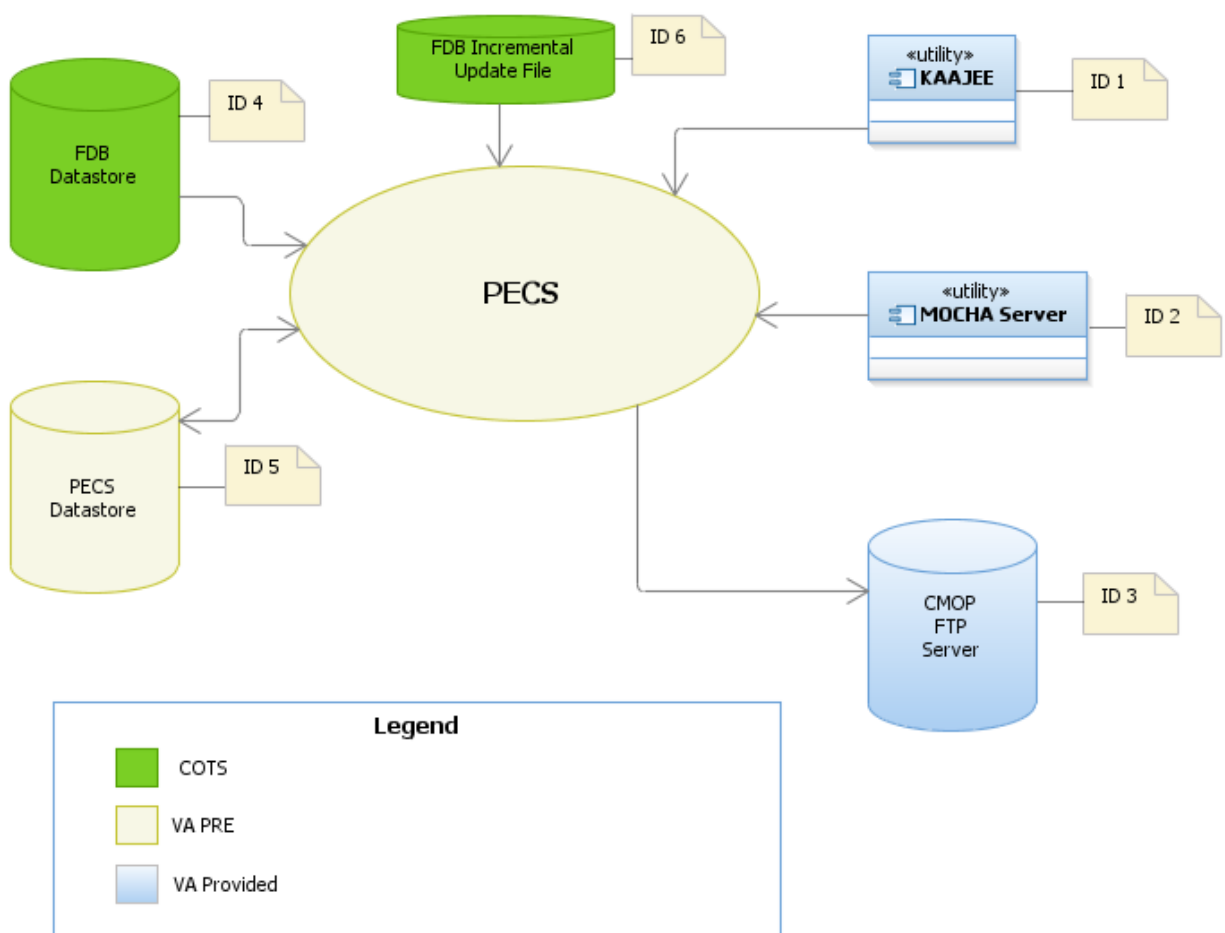


Figure 4: PECS Application Context Diagram

The table below describes the drawing above as follows: it describes each of the objects in the drawing and then displays the context of each of the interfaces, external and internal, to the Office of Information & Technology, which must be aware of all VA applications.

Table 5: Application Context Description

| | Objects | | | | |
|-----------------|-------------------------------|---|---------------------|--|-----------------|
| ID from Drawing | Name | Description | Interface Name | Interface System | |
| | | | | | |
| 4 | FDB Datastore | Retrieve Drug information for customization or research purposes. | JDBC | | |
| 5 | PECS Datastore | Retrieve/Update customization information. | JDBC | | |
| | Interfaces External to OI&T | | | | |
| ID | Interface Name | Related Object | Input Messages | Output Messages | External Party |
| | N/A | | | | |
| | Interfaces Internal to OI&T | | | | |
| ID | Interface Name | Related Object | Input Messages | Output Messages | Other CBP Party |
| 1 | KAAJEE | KAAJEE/VistALink | N/A | User Login is based on role based security, provided by KAAJEE Interface. Login success/failure. | N/A |
| 2 | MOCHA Server | MOCHA Server | Order Check Request | Order Check Response | N/A |
| | Externally Shared Data Stores | | | | |
| ID | Name | Data Stored | Owner | Access | |
| 3 | FTP Server | Custom Update Files | CMOP | Create | N/A |
| 6 | FDB Incremental Update File | FDB Update Data | PBM | Read | |

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3.1.2 High Level Application Design

The figure below provides a high level dataflow diagram for the PECS system.

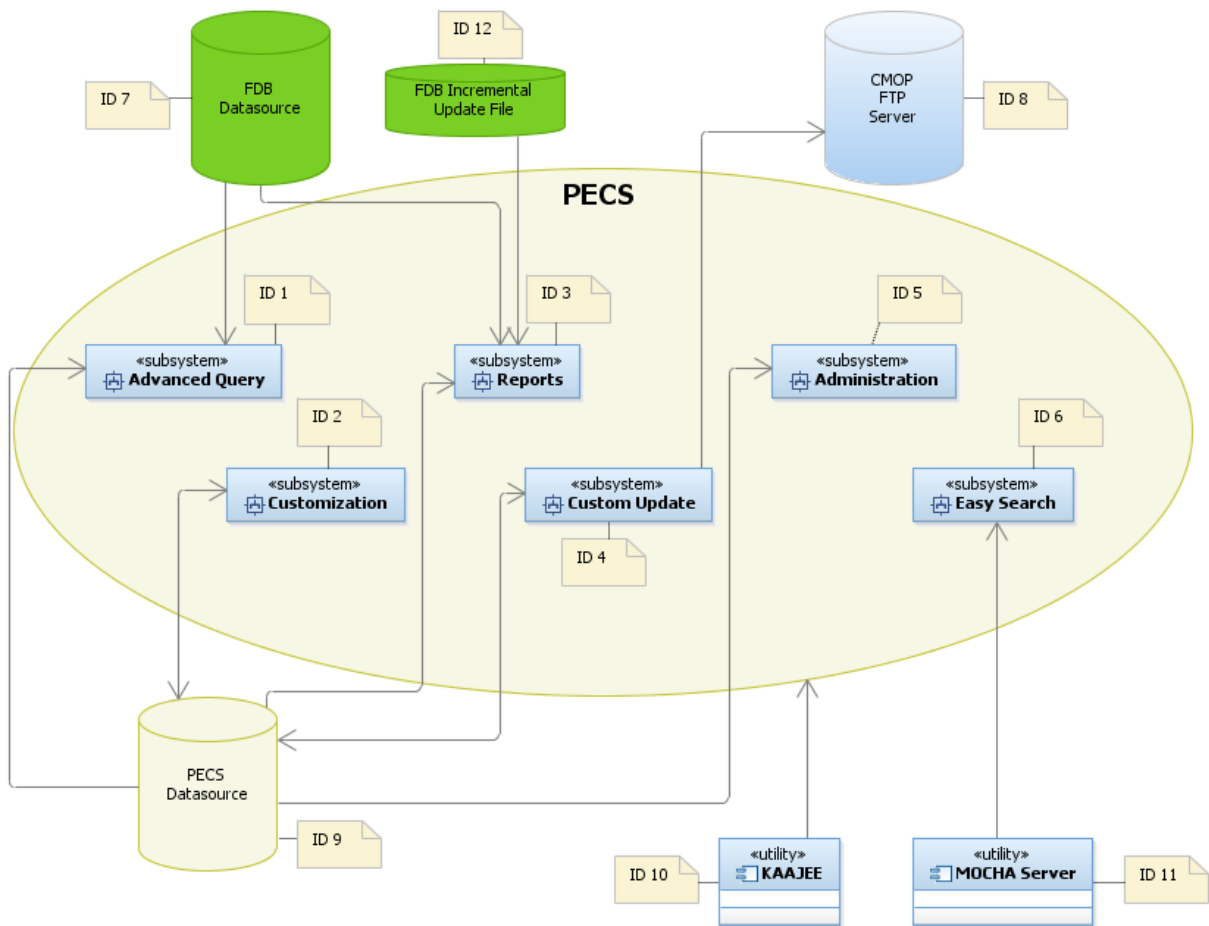


Figure 5: PECS High Level Application Design

(This page included for two-sided copying.)

Table 6: Objects in the High Level Application Design

| Objects | | | | | | | | |
|-----------------------|----|---|------------------------|--|-----------------------|-----------------------------------|-----------------------|----------|
| | ID | Description | Service or Legacy Code | External Interface Name | External Interface ID | Internal Interface Name | Internal Interface ID | SD Se 1& |
| Advanced Query | 1 | The <i>Advanced Query Service</i> is used to Query Drug Information from PECS and FDB-DIF Database. | Service | N/A | N/A | FDB Datasource PECS Datasource | 7 and 9 | Ap |
| Customization | 2 | The <i>Customization Service</i> is used to customize five drug concepts and handles CRUD operations with the PECS data entities | Service | N/A | N/A | FDB Datasource PECS Datasource | 7 and 9 | Ap |
| Reports | 3 | The <i>Report Service</i> is used to list all reports created by PECS. | Service | FDB Incremental Update File | 12 | FDB Datasource PECS Datasource | 7 and 9 | Ap |
| Custom Updates | 4 | The <i>Custom Update Service</i> is used to generate Full and incremental Drug-Data customizations for five drug concepts and put updates on the National FTP Server. | Service | CMOP FTP Server | 8 | PECS Datasource | 9 | Ap |
| Administration | 5 | The Administration subsystem allows a PECS administrator to perform administrative tasks. | Subsystem | N/A | N/A | PECS Datasource | 9 | Ap |
| Easy Search | 6 | The Easy Search subsystem allows PECS users to enter Drugs so that Order Checks can be executed and checked for problems. | Subsystem | MOCHA Server | 11 | | | |
| CMOP FTP | 8 | The CMOP FTP Server is used to place PECS generated Custom Update Files so that those updates can be applied to the National and Regional FDB Databases. | Data store | | | | | |
| KAJEE Security System | 10 | The <i>KAJEE Security System</i> Provides Authentication and role based Service to PECS | Service | KAJEE is the interface mechanism for security for PECS | | | | |
| MOCHA Server | 11 | MOCHA Server is utilized by PECS to perform Order Checks. | Service | | | | | |
| Incremental File | 12 | The PECS Report subsystem uses data contained in this file to generate Comparison reports that show FDB updated/deleted data and if that data has been customized by PBM. | Data store | | | | | |

Table 7: Internal Data Stores

| Internal Data Stores | | | | |
|----------------------|----|--|-----------------------|---|
| | ID | Data Stored | Steward | Access |
| datasource | 7 | The PECS database is a COTS database which contains the drug-data information. | | FDB-DIF is used as read-only database by |
| Database | 9 | The PECS database is used to store the customized drug-data information. | Customization Service | Customization does all the CRUD operation with the Query Service, which does a Read operation). |

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3.1.3 Application Locations

The following table denotes the location of the components in the PECS system.

Table 8: Application Locations

| Application Component | Description | Location at Which Component is Run | Type |
|-----------------------------|---|---|-----------------------------------|
| PECS | The PECS application. | Information Technology Center – PECS Application Server | Presentation Logic/Business Logic |
| | | | |
| | | | |
| | | | |
| KAAJEE Security System | Supports the PECS security interface. | Information Technology Center (ITC) – PECS Application Server | Interface Code |
| FDB-DIF Database | Stores Drug information for the PECS application | Information Technology Center (ITC) – PECS Database Server | Data Logic (via Oracle) |
| PECS Database | Stores Customized Drug information for the PECS application | Information Technology Center (ITC) – PECS Database Server | Data Logic (via Oracle) |
| CMOP FTP Server | Used to distribute PECS generated custom update files. | Hines | Data Logic (via file) |
| FDB Incremental Update File | Used to generate FDB Comparison Reports in PECS. | Hines | Data Logic (via file) |
| MOCHA Server | Used to perform Order Checks. | Information Technology Center (ITC) – PECS Application Server | Business Logic |

3.1.4 Application Users

The table below specifies the users of the PECS application.

Table 9: Application Users

| Application Component | Location | User |
|-----------------------|---|---|
| PECS Application | Austin Information Technology Center (ITC) – PECS Database Server | Pharmacy Benefits Management (PBM) group, ADPAC users, NDF manager or designee. |
| Advanced Query | PBM, ADPAC, NDF Manager or Designee | Requestor Approver Release Manager Administrator |
| Customization | PBM, ADPAC, NDF Manager or Designee | Requestor Approver |
| Reports | PBM, ADPAC | Approver |
| Custom Update | PBM | Release Manager |
| Administration | PBM | Administrator |

| Application Component | Location | User |
|-----------------------|-------------------------------------|-----------------------|
| Easy Search | PBM, ADPAC, NDF Manager or Designee | Requestor Approver |

3.2 Conceptual Data Design

3.2.1 Project Conceptual Data Model

PECS will only handle five different types of entities as depicted below.

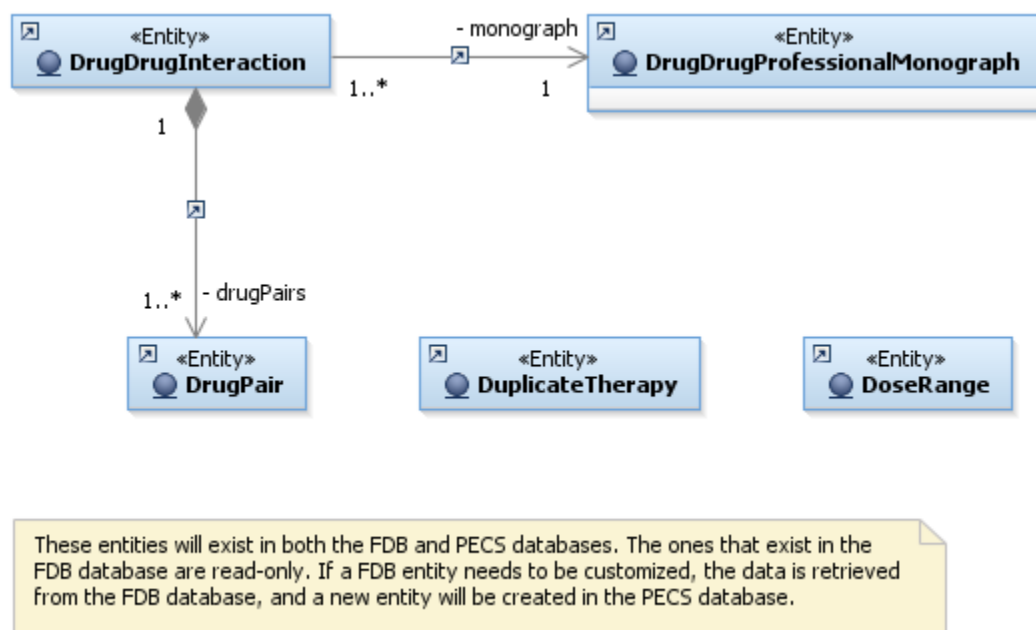


Figure 6: Conceptual Entities

The diagram below depicts the pattern followed in the design of the PECS data model for each concept.

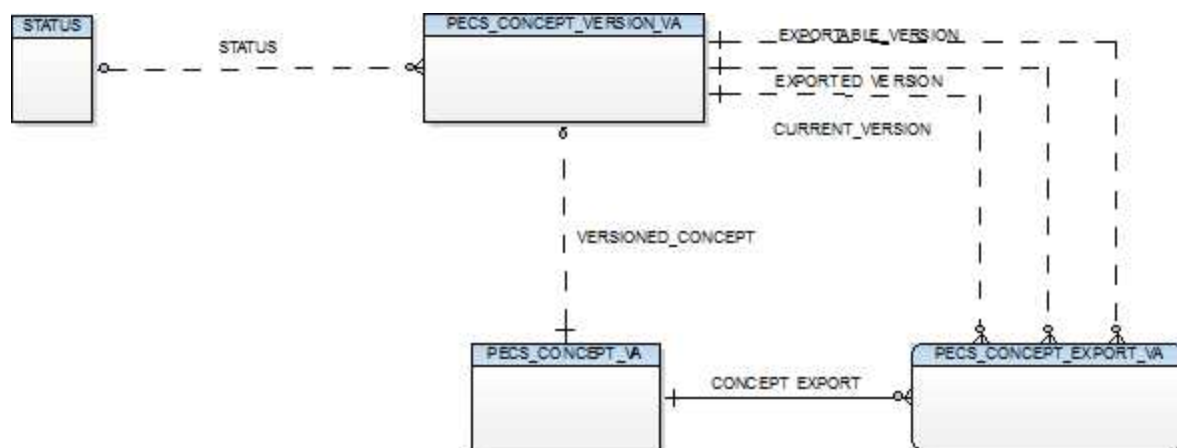


Figure 7: Design of PECS Data Model

The semantics of the entities and the relationships will be detailed in the subsequent sections.

3.2.2 Database Information

For the PECS application, the table below identifies all databases that will be created and interfaced with, or whose structure will be modified.

Table 10: Database Inventory

| Database Name | Description | Type | Steward |
|---------------|---|-----------------------|----------------|
| PECS | Database used for storing customization requests and audit information related to the customization process | Modify | PRE |
| FDB-DIF | COTS drug database used as the source of customization information | Interface (Read only) | First Databank |

3.3 User Interface Data Mapping

The following sections discuss the Database Mapping for PECS 6.0.

Application Screen Interface

The GUI Field listed in the following tables is the label for the field from the UI. Since the user has the ability to customize these labels, the label may not exactly match the UI.

3.3.1 Duplicate Therapy

The Duplicate Therapy Detail screen allows user to view/edit the fields of the Duplicate Therapy record and to take actions on the record (customize/modify/approve/delete etc.).

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Duplicate Therapy

Page Help

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Edit

History

Print Page

Action Status

Modified

Description (Required)

Low dose Aspirin (81 mg or less) modified

DTCID

1634

Duplication Allowance (Required)

1

Action Date

2013-11-08 13:36:44

Action Performed By

Export Date

Request Assigned To

Request Submitted By

Reference Text

Action Reason History

2013/11/08 13:36:44 TWO_CUSTOM: aspirin
2013/11/08 13:36:07 TWO_CUSTOM: dup allowance to 1

Current Action Reason (Required)

Pre-Customization Comment History

Edit

History

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Duplicate Therapy

Page Help

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Edit

History

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Dtcid

88

Custom Dup Allowance (Required)

1

Description (Required)

Bacitracin

Action Status

New

Action Date

2013-05-28 12:47:46

Action Performed By

Request Assigned To

Request Submitted By

Reference Text

zewq

Action Reason History

2013/05/28 12:47:46 FOUR_APPROVER: cart

Current Action Reason (Required)

Pre-Customization Comment History

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Figure 8: Duplicate Therapy Details

Table 11: Duplicate Therapy Database Details

| UI Field Label | Table | Field | Comments |
|----------------------|-----------------------------|-----------------------|---|
| | PECS_DUPL_THERAPY_VA | VA_DUPL_THERAPY_ID | A PECS assigned identifier to the custom Duplicate Therapy. This column is not displayed in the UI. |
| DTCID | PECS_DUPL_THERAPY_VA | DTCID | The Duplicate Therapy Class Identifier assigned to this Duplicate Therapy. A custom Duplicate Therapy can only override a FDB Duplicate Therapy, so this identifier must match a FDB Duplicate Therapy. |
| | PECS_DUPL_THERAPY_VA | CATEGORY_CODE | The Category associated to this Duplicate Therapy. The only Category used by PECS is 'VA'. This column is not displayed in the UI. |
| Request Submitted By | PECS_DUPL_THERAPY_VA | REQUESTOR | The user who entered the custom Duplicate Therapy in to the system. |
| | PECS_DUPL_THERAPY_EXPORT_VA | ACTIVE_VERSION_ID | The identifier of the row in the PECS_DUPL_THERAPY_VERSION_VA table that is the current version of this custom Duplicate Therapy. This column is not displayed in the UI. |
| | PECS_DUPL_THERAPY_EXPORT_VA | EXPORTABLE_VERSION_ID | The identifier of the row in the PECS_DUPL_THERAPY_VERSION_VA table that will be sent out in the next Custom Update. This column is not displayed in the UI. |
| | PECS_DUPL_THERAPY_EXPORT_VA | EXPORTED_VERSION_ID | The identifier of the row in the PECS_DUPL_THERAPY_VERSION_VA table that was last sent out in a Custom Update. This column is not displayed in the UI. |
| | PECS_DUPL_THERAPY_VA | FDB_REFERENCE_ID | A PECS assigned identifier to the FDB version of the Duplicate Therapy. This column is not displayed in the UI. |

| UI Field Label | Table | Field | Comments |
|-----------------------|------------------------------|--------------------------|---|
| | PECS_DUPL_THERAPY_VERSION_VA | VERSION_ID | A PECS assigned identifier to the version of this custom Duplicate Therapy. This column is not displayed in the UI. |
| | PECS_DUPL_THERAPY_VERSION_VA | VA_DUPL_THERAPY_ID | A pointer to the PECS_DUPL_THERAPY_VA row that this version is associated with. This column is not displayed in the UI. |
| | PECS_DUPL_THERAPY_VERSION_VA | VERSION_NUM | The version number of this row. This column is not displayed in the UI. |
| Current Action Reason | PECS_DUPL_THERAPY_VERSION_VA | VERSION_COMMENT | The Current Action Reason entered by the user when saving this row. |
| Action Date | PECS_DUPL_THERAPY_VERSION_VA | VERSION_DATE | The system date when this version was created. |
| | PECS_DUPL_THERAPY_VERSION_VA | VERSION_USER | The user who created this row in the database. |
| Action Performed By | PECS_DUPL_THERAPY_VERSION_VA | ACTION_BY | The user who last performed a state change on this object. |
| Export Date | PECS_DUPL_THERAPY_VERSION_VA | EXPORT_DATE | The date this version was sent out in a Custom Update. |
| | PECS_DUPL_THERAPY_VERSION_VA | STATUS_ID | The identifier of the PECS_STATUS row that holds the Status associated to this version. This column is not displayed in the UI. |
| Action Status | PECS_STATUS | NAME | The Status of this version of the custom Duplicate Therapy. |
| Custom Dup Allowance | PECS_DUPL_THERAPY_VERSION_VA | CUSTOM_DUP_ALLOWANCE | The Custom Duplicate Allowances entered by the user. |
| | PECS_DUPL_THERAPY_VERSION_VA | CUSTOM_DUP_ALLOWANCE_IND | An indicator used to tell FDB if this Duplicate Therapy should be used or not. Since a custom Duplicate Therapy should always be used, this indicator is always set to X. This column is not displayed in the UI. |
| Description | PECS_DUPL_THERAPY_VERSION_VA | CUSTOM_STRING | A description for the custom Duplicate Therapy. |

| UI Field Label | Table | Field | Comments |
|-----------------------------------|------------------------------|--|--|
| Request Assigned To | PECS_DUPL_THERAPY_VERSION_VA | ASSIGNED_USER | The Approver who should make the next state change on the object. |
| Reference Text | PECS_DUPL_THERAPY_VERSION_VA | REFERENCE_TEXT | A text field to hold reference data for the custom Duplicate Therapy. |
| Action Effective Date | PECS_DUPL_THERAPY_VERSION_VA | VERSION_DATE | The system date when this version was created. |
| Action Reason History | | | This item is not stored in the database. It is calculated by collecting all of the VERSION_COMMENT, VERSION_DATE and VERSION_USER columns from the versions associated with this custom Duplicate Therapy. |
| Pre-Customization Comment History | DUPLTHERAPY_COMMENT | COMMENT_TEXT COMMENT_DATE COMMENT_USER | This item is not stored in the database. It is calculated by collecting all of the COMMENT_TEXT, COMMENT_DATE and COMMENT_USER columns for the originating associated FDB Duplicate Therapy. |

3.3.2 Professional Monograph Detail

The Professional Monograph Detail screen allows user to view/edit the fields of the Professional Monograph record and to take actions on the record (customize / modify / approve / delete etc.).

PECS is following the FDB way of storing Professional Monograph information. Each line of text in the Monograph is stored in a separate row in the database. These lines of text are grouped by Section and ordered by a line number within the Section.

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Professional Monograph
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To update this record click on the edit button below:

Edit

History
Print Page

| | |
|---|--|
| Action Status | Approved |
| Monograph Title (Required) | Anticoagulant/Quinine |
| Corresponding FDB Monograph ID | 140 |
| Monograph ID | 150425 |
| Severity Level (Required) | 1 critical - versus von D-Severe interaction: action is required to reduce the risk of severe adverse interaction. |
| Mechanism Of Action | not established. |
| Clinical Effects (Required) | possible reduced prothrombin activity or increased bleeding.xxx |
| Predisposing Factors | none determined. |
| Patient Management | if both drugs are administered, adjust the anticoagulant dose as needed based on prothrombin activity. the time of highest risk for a coumarin-type drug interaction is when the precipitant drug is initiated or discontinued. Contact the prescriber before initiating, altering the dose or discontinuing either drug. |
| Discussion | this interaction has not been reported with quinine, only with quinidine; however, if an interaction occurs, the consequences could be severe. |
| Reference | xxxxxxCo: 1.soch-wesser J. Quinidine-induced hypoprothrombinemic hemorrhage in patients on chronic warfarin therapy. Ann intern med 1964 mar;62(3):511-7. |
| Disclaimer | the information contained in this monograph is intended to supplement the knowledge of physicians, pharmacists, and other healthcare professionals regarding drug therapy problems and patient counseling information.this information is advisory only and is not intended to replace sound clinical judgment in the delivery of healthcare services. |
| Action Date | 2013-11-26 16:35:05 |
| Action Performed By | [Redacted] |
| Export Date | [Redacted] |
| Request Assigned To | [Redacted] |
| Request Submitted By | [Redacted] |
| Reference Text | |
| Action Reason History | 2013/11/26 11:17:56 txxxx_aynnOvnn: mlll comment |
| Current Action Reason (Required) | |
| Pre-Customization Comment History | 2013/11/26 11:17:30 txxxx_aynnOvnn: mlll comment1 |

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Professional Monograph
Page Help

To update this record click on the edit button below.

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Action Status

Reviewed

Monograph Title (Required)

Ergot Derivatives/Dopamine

Monograph ID

150194

Corresponding FDB Monograph ID

165

Severity Level (Required)

2-Severe Interaction: Action is required to reduce the risk of severe adverse interaction.aa
bb

Mechanism Of Action

Additive or synergistic effect on peripheral blood vessels.aa
bb

Clinical Effects (Required)

May observe increased blood pressure due to peripheral vasoconstriction.aa
bb

Predisposing Factors

None determined.

Patient Management

If both drugs are administered, monitor blood pressure. If hypertension occurs, decreasing the dose of one or both drugs may be necessary. If hypertension persists, administration of an alpha adrenergic blocking agent may be indicated.

Discussion

Documentation is lacking; however, if an interaction occurs, the consequences could be severe.

Reference

REFERENCE:
1.Buchanan N, Cane RD, Miller M. Symmetrical gangrene of the extremities associated with the use of dopamine subsequent to ergometrine administration. Intensive Care Med 1977 Aug;3(2):55-6.

Disclaimer

The information contained in this monograph is intended to supplement the knowledge of physicians, pharmacists, and other healthcare professionals regarding drug therapy problems and patient counseling information.This information is advisory only and is not intended to replace sound clinical judgment in the delivery of healthcare services.

Action Date

2013-03-22 11:06:10

Action Performed By

Request Assigned To

Request Submitted By

Reference Text

Action Reason History

2013/03/22 10:26:52 FOUR_APPROVER: aabb

Current Action Reason (Required)

Pre-Customization Comment History

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Figure 9: Professional Monograph Detail Screen

Table 12: Professional Monograph Database Details

| GUI Field | Table | Field | Comments |
|---------------------|---------------------------|-----------------|--|
| Monograph Title | PECS_MONOGRAPH_VERSION_VA | TITLE | The Title of the Monograph. |
| Action Performed By | PECS_MONOGRAPH_VERSION_VA | ACTION_BY | The user who last performed a state change on this object. |
| Action Date | PECS_MONOGRAPH_VERSION_VA | VERSION_DATE | The system date when this version was created. |
| Monograph Id | PECS_MONOGRAPH_VA | VA_MONOGRAPH_ID | A unique identifier assigned to the Monograph. |

| GUI Field | Table | Field | Comments |
|--------------------------------|------------------------------------|---------------|---|
| | PECS_MONOGRAPH_VERSION _VA | STATUS_ID | The identifier of the PECS_STATUS row that holds the Status associated to this version. This column is not displayed in the UI. |
| Action Status | PECS_STATUS | NAME | The Status of this version of the custom Monograph. |
| Action Effective Date | PECS_MONOGRAPH_VERSION _VA | VERSION_DATE | The system date when this version was created. |
| Corresponding FDB Monograph ID | PECS_MONOGRAPH_VA | MONOGRAPH_ID | The identifier of the FDB Monograph associated with this custom Monograph. |
| Request Assigned To | PECS_MONOGRAPH_VERSION _VA | ASSIGNED_USER | The Approver who should make the next state change on the object. |
| Severity Level | PECS_MONOGRAPH_SECTION _LINE_VA | LINE_TEXT | This field is a consolidation all of current lines where the SECTION_CODE = 'L'. |
| Mechanism of Action | PECS_MONOGRAPH_SECTION _LINE_VA | LINE_TEXT | This field is a consolidation all of current lines where the SECTION_CODE = 'A'. |
| Clinical Effects | PECS_MONOGRAPH_SECTION _LINE_VA | LINE_TEXT | This field is a consolidation all of current lines where the SECTION_CODE = 'E'. |
| Predisposing Factors | PECS_MONOGRAPH_SECTION _LINE_VA | LINE_TEXT | This field is a consolidation all of current lines where the SECTION_CODE = 'P'. |
| Patient Management | PECS_MONOGRAPH_SECTION _LINE_VA | LINE_TEXT | This field is a consolidation all of current lines where the SECTION_CODE = 'M'. |
| Discussion | PECS_MONOGRAPH_SECTION _LINE_VA | LINE_TEXT | This field is a consolidation all of current lines where the SECTION_CODE = 'D'. |
| Reference | PECS_MONOGRAPH_SECTION _LINE_VA | LINE_TEXT | This field is a consolidation all of current lines where the SECTION_CODE = 'R'. |
| Disclaimer | PECS_MONOGRAPH_SECTION _LINE_VA | LINE_TEXT | This field is a consolidation all of current lines where the SECTION_CODE = 'Z'. |
| Export Date | PECS_MONOGRAPH_VERSION _VA | EXPORT_DATE | The date this version was sent out in a Custom Update. |

| GUI Field | Table | Field | Comments |
|-----------------------|--------------------------------|-------------------|--|
| Current Action Reason | PECS_MONOGRAPH_VERSION_VA | VERSION_COMMENT | The Current Action Reason entered by the user when saving this row. |
| Action Reason History | | | This item is not stored in the database. It is calculated by collecting all of the VERSION_COMMENT, VERSION_DATE and VERSION_USER columns from the versions associated with this custom Duplicate Therapy. |
| Request Submitted By | PECS_MONOGRAPH_VA | REQUESTOR | The user who entered the custom Monograph in to the system. |
| Reference Text | PECS_MONOGRAPH_VERSION_VA | REFERENCE_TEXT | A text field to hold reference data for the custom Professional Monograph. |
| Language ID | PECS_MONOGRAPH_VA | LANGUAGE_ID | The FDB identifier for the English language. |
| | PECS_MONOGRAPH_SECTION_LINE_VA | LINE_ID | An identifier assigned to a line of text. This column is not displayed. |
| | PECS_MONOGRAPH_SECTION_LINE_VA | SECTION_CODE | The section this line of text is associated with. See the 'Severity Level', 'Clinical Effect', etc. sections above. |
| | PECS_MONOGRAPH_SECTION_LINE_VA | FORMAT_CODE | A code that represents how this line should be formatted. This column is not displayed. |
| | PECS_MONOGRAPH_VA | CATEGORY_CODE | The category associated with this Professional Monograph. PECS currently always sets this to 'VA'. This column is not displayed. |
| | PECS_MONOGRAPH_EXPORT_VA | ACTIVE_VERSION_ID | The identifier of the row in the PECS_MONOGRAPH_VERSION_VA table that is the current version of this custom Duplicate Therapy. This column is not displayed in the UI. |

| GUI Field | Table | Field | Comments |
|-----------|--------------------------------|-----------------------|---|
| | PECS_MONOGRAPH_EXPORT_VA | EXPORTABLE_VERSION_ID | The identifier of the row in the PECS_MONOGRAPH_VERSION_VA table that was last sent out in a Custom Update. This column is not displayed in the UI. |
| | PECS_MONOGRAPH_EXPORT_VA | EXPORTED_VERSION_ID | The identifier of the row in the PECS_MONOGRAPH_VERSION_VA table that was last sent out in a Custom Update. This column is not displayed in the UI. |
| | PECS_MONOGRAPH_VA | FDB_REFERENCE_ID | A PECS assigned identifier to the FDB version of the Monograph. This column is not displayed in the UI. |
| | PECS_MONOGRAPH_VERSION_LINE_VA | VERSION_ID | A PECS assigned identifier to the version of this custom Monograph Version Line. This column is not displayed in the UI. |
| | PECS_MONOGRAPH_VERSION_LINE_VA | LINE_ID | An identifier assigned to a version of a line. This column is not displayed. |
| | PECS_MONOGRAPH_VERSION_LINE_VA | SEQUENCE_NUMBER | The sequence of a line within a section. This column is not displayed. |
| | PECS_MONOGRAPH_VERSION_VA | VERSION_ID | A PECS assigned identifier to the version of this custom Monograph Version. This column is not displayed in the UI. |
| | PECS_MONOGRAPH_VERSION_VA | VA_MONOGRAPH_ID | The identifier of the Professional Monograph this version is associated with. |
| | PECS_MONOGRAPH_VERSION_VA | VERSION_NUM | The version number of this row. This column is not displayed in the UI. |
| | PECS_MONOGRAPH_VERSION_VA | VERSION_USER | The user who last modified the information. |

| GUI Field | Table | Field | Comments |
|-----------------------------------|-------------------|--|--|
| Pre-Customization Comment History | MONOGRAPH_COMMENT | COMMENT_TEXT COMMENT_DATE COMMENT_USER | This item is not stored in the database. It is calculated by collecting all of the COMMENT_TEXT, COMMENT_DATE and COMMENT_USER columns for the originating associated FDB Monograph. |

3.3.3 Drug-Drug Interaction Detail

The Drug-Drug Interaction Detail screen allows user to view/edit the fields of the Drug-Drug Interaction record and to take actions on the record (customize/modify/approve/delete etc.). This screen gives a button for navigation to the Drug pairs screen to view and edit the list of associated drug pairs.

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Drug-Drug Interaction [Page Help](#)

Informational Messages:

- The associated drug pairs are not all reviewed yet. To submit this interaction as reviewed, you must review all associated drug pairs. First click on the Drug Pairs button and then, take appropriate action.
- To update this record click on the edit button below.

[Edit](#) [Drug Pairs](#) [History](#) [Print Page](#)

| Interaction Type | Interaction ID | Interaction Description | Interaction Severity | Interaction Action Status |
|------------------|---------------------|---|----------------------|---------------------------|
| FDB Interaction | 175 | CARBONIC ANHYDRASE INHIBITORS/SALICYLATES | 3 | N/A |

Action Status: New

Interaction Description (Required) CARBONIC ANHYDRASE INHIBITORS/SALICYLATESzz

Severity Level Code (Required) 2 - Severe Interaction

Interaction ID: 2021227

[Monograph ID](#): Carbonic Anhydrase Inhibitors/Salicylates - 175

[Corresponding FDB Interaction ID](#): 175

Clinical Effect Code 1 (Required) Adverse reaction of the latter drug

Clinical Effect Code 2: Increased effect of the former drug

Figure 10: Drug-Drug Interaction Detail Screen

Table 13: Drug-Drug Interaction Database Details

| UI Field Label | Table | Field | Comments |
|----------------|-------------|----------------|---|
| | PECS_DDI_VA | PECS_DDI_VA_ID | A PECS assigned identifier to the custom Drug-Drug Interaction. This column is not displayed in the UI. |

| UI Field Label | Table | Field | Comments |
|----------------------------------|---------------------|-----------------------|--|
| | PECS_DDI_EXPORT_VA | EXPORTABLE_VERSION_ID | The identifier of the row in the PECS_DDI_VERSION_VA table that will be sent out in the next Custom Update. This column is not displayed in the UI. |
| | PECS_DDI_EXPORT_VA | EXPORTED_VERSION_ID | The identifier of the row in the PECS_DDI_VERSION_VA table that was last sent out in a Custom Update. This column is not displayed in the UI. |
| | PECS_DDI_EXPORT_VA | ACTIVE_VERSION_ID | The identifier of the row in the PECS_DDI_VERSION_VA table that is the current version of this custom Drug-Drug Interaction. This column is not displayed in the UI. |
| Interaction Id | PECS_DDI_VA | INTERACTION_ID | A unique identifier from a business perspective that identifies this Drug-Drug Interaction. Custom Drug-Drug Interaction Identifiers start at 150,000 and is incremented by 1 for each new custom Drug-Drug Interaction. |
| Request Submitted By | PECS_DDI_VA | REQUESTOR | The user who entered the custom Drug-Drug Interaction in to the system. |
| Corresponding FDB Interaction Id | PECS_DDI_VA | FDB_ID | The Drug-Drug Interaction Identifier from FDB that this custom Drug-Drug Interaction is associated. |
| Reverse FDB ID | PECS_DDI_VA | REVERSE_FDB_ID | The reverse FDB Drug-Drug Interaction Id. |
| | PECS_DDI_VA | FDB_REFERENCE_ID | A PECS assigned identifier to the FDB version of the Drug-Drug Interaction. This column is not displayed in the UI. |
| | PECS_DDI_VERSION_VA | VERSION_ID | A PECS assigned identifier to the version of this custom Drug-Drug Interaction. This column is not displayed in the UI. |
| | PECS_DDI_VERSION_VA | PECS_DDI_VA_ID | The identifier of the PECS_DDI_VA row that this version is associated. |
| | PECS_DDI_VERSION_VA | STATUS_ID | The identifier of the PECS_STATUS row that holds the Status associated to this version. This column is not displayed in the UI. |
| Action Status | PECS_STATUS | NAME | The Status of this version. |
| | PECS_DDI_VERSION_VA | SEVERITY_LEVEL_ID | The identifier of the Severity Level associated to this version. |

| UI Field Label | Table | Field | Comments |
|-------------------------|---------------------|------------------------------|--|
| Severity Level Code | SEVERITY_LEVEL | CODE | The CODE for the associated SEVERITY_LEVEL_ID. |
| | PECS_DDI_VERSION_VA | CLINICAL_EFFECT1_ID | The identifier of the first Clinical Effect associated to this version. |
| Clinical Effect Code 1 | CLINICAL_EFFECT | CODE | The CODE for the associated CLINICAL_EFFECT1_ID. |
| | PECS_DDI_VERSION_VA | CLINICAL_EFFECT2_ID | The identifier of the second Clinical Effect associated to this version. |
| Clinical Effect Code 2 | CLINICAL_EFFECT | CODE | The CODE for the associated CLINICAL_EFFECT2_ID. |
| Interaction Description | PECS_DDI_VERSION_VA | DESCRIPTION | The Description of the Drug-Drug Interaction. |
| Monograph Id | PECS_DDI_VERSION_VA | MONOGRAPH_ID | The identifier of the DDI Professional Monograph associated to this version. |
| | PECS_DDI_VERSION_VA | EDI_NUMBER_ID | The identifier of the EDI Number associated to this version. |
| EDI Number | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated EDI Number. |
| | PECS_DDI_VERSION_VA | DI_FACT_NUMBER_ID | The identifier of the DI Fact Number associated to this version. |
| DI Facts Number | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated DI Facts Number. |
| | PECS_DDI_VERSION_VA | DI_FACT_DOCUMENTATION_ID | The identifier of the associated DI Facts Documentation. |
| DI Facts Documentation | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated DI Facts Documentation. |
| | PECS_DDI_VERSION_VA | DI_FACT_ONSET_ID | The identifier of the associated DI Facts Onset. |
| DI Facts Onset | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated DI Facts Onset. |
| | PECS_DDI_VERSION_VA | DI_FACT_SEVERITY_ID | The identifier of the associated DI Facts Severity. |
| DI Facts Severity | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated DI Facts Severity. |
| | PECS_DDI_VERSION_VA | MICROMEDEX_ONSET_ID | The identifier of the associated Micromedex Onset. |
| Micromedex Onset | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated Micromedex Onset. |
| | PECS_DDI_VERSION_VA | MICROMEDEX_SEVERITY_ID | The identifier of the associated Micromedex Severity. |
| Micromedex Severity | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated Micromedex Severity. |
| | PECS_DDI_VERSION_VA | MICROMEDEX_SUBSTANTIATION_ID | The identifier of the associated Micromedex Substantiation. |

| UI Field Label | Table | Field | Comments |
|---------------------------|---------------------|-----------------------|--|
| Micromedex Substantiation | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated Micromedex Substantiation. |
| | PECS_DDI_VERSION_VA | MEDLINE_HIT_ID | The identifier of the associated Medline Hits. |
| Medline Hits | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated Medline Hits. |
| | PECS_DDI_VERSION_VA | PACKAGE_INSERT_ID | The identifier of the associated Package Insert. |
| Package Insert | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated Package Insert. |
| | PECS_DDI_VERSION_VA | PBM_CRITERIA_ID | The identifier of the associated PBM Criteria. |
| PBM Criteria | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated PBM Criteria. |
| | PECS_DDI_VERSION_VA | AIDS_GUIDELINE_ID | The identifier of the associated AIDS Guideline. |
| AIDS Guidelines | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated AIDS Guideline. |
| | PECS_DDI_VERSION_VA | INTERACTION_SOURCE_ID | The identifier of the associated Interaction Source. |
| Interaction Source | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated Interaction Source. |
| | PECS_DDI_VERSION_VA | INTERACTION_TYPE_ID | The identifier of the associated Interaction Type. |
| Interaction Type | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated Interaction Type. |
| | PECS_DDI_VERSION_VA | LEVEL_OF_EVIDENCE_ID | The identifier of the associated Level of Evidence. |
| Highest Level of Evidence | REFERENCE_TEXT_VA | REFERENCE_TEXT_NAME | The NAME of the associated Level of Evidence. |
| EDI Text | PECS_DDI_VERSION_VA | EDI_TEXT | Any items the user feels necessary to explain the EDI information. |
| DI Facts Text | PECS_DDI_VERSION_VA | DI_FACT_TEXT | Any text the user feels necessary to explain the DI Facts information. |
| Micromedex Text | PECS_DDI_VERSION_VA | MICROMEDEX_TEXT | Any text the user feels necessary to explain the Micromedex information. |
| Medline Text | PECS_DDI_VERSION_VA | MEDLINE_TEXT | Any text the user feels necessary to explain the Medline information. |
| Package Insert Text | PECS_DDI_VERSION_VA | PACKAGE_INSERT_TEXT | Any text the user feels necessary to explain the Package Insert information. |
| PBM Criteria Text | PECS_DDI_VERSION_VA | PBM_CRITERIA_TEXT | Any text the user feels necessary to explain the PBM Criteria information. |

| UI Field Label | Table | Field | Comments |
|-----------------------------------|-------------------------|--|--|
| AIDS Guideline Text | PECS_DDI_VERSION_VA | AIDS_GUIDELINE_TEXT | Any text the user feels necessary to explain the AIDS Guideline information. |
| Group Discussion | PECS_DDI_VERSION_VA | GROUP_DISCUSSION | Any text a user feels necessary. |
| Current Action Reason | PECS_DDI_VERSION_VA | VERSION_COMMENT | The Current Action Reason entered by the user when saving this row. |
| Action Date | PECS_DDI_VERSION_VA | VERSION_DATE | The system date when this version was created. |
| | PECS_DDI_VERSION_VA | VERSION_USER | The user who created the version. |
| Action Performed By | PECS_DDI_VERSION_VA | ACTION_BY | The user who last performed a state change on this object. |
| Export Date | PECS_DDI_VERSION_VA | EXPORT_DATE | The date this version was sent out in a Custom Update. |
| Request Assigned To | PECS_DDI_VERSION_VA | ASSIGNED_USER | The Approver who should make the next state change on the object. |
| | PECS_DDI_VERSION_VA | REFERENCE_TEXT | This column is not utilized by Drug-Drug Interactions. |
| | PECS_DDI_VERSION_VA | VERSION_NUM | The version number of this row. This column is not displayed in the UI. |
| Action Effective Date | PECS_DDI_VERSION_VA | VERSION_DATE | The system date when this version was created. |
| Action Reason History | | | This item is not stored in the database. It is calculated by collecting all of the VERSION_COMMENT, VERSION_DATE and VERSION_USER columns from the versions associated with this custom Duplicate Therapy. |
| Pre-Customization Comment History | DDIMINTERACTION_COMMENT | COMMENT_TEXT COMMENT_DATE COMMENT_USER | This item is not stored in the database. It is calculated by collecting all of the COMMENT_TEXT, COMMENT_DATE and COMMENT_USER columns for the originating associated FDB DDI. |

3.3.4 Drug-Drug Pairs Customization

The Drug Pairs Customization Detail screen allows user to view/edit the List of Drug Pairs records for one Drug-Drug Interaction and to take actions on this list (add/modify/approve/delete etc.).

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Drug Pair Customization (Non 508 Compliant) 508 Compliant Page Page Help

To update this record click on the edit button below.

Edit

| Interaction Type | Interaction ID | Interaction Description | Interaction Severity | Interaction Action Status |
|------------------|----------------|---|----------------------|---------------------------|
| VA Interaction | 2020995 | SELECTED 5HT-1D AGONISTS/MAO INHIBITORS | 2 | Modified |
| FDB Interaction | 436 | SELECTED 5HT-1D AGONISTS/MAO INHIBITORS | 1 | N/A |

☐ Select Drug Pairs to add to the above VA Custom Interaction

Select Drug Pair(s) Source

Drug pairs from corresponding FDB Interaction

Drug pair from Routed Generic Drug lists

Select from list of FDB drug pairs - note that at least one drug pair must be chosen before clicking the Customize button.

| Routed Generic #1 Description | Routed Generic #2 Description |
|--|---|
| <input type="checkbox"/> RIZATRIPTAN BENZOATE ORAL | <input type="checkbox"/> PARGYLINE HCL ORAL |
| <input type="checkbox"/> RIZATRIPTAN BENZOATE ORAL | <input type="checkbox"/> ISOCARBOXAZID ORAL |
| <input type="checkbox"/> RIZATRIPTAN BENZOATE ORAL | <input type="checkbox"/> PHENELZINE SULFATE ORAL |
| <input type="checkbox"/> RIZATRIPTAN BENZOATE ORAL | <input type="checkbox"/> TRANILCYPROMINE SULFATE ORAL |
| <input type="checkbox"/> RIZATRIPTAN BENZOATE ORAL | <input type="checkbox"/> PROCARBAZINE HCL ORAL |

Figure 11: Drug Pairs Customization Page – Top

☐ TAPENTADOL HCL ORAL
☐ TAPENTADOL HCL ORAL
☐ TRAMADOL HCL MISCELLANEOUS

☐ SUMATRIPTAN SUCCLINATE ORAL
☐ SUMATRIPTAN SUCCLINATE MISCELLANEOUS
☐ SUMATRIPTAN SUCCLINATE ORAL

☐ Select/Deselect Drug Pairs from Corresponding FDB Interaction

☐ 100 Max ☐ 200 Max ☐ 1000 Max ☒ All

Enter values in text boxes below and click 'Customize' to add drug pairs to interaction.

Reference Text (drug pair reference text):

Current Action Reason (for drug pair creation): (Required)

Assigned To (Required)
UNASSIGNED

☒ Drug Pairs

☒ NEW ☒ MODIFIED ☒ REVIEWED ☒ APPROVED ☒ DELETE REVIEWED

| Select | Action Status | Routed Generic #1 Description | Routed Generic #2 Description | Interaction Description | Severity Level Code | Severity Level Description | Interaction ID | Corresponding FDB Interaction ID | Request Submitted By | Request Assigned To | Action Performed By | Action Date | Current Action Reason | Routed Generic #2 | Routed Generic #1 |
|--------------------------|---------------|-------------------------------|-------------------------------|--|---------------------|----------------------------|----------------|----------------------------------|----------------------|---------------------|---------------------|---------------------|-----------------------|-------------------|-------------------|
| <input type="checkbox"/> | Reviewed | TRAMADOL HCL ORAL | SUMATRIPTAN SUCCLINATE ORAL | TAPENTADOL: TRAMADOL/5HT-1D AGONISTS (TRIPITANS) | 2 | Severe Interaction | 2020530 | 2035 | T | | | 2012-02-01 10:46:40 | | 1055163 | 1055163 |

Figure 12: Drug Pairs Customization Page – Bottom

Table 14: Drug-Drug Pairs Customization Database Details

| GUI Field | Table | Field | Comments |
|-------------------------------|---------------------------|-----------------------|--|
| | PECS_DRUG_PAIR_VA | VA_DRUG_PAIR_ID | A PECS assigned identifier to the custom Drug Pair. This column is not displayed in the UI. |
| Routed Generic #1 | PECS_DRUG_PAIR_VA | ROUTED_GENERIC_ID1 | The identifier of the Routed Generic #1 Drug this Drug Pair is associated. |
| Routed Generic #1 Description | FDB_GENERIC_ROUTEDDRUG | DESCRIPTION1 | The description of the Routed Generic #1 Drug this Drug Pair is associated. |
| Routed Generic #2 | PECS_DRUG_PAIR_VA | ROUTED_GENERIC_ID2 | The identifier of the Routed Generic #2 Drug this Drug Pair is associated. |
| Routed Generic #2 Description | FDB_GENERIC_ROUTEDDRUG | DESCRIPTION1 | The description of the Routed Generic #2 Drug this Drug Pair is associated. |
| | PECS_DRUG_PAIR_VA | PECS_DDI_VA_ID | The identifier of the custom Drug-Drug Interaction this Drug Pair is associated. |
| | PECS_DRUG_PAIR_EXPORT_VA | ACTIVE_VERSION_ID | The identifier of the row in the PECS_DRUG_PAIR_VERSION_VA table that is the current version of this custom Drug Pair. This column is not displayed in the UI. |
| | PECS_DRUG_PAIR_EXPORT_VA | EXPORTABLE_VERSION_ID | The identifier of the row in the PECS_DRUG_PAIR_VERSION_VA table that will be sent out in the next Custom Update. This column is not displayed in the UI. |
| | PECS_DRUG_PAIR_EXPORT_VA | EXPORTED_VERSION_ID | The identifier of the row in the PECS_DRUG_PAIR_VERSION_VA table that was last sent out in a Custom Update. This column is not displayed in the UI. |
| Request Submitted By | PECS_DRUG_PAIR_VA | REQUESTOR | The user who entered the custom Drug Pair in to the system. |
| | PECS_DRUG_PAIR_VERSION_VA | VERSION_ID | A PECS assigned identifier to the version of this custom Drug Pair. This column is not displayed in the UI. |
| | PECS_DRUG_PAIR_VERSION_VA | VA_DRUG_PAIR_ID | An identifier assigned to a Drug Pair when it is created. This column is not displayed in the UI. |

| GUI Field | Table | Field | Comments |
|----------------------------------|---------------------------|-----------------|--|
| | PECS_DRUG_PAIR_VERSION_VA | VERSION_NUM | The version number of this row. This column is not displayed in the UI. |
| Current Action Reason | PECS_DRUG_PAIR_VERSION_VA | VERSION_COMMENT | The Current Action Reason entered by the user when saving this row. |
| Action Date | PECS_DRUG_PAIR_VERSION_VA | VERSION_DATE | The system date when this version was created. |
| Action Performed By | PECS_DRUG_PAIR_VERSION_VA | VERSION_USER | The user who created the version. |
| | PECS_DRUG_PAIR_VERSION_VA | ACTION_BY | The user who last performed a state change on this object. |
| | PECS_DRUG_PAIR_VERSION_VA | STATUS_ID | The identifier of the PECS_STATUS row that holds the Status associated to this version. This column is not displayed in the UI. |
| Action Status | PECS_STATUS | NAME | The Status of this version of the custom Duplicate Therapy. |
| Request Assigned To | PECS_DRUG_PAIR_VERSION_VA | ASSIGNED_USER | The Approver who should make the next state change on the object. |
| Reference Text | PECS_DRUG_PAIR_VERSION_VA | REFERENCE_TEXT | A text field to hold reference data for the custom Drug Pair. |
| Action Effective Date | PECS_DRUG_PAIR_VERSION_VA | VERSION_DATE | The system date when this version was created. |
| Action Reason History | | | This item is not stored in the database. It is calculated by collecting all of the VERSION_COMMENT, VERSION_DATE and VERSION_USER columns from the versions associated with this custom Duplicate Therapy. |
| Corresponding FDB Interaction Id | PECS_DDI_VA | FDB_ID | The FDB Drug-Drug Interaction Id. |
| Reverse FDB ID | PECS_DDI_VA | REVERSE_FDB_ID | The reverse FDB Drug-Drug Interaction Id. |
| Interaction Id | PECS_DDI_VA | INTERACTION_ID | The Interaction Identifier of the custom Drug-Drug Interaction this Drug Pair is associated. |
| Severity Level Code | SEVERITY_LEVEL | CODE | The Severity Level Code of the associated Drug-Drug Interaction. |
| Severity Level Description | SEVERITY_LEVEL | DESCRIPTION | The Severity Level Description of the associated Drug-Drug Interaction. |

3.3.5 Dose Range Check Details

The Dose Range Check Details screen allows user to view/edit the fields of the Dose Range Check record and to take actions on the record (modify/approve, etc.).

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Dose Range [Page Help](#)

To update this record click on the edit button below.

[Edit](#) [History](#) [Print Page](#)

Concept Type 6
 Concept ID Number (Required) 464
 Concept ID Description NITROGLYCERIN TRANSDERMAL OINTMENT 2 %
 Action Status New
 Age Low In Days (Required) 6570
 Age High In Days (Required) 23724
 Dose Route (Required) 083 - TOPICAL
 Dose Type (Required) 01 - LOADING
 FDBDX 999
 DXID 4892
 Dose Low 0.0
 Dose Low Units
 Dose High 0.0
 Dose High Units
 Dose Form Low 1.0
 Dose Form Low Units

Figure 13: Dose Range Details

Table 15: Dose Range Check Database Details

| GUI Field | Table | Field | Comments |
|----------------------|---------------------------|-------------------|--|
| | PECS_DOSE_RANGE_VA | VA_DOSE_RANGE_ID | A PECS assigned identifier to the custom Dose Range. This column is not displayed in the UI. |
| Request Submitted By | PECS_DOSE_RANGE_VA | REQUESTOR | The user who entered the custom Dose Range in to the system. |
| | PECS_DOSE_RANGE_EXPORT_VA | ACTIVE_VERSION_ID | The identifier of the row in the PECS_DOSE_RANGE_VERSION_VA table that is the current version of this custom Dose Range. This column is not displayed in the UI. |

| GUI Field | Table | Field | Comments |
|-------------------|----------------------------|-----------------------|--|
| | PECS_DOSE_RANGE_EXPORT_VA | EXPORTABLE_VERSION_ID | The identifier of the row in the PECS_DOSE_RANGE_VERSION_VA table that will be sent out in the next Custom Update. This column is not displayed in the UI. |
| | PECS_DOSE_RANGE_EXPORT_VA | EXPORTED_VERSION_ID | The identifier of the row in the PECS_DOSE_RANGE_VERSION_VA table that was last sent out in a Custom Update. This column is not displayed in the UI. |
| | PECS_DOSE_RANGE_VA | FDB_REFERENCE_ID | A PECS assigned identifier to the FDB version of the Dose Range. This column is not displayed in the UI. |
| | PECS_DOSE_RANGE_VERSION_VA | VERSION_ID | A PECS assigned identifier to the version of this custom Dose Range. This column is not displayed in the UI. |
| | PECS_DOSE_RANGE_VERSION_VA | VA_DOSE_RANGE_ID | The identifier of the PECS_DOSE_RANGE_VA row that this version is associated. |
| | PECS_DOSE_RANGE_VERSION_VA | STATUS_ID | The identifier of the PECS_STATUS row that holds the Status associated to this version. This column is not displayed in the UI. |
| Action Status | PECS_STATUS | NAME | The Status of this version of the custom Dose Range. |
| Reference Text | PECS_DOSE_RANGE_VERSION_VA | REFERENCE_TEXT | A text field to hold reference data for the custom Dose Range. |
| Category | PECS_DOSE_RANGE_VERSION_VA | CATEGORY | |
| Concept Type | PECS_DOSE_RANGE_VERSION_VA | CONCEPTTYPE | |
| Concept ID Number | PECS_DOSE_RANGE_VERSION_VA | CONCEPTID | |
| Age Low In Days | PECS_DOSE_RANGE_VERSION_VA | AGELOWINDAYS | |
| Age High In Days | PECS_DOSE_RANGE_VERSION_VA | AGEHIGHINDAYS | |
| Dose Route | PECS_DOSE_RANGE_VERSION_VA | DOSE_ROUTE_ID | |

| GUI Field | Table | Field | Comments |
|--------------------------------|----------------------------|-------------------------|----------|
| Dose Route Description | DOSE_ROUTE | NAME | |
| Dose Type | PECS_DOSE_RANGE_VERSION_VA | DOSE_TYPE_ID | |
| Dose Type Description | DOSE_TYPE | NAME | |
| FDBDX | PECS_DOSE_RANGE_VERSION_VA | FDBDX | |
| Dose Low | PECS_DOSE_RANGE_VERSION_VA | DOSELOW | |
| Dose Low Units | PECS_DOSE_RANGE_VERSION_VA | DOSELOWUNITS | |
| Dose High | PECS_DOSE_RANGE_VERSION_VA | DOSEHIGH | |
| Dose High Units | PECS_DOSE_RANGE_VERSION_VA | DOSEHIGHUNITS | |
| Dose Form Low | PECS_DOSE_RANGE_VERSION_VA | DOSEFORMLOW | |
| Dose Form Low Units | PECS_DOSE_RANGE_VERSION_VA | DOSEFORMLOWUNITS | |
| Dose Form High | PECS_DOSE_RANGE_VERSION_VA | DOSEFORMHIGH | |
| Dose Form High Units | PECS_DOSE_RANGE_VERSION_VA | DOSEFORMHIGHUNITS | |
| Maximum Single Dose | PECS_DOSE_RANGE_VERSION_VA | MAXSINGLEDOSE | |
| Maximum Single Dose Units | PECS_DOSE_RANGE_VERSION_VA | MAXSINGLEDOSEUNITS | |
| Maximum Single Dose Form | PECS_DOSE_RANGE_VERSION_VA | MAXSINGLEDOSEFORM | |
| Maximum Single Dose Form Units | PECS_DOSE_RANGE_VERSION_VA | MAXSINGLEDOSEFORM UNITS | |
| Maximum Daily Dose | PECS_DOSE_RANGE_VERSION_VA | MAXDAILYDOSE | |
| Maximum Daily Dose Units | PECS_DOSE_RANGE_VERSION_VA | MAXDAILYDOSEUNITS | |
| Maximum Daily Dose Form | PECS_DOSE_RANGE_VERSION_VA | MAXDAILYDOSEFORM | |
| Maximum Daily Dose Form Units | PECS_DOSE_RANGE_VERSION_VA | MAXDAILYDOSEFORM UNITS | |
| Maximum Lifetime Dose | PECS_DOSE_RANGE_VERSION_VA | MAXLIFETIMEDOSE | |

| GUI Field | Table | Field | Comments |
|----------------------------------|----------------------------|--------------------------|----------|
| Maximum Lifetime Dose Units | PECS_DOSE_RANGE_VERSION_VA | MAXLIFETIMEDOSEUNITS | |
| Maximum Lifetime Dose Form | PECS_DOSE_RANGE_VERSION_VA | MAXLIFETIMEDOSEFORM | |
| Maximum Lifetime Dose Form Units | PECS_DOSE_RANGE_VERSION_VA | MAXLIFETIMEDOSEFORMUNITS | |
| Low Elimination Half Life | PECS_DOSE_RANGE_VERSION_VA | LOWELIMINATIONHALFLIFE | |
| High Elimination Half Life | PECS_DOSE_RANGE_VERSION_VA | HIGHELIMINATIONHALFLIFE | |
| Half Life Units | PECS_DOSE_RANGE_VERSION_VA | HALFLIFEUNITS | |
| Frequency Low | PECS_DOSE_RANGE_VERSION_VA | FREQUENCYLOW | |
| Frequency High | PECS_DOSE_RANGE_VERSION_VA | FREQUENCYHIGH | |
| Duration Low | PECS_DOSE_RANGE_VERSION_VA | DURATIONLOW | |
| Duration High | PECS_DOSE_RANGE_VERSION_VA | DURATIONHIGH | |
| Maximum Duration | PECS_DOSE_RANGE_VERSION_VA | MAXDURATION | |
| Hepatic Impairment Indicator | PECS_DOSE_RANGE_VERSION_VA | HEPATICIMPAIRMENTIND | |
| Renal Impairment Indicator | PECS_DOSE_RANGE_VERSION_VA | RENALIMPAIRMENTIND | |
| CRCL Threshold | PECS_DOSE_RANGE_VERSION_VA | CRCLTHRESHHOLD | |
| CRCL Threshold Units | PECS_DOSE_RANGE_VERSION_VA | CRCLTHRESHHOLDUNITS | |
| Weight Required Indicator | PECS_DOSE_RANGE_VERSION_VA | WEIGHTREQUIREDIND | |
| BSA Required Indicator | PECS_DOSE_RANGE_VERSION_VA | BSAREQUIREDIND | |
| Dose Rate Low | PECS_DOSE_RANGE_VERSION_VA | DOSERATELOW | |
| Dose Rate Low Units | PECS_DOSE_RANGE_VERSION_VA | DOSERATELOWUNITS | |
| Dose Rate High | PECS_DOSE_RANGE_VERSION_VA | DOSERATEHIGH | |

| GUI Field | Table | Field | Comments |
|-------------------------------------|----------------------------|---------------------------------|---|
| Dose Rate High Units | PECS_DOSE_RANGE_VERSION_VA | DOSE_RATE_HIGH_UNITS | |
| Dose Form Rate Low | PECS_DOSE_RANGE_VERSION_VA | DOSE_FORM_RATE_LOW | |
| Dose Form Rate Low Units | PECS_DOSE_RANGE_VERSION_VA | DOSE_FORM_RATE_LOW_UNITS | |
| Dose Form Rate High | PECS_DOSE_RANGE_VERSION_VA | DOSE_FORM_RATE_HIGH | |
| Dose Form Rate High Units | PECS_DOSE_RANGE_VERSION_VA | DOSE_FORM_RATE_HIGH_UNITS | |
| Maximum Single Dose Rate | PECS_DOSE_RANGE_VERSION_VA | MAX_SINGLE_DOSE_RATE | |
| Maximum Single Dose Rate Units | PECS_DOSE_RANGE_VERSION_VA | MAX_SINGLE_DOSE_RATE_UNITS | |
| Maximum Single Dose Form Rate | PECS_DOSE_RANGE_VERSION_VA | MAX_SINGLE_DOSE_FORM_RATE | |
| Maximum Single Dose Form Rate Units | PECS_DOSE_RANGE_VERSION_VA | MAX_SINGLE_DOSE_FORM_RATE_UNITS | |
| Maximum Daily Dose Rate | PECS_DOSE_RANGE_VERSION_VA | MAX_DAILY_DOSE_RATE | |
| Maximum Daily Dose Rate Units | PECS_DOSE_RANGE_VERSION_VA | MAX_DAILY_DOSE_RATE_UNITS | |
| Maximum Daily Dose Form Rate | PECS_DOSE_RANGE_VERSION_VA | MAX_DAILY_DOSE_FORM_RATE | |
| Maximum Daily Dose Form Rate Units | PECS_DOSE_RANGE_VERSION_VA | MAX_DAILY_DOSE_FORM_RATE_UNITS | |
| DXID | PECS_DOSE_RANGE_VERSION_VA | DXID | |
| | PECS_DOSE_RANGE_VERSION_VA | VERSION_NUM | The version number of this row. This column is not displayed in the UI. |
| Current Action Reason | PECS_DOSE_RANGE_VERSION_VA | VERSION_COMMENT | |
| Action Date | PECS_DOSE_RANGE_VERSION_VA | VERSION_DATE | |
| | PECS_DOSE_RANGE_VERSION_VA | VERSION_USER | |

| GUI Field | Table | Field | Comments |
|-----------------------------------|----------------------------|--|--|
| Action Performed By | PECS_DOSE_RANGE_VERSION_VA | ACTION_BY | The user who last performed a state change on this object. |
| Export Date | PECS_DOSE_RANGE_VERSION_VA | EXPORT_DATE | The date this version was sent out in a Custom Update. |
| Request Assigned To | PECS_DOSE_RANGE_VERSION_VA | ASSIGNED_USER | The Approver who should make the next state change on the object. |
| Action Effective Date | PECS_DOSE_RANGE_VERSION_VA | VERSION_DATE | The system date when this version was created. |
| Action Reason History | | | This item is not stored in the database. It is calculated by collecting all of the VERSION_COMMENT, VERSION_DATE and VERSION_USER columns from the versions associated with this custom Duplicate Therapy. |
| Max Single NTE Dose | PECS_DOSE_RANGE_VERSION_VA | NTESINGLEDOSE | The Not-To-Exceed value for a Single Dose. |
| Max Single NTE Dose Units | PECS_DOSE_RANGE_VERSION_VA | NTESINGLEDOSEUNITS | The Units associated with the Max Single NTE Dose. |
| Max Single NTE Dose Form | PECS_DOSE_RANGE_VERSION_VA | NTESINGLEDOSEFORM | The Not-To-Exceed value for a Single Dose Form. |
| Max Single NTE Dose Form Units | PECS_DOSE_RANGE_VERSION_VA | NTESINGLEDOSEFORM UNITS | The Units associated with the Max Single NTE Dose Form. |
| Pre-Customization Comment History | DOSERANGE_COMMENT | COMMENT_TEXT COMMENT_DATE COMMENT_USER | This item is not stored in the database. It is calculated by collecting all of the COMMENT_TEXT, COMMENT_DATE and COMMENT_USER columns for the originating associated FDB Dose Range. |

3.4 Application Report Interface

PECS has a range of reports available.

Active Customization Reports

- FDB Custom Dose Range Check – a list of Custom Dose Range Check as XLSX file type.
- FDB Custom Drug-Drug Interaction report – a list of Custom Drug-Drug Interactions as XLSX file type.

- FDB Custom Duplicate Therapy report - a list of Custom Duplicate Therapy as XLSX file type.
- FDB Custom Professional Monograph report – a list of Custom Professional Monographs as XLSX file type.
- Deleted Monograph Customization Report – a list of Custom Drug-Drug Interactions that point to a deleted FDB monograph (a list of custom interactions that need manual intervention to replace the invalid monograph with a valid monograph).
- Null Drug-Drug Pairs Customization Report – a list of Custom Drug Pairs that have at least one of the Generic Routed Drug Descriptions null (a list of invalid drug pairs that need to be corrected). Note: only approved drug pairs are included in this report.

FDB Comparison Reports

- Drug-Drug Interaction/Drug Pair FDB Comparison Report
- Dose Range FDB Comparison Report
- Duplicate Therapy FDB Comparison Report

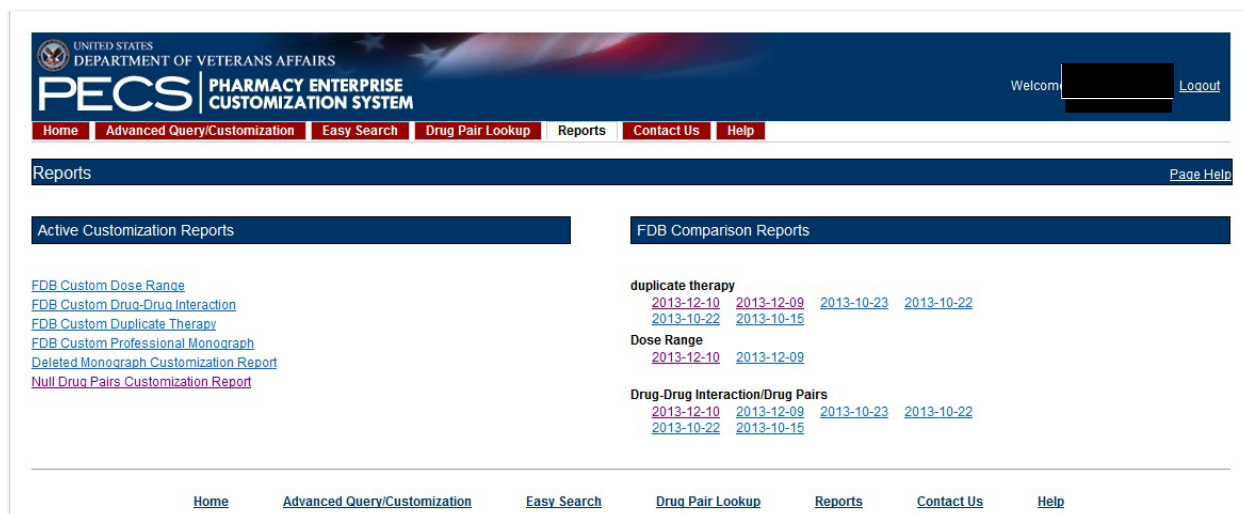


Figure 14: Reports Main Screen

3.4.1 FDB Custom Dose Range Check Report

The FDB Custom Dose Range Report contains active VA custom Dose Range records in an Approved status along with their corresponding FDB record data.

| Dosing_Total_Customization_Report.xlsx | | | | |
|--|-------------------|---|---------------|-----------------|
| | A | B | C | D |
| 1 | Concept ID Number | Concept ID Description | Action Status | Age Low In Days |
| 2 | 19 | DIGOXIN ORAL TABLET 250 MCG | Approved | 5 |
| 3 | 19 | DIGOXIN ORAL TABLET 250 MCG | Approved | 123 |
| 4 | 35 | THEOPHYLLINE/IODINATED GLYCEROL ORAL ELIXIR | Approved | 23725 |
| 5 | 1234 | POTASSIUM BICARBONATE/POTASSIUM CITRATE/CITRIC ACID ORAL TABLET,EFFERVESCENT 50 MEQ | Approved | 4745 |
| 6 | 3046 | PSYLLIUM SEED ORAL POWDER | Approved | 4380 |
| 7 | 3726 | HYDROXYZINE HCL ORAL TABLET 10 MG | Approved | 4745 |
| 8 | 3726 | HYDROXYZINE HCL ORAL TABLET 10 MG | Approved | 4745 |
| 9 | 3757 | LORAZEPAM ORAL TABLET 0.5 MG | Approved | 4745 |
| 10 | 3757 | LORAZEPAM ORAL TABLET 0.5 MG | Approved | 4746 |
| 11 | 3758 | LORAZEPAM ORAL TABLET 1 MG | Approved | 4745 |
| 12 | 3758 | LORAZEPAM ORAL TABLET 1 MG | Approved | 4745 |
| 13 | 4338 | ASPIRIN/CALCIUM CARBONATE/MAGNESIUM/ALUMINUM HYDROXIDE ORAL TABLET 500 MG | Approved | 4380 |
| 14 | 4338 | ASPIRIN/CALCIUM CARBONATE/MAGNESIUM/ALUMINUM HYDROXIDE ORAL TABLET 500 MG | Approved | 4380 |
| 15 | 6329 | ALBUMIN HUMAN INTRAVENOUS SOLUTION,INTRAVENOUS 25 % | Approved | 4745 |
| 16 | 6329 | ALBUMIN HUMAN INTRAVENOUS SOLUTION,INTRAVENOUS 25 % | Approved | 4745 |
| 17 | 8079 | FLUNISOLIDE NASAL AEROSOL,SPRAY 25 MCG (0.025 %) | Approved | 5110 |
| 18 | 8079 | FLUNISOLIDE NASAL AEROSOL,SPRAY 25 MCG (0.025 %) | Approved | 5110 |
| 19 | 8120 | CARBAMIDE PEROXIDE OTIC DROPS 6.5 % | Approved | 4380 |
| 20 | 8120 | CARBAMIDE PEROXIDE OTIC DROPS 6.5 % | Approved | 4380 |
| 21 | 8175 | TRIAMTERENE/HYDROCHLOROTHIAZIDE ORAL CAPSULE 50 MG-25 MG | Approved | 23725 |
| 22 | 8175 | TRIAMTERENE/HYDROCHLOROTHIAZIDE ORAL CAPSULE 50 MG-25 MG | Approved | 23725 |
| 23 | 8213 | CHLORTHALIDONE ORAL TABLET 25 MG | Approved | 6570 |
| 24 | 8213 | CHLORTHALIDONE ORAL TABLET 25 MG | Approved | 6570 |
| 25 | 15960 | ETODOLAC ORAL CAPSULE 200 MG | Approved | 6570 |
| 26 | 15961 | ETODOLAC ORAL CAPSULE 300 MG | Approved | 6570 |

Figure 15: FDB Custom Dose Range Report

Table 16: FDB Custom Dose Range Check Report

| Report Column | Data Source (TableName.FieldName) |
|------------------------|---|
| Request Submitted By | CTSTAGING.PECS_DOSE_RANGE_VA.REQUESTOR |
| Action Status | CTSTAGING.PECS_STATUS.NAME |
| Reference Text | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.REFERENCE_TEXT |
| Category | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CATEGORY |
| Concept Type | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CONCEPTTYPE |
| Concept ID Number | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CONCEPTID |
| Concept ID Description | FDB_DIF.FDB_DISPENSABLE_GENERIC.DESCRPTION1 |
| Age Low In Days | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.AGELOWINDAYS |
| Age High In Days | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.AGEHIGHINDAYS |
| Dose Route | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSE_ROUTE_ID |
| Dose Route Description | CTSTAGING.DOSE_ROUTE.NAME |
| Dose Type | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSE_TYPE_ID |
| Dose Type Description | CTSTAGING.DOSE_TYPE.NAME |
| FDBDX | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FDBDX |
| Dose Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSELOW |
| Dose Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSELOWUNITS |
| Dose High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEHIGH |
| Dose High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEHIGHUNITS |
| Dose Form Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMLOW |
| Dose Form Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMLOWUNITS |

| Report Column | Data Source (TableName.FieldName) |
|----------------------------------|---|
| Dose Form High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMHIGH |
| Dose Form High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMHIGH UNITS |
| Maximum Single Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSE |
| Maximum Single Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSE UNITS |
| Maximum Single Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSE FORM |
| Maximum Single Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSE FORMUNITS |
| Maximum Daily Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSE |
| Maximum Daily Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEU NITS |
| Maximum Daily Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEF ORM |
| Maximum Daily Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEF ORMUNITS |
| Maximum Lifetime Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOS E |
| Maximum Lifetime Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOS EUNITS |
| Maximum Lifetime Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOS EFORM |
| Maximum Lifetime Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOS EFORMUNITS |
| Low Elimination Half Life | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.LOWELIMINATION HALFLIFE |
| High Elimination Half Life | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HIGHELIMINATIO NHALFLIFE |
| Half Life Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HALFLIFEUNITS |
| Frequency Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FREQUENCYLOW |
| Frequency High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FREQUENCYHIGH |
| Duration Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DURATIONLOW |
| Duration High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DURATIONHIGH |
| Maximum Duration | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDURATION |
| Hepatic Impairment Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HEPATICIMPAIRM ENTIND |
| Renal Impairment Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.RENALIMPAIRME NTIND |
| CRCL Threshold | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CRCLTHRESHHO LD |
| CRCL Threshold Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CRCLTHRESHHO LDUNITS |
| Weight Required Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.WEIGHTREQUIRE DIND |
| BSA Required Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.BSAREQUIREDIN D |
| Dose Rate Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATELOW |

| Report Column | Data Source (TableName.FieldName) |
|--|---|
| Dose Rate Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATELOWU NITS |
| Dose Rate High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATEHIGH |
| Dose Rate High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATEHIGHU NITS |
| Dose Form Rate Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATE LOW |
| Dose Form Rate Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATE LOWUNITS |
| Dose Form Rate High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATE HIGH |
| Dose Form Rate High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATE HIGHUNITS |
| Maximum Single Dose Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOS E RATE |
| Maximum Single Dose Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOS E RATEUNITS |
| Maximum Single Dose Form Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOS E FORMRATE |
| Maximum Single Dose Form Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOS E FORMRATEUNITS |
| Maximum Daily Dose Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOS E RATE |
| Maximum Daily Dose Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOS E RATEUNITS |
| Maximum Daily Dose Form Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSE F ORMRATE |
| Maximum Daily Dose Form Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSE F ORMRATEUNITS |
| DXID | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DXID |
| Action Date | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.VERSION_DATE |
| Action Performed By | ACTION_CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.BY |
| Request Assigned To | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.ASSIGNED_USER |
| Action Effective Date | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.VERSION_DATE |
| Max Single NTE Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOS E |
| Max Single NTE Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOS E UNITS |
| Max Single NTE Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOS E FORM |
| Max Single NTE Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOS E FORMUNITS |
| Category | FDB_DIF.FDB_DOSING.CATEGORY |
| Concept Type | FDB_DIF.FDB_DOSING.CONCEPTTYPE |
| Concept ID Number | FDB_DIF.FDB_DOSING.CONCEPTID |
| Concept ID Description | FDB_DIF.FDB_DISPENSABLE_GENERIC.DESCRPTION1 |
| Age Low In Days | FDB_DIF.FDB_DOSING.AGELOWINDAYS |
| Age High In Days | FDB_DIF.FDB_DOSING.AGEHIGHINDAYS |

| Report Column | Data Source (TableName.FieldName) |
|----------------------------------|---|
| Dose Route | FDB_DIF.FDB_DOSING.DOSE_ROUTE_ID |
| Dose Route Description | CTSTAGING.DOSE_ROUTE.NAME |
| Dose Type | FDB_DIF.FDB_DOSING.DOSE_TYPE_ID |
| Dose Type Description | CTSTAGING.DOSE_TYPE.NAME |
| FDBDX | FDB_DIF.FDB_DOSING.FDBDX |
| Dose Low | FDB_DIF.FDB_DOSING.DOSELOW |
| Dose Low Units | FDB_DIF.FDB_DOSING.DOSELOWUNITS |
| Dose High | FDB_DIF.FDB_DOSING.DOSEHIGH |
| Dose High Units | FDB_DIF.FDB_DOSING.DOSEHIGHUNITS |
| Dose Form Low | FDB_DIF.FDB_DOSING.DOSEFORMLOW |
| Dose Form Low Units | FDB_DIF.FDB_DOSING.DOSEFORMLOWUNITS |
| Dose Form High | FDB_DIF.FDB_DOSING.DOSEFORMHIGH |
| Dose Form High Units | FDB_DIF.FDB_DOSING.DOSEFORMHIGHUNITS |
| Maximum Single Dose | FDB_DIF.FDB_DOSING.MAXSINGLEDOSE |
| Maximum Single Dose Units | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEUNITS |
| Maximum Single Dose Form | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORM |
| Maximum Single Dose Form Units | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORMUNITS |
| Maximum Daily Dose | FDB_DIF.FDB_DOSING.MAXDAILYDOSE |
| Maximum Daily Dose Units | FDB_DIF.FDB_DOSING.MAXDAILYDOSEUNITS |
| Maximum Daily Dose Form | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORM |
| Maximum Daily Dose Form Units | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORMUNITS |
| Maximum Lifetime Dose | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSE |
| Maximum Lifetime Dose Units | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEUNITS |
| Maximum Lifetime Dose Form | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEFORM |
| Maximum Lifetime Dose Form Units | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEFORMUNITS |
| Low Elimination Half Life | FDB_DIF.FDB_DOSING.LOWELIMINATIONHALFLIFE |
| High Elimination Half Life | FDB_DIF.FDB_DOSING.HIGHELIMINATIONHALFLIFE |
| Half Life Units | FDB_DIF.FDB_DOSING.HALFLIFEUNITS |
| Frequency Low | FDB_DIF.FDB_DOSING.FREQUENCYLOW |
| Frequency High | FDB_DIF.FDB_DOSING.FREQUENCYHIGH |
| Duration Low | FDB_DIF.FDB_DOSING.DURATIONLOW |
| Duration High | FDB_DIF.FDB_DOSING.DURATIONHIGH |
| Maximum Duration | FDB_DIF.FDB_DOSING.MAXDURATION |
| Hepatic Impairment Indicator | FDB_DIF.FDB_DOSING.HEPATICIMPAIRMENTIND |
| Renal Impairment Indicator | FDB_DIF.FDB_DOSING.RENALIMPAIRMENTIND |
| CRCL Threshold | FDB_DIF.FDB_DOSING.CRCLTHRESHHOLD |
| CRCL Threshold Units | FDB_DIF.FDB_DOSING.CRCLTHRESHHOLDUNITS |
| Weight Required Indicator | FDB_DIF.FDB_DOSING.WEIGHTREQUIREDIND |
| BSA Required Indicator | FDB_DIF.FDB_DOSING.BSAREQUIREDIND |
| Dose Rate Low | FDB_DIF.FDB_DOSING.DOSERATELOW |
| Dose Rate Low Units | FDB_DIF.FDB_DOSING.DOSERATELOWUNITS |

| Report Column | Data Source (TableName.FieldName) |
|-------------------------------------|--|
| Dose Rate High | FDB_DIF.FDB_DOSING.DOSE RATE HIGH |
| Dose Rate High Units | FDB_DIF.FDB_DOSING.DOSE RATE HIGH UNITS |
| Dose Form Rate Low | FDB_DIF.FDB_DOSING.DOSE FORM RATE LOW |
| Dose Form Rate Low Units | FDB_DIF.FDB_DOSING.DOSE FORM RATE LOW UNITS |
| Dose Form Rate High | FDB_DIF.FDB_DOSING.DOSE FORM RATE HIGH |
| Dose Form Rate High Units | FDB_DIF.FDB_DOSING.DOSE FORM RATE HIGH UNITS |
| Maximum Single Dose Rate | FDB_DIF.FDB_DOSING.MAX SINGLE DOSE RATE |
| Maximum Single Dose Rate Units | FDB_DIF.FDB_DOSING.MAX SINGLE DOSE RATE UNITS |
| Maximum Single Dose Form Rate | FDB_DIF.FDB_DOSING.MAX SINGLE DOSE FORM RATE |
| Maximum Single Dose Form Rate Units | FDB_DIF.FDB_DOSING.MAX SINGLE DOSE FORM RATE UNITS |
| Maximum Daily Dose Rate | FDB_DIF.FDB_DOSING.MAX DAILY DOSE RATE |
| Maximum Daily Dose Rate Units | FDB_DIF.FDB_DOSING.MAX DAILY DOSE RATE UNITS |
| Maximum Daily Dose Form Rate | FDB_DIF.FDB_DOSING.MAX DAILY DOSE FORM RATE |
| Maximum Daily Dose Form Rate Units | FDB_DIF.FDB_DOSING.MAX DAILY DOSE FORM RATE UNITS |
| DXID | FDB_DIF.FDB_DOSING.DXID |
| Max Single NTE Dose | FDB_DIF.FDB_DOSING.NTE SINGLE DOSE |
| Max Single NTE Dose Units | FDB_DIF.FDB_DOSING.NTE SINGLE DOSE UNITS |
| Max Single NTE Dose Form | FDB_DIF.FDB_DOSING.NTE SINGLE DOSE FORM |
| Max Single NTE Dose Form Units | FDB_DIF.FDB_DOSING.NTE SINGLE DOSE FORM UNITS |

3.4.2 FDB Custom Drug-Drug Interaction Report

The FDB Custom Drug-Drug Interaction Report contains active VA custom Drug-Drug interaction records in an Approved status along with their corresponding FDB record data.

Table 17: FDB Custom Drug-Drug Interaction Report

| Report Column | Data Source (TableName.FieldName) |
|----------------------------------|--|
| Action Status | CTSTAGING.PECS_STATE.CODE |
| Interaction Description | CTSTAGING.PECS_DDI_VERSION_VA.DESCRPTION |
| Severity Level Code | CTSTAGING.SEVERITY_LEVEL.CODE |
| Interaction ID | CTSTAGING.PECS_DDI_VA.INTERACTION_ID |
| Monograph ID | CTSTAGING.PECS_DDI_VERSION_VA.MONOGRAPH_ID |
| Clinical Effect Code 1 | CTSTAGING.CLINICAL_EFFECT.CODE |
| Clinical Effect Code 2 | CTSTAGING.CLINICAL_EFFECT.CODE |
| Corresponding FDB Interaction ID | CTSTAGING.PECS_DDI_VA.FDB_ID |
| Action Date | CTSTAGING.PECS_DDI_VERSION_VA.VERSION_DATE |
| Action Performed By | CTSTAGING.PECS_DDI_VERSION_VA.VERSION_USER |
| Request Submitted By | CTSTAGING.PECS_DDI_VA.REQUESTOR |

| Report Column | Data Source (TableName.FieldName) |
|-------------------------|---|
| Request Assigned To | CTSTAGING.PECS_DDI_VERSION_VA.ASSIGNED_USER |
| Action Reason History | Calculated |
| Interaction Description | FDB_DIF.FDB_DDIMINTERACTION.DESCRPTION1 |
| Severity Level Code | FDB_DIF.FDB_DDIMINTERACTION.SEVERITYLEVELCODE |
| Interaction Id | FDB_DIF.FDB_DDIMINTERACTION.INTERACTIONID |
| Monograph Id | FDB_DIF.FDB_DDIMINTERACTION.MONOGRAPHID |
| Clinical Effect Code 1 | FDB_DIF.FDB_DDIMINTERACTION.CLINICALEFFECTCODE1 |
| Clinical Effect Code 2 | FDB_DIF.FDB_DDIMINTERACTION.CLINICALEFFECTCODE2 |

3.4.3 FDB Custom Duplicate Therapy Report

The FDB Custom Duplicate Therapy Report contains active VA custom Duplicate Therapy records in an Approved status along with their corresponding FDB record data.

| DTICID | Custom Dup Allowance | Description | Action Status | Action Date | Action Performed By | Request Assigned To |
|--------|----------------------|---|---------------|---------------------|---------------------|---------------------|
| 376 | | 1 Stimulant Laxatives | Approved | 2012-04-16 23:07:32 | FOUR_APPROVER | FOUR |
| 379 | | 0 Hypoglycemics, Sulfonyleureas & Related Non-Sulfonyleureas | Approved | 2011-10-20 10:42:13 | TWO_APPROVER | UNA |
| 446 | | 1 Zinc, Systemic | Approved | 2011-11-08 13:55:20 | FOUR_APPROVER | FOUR |
| 458 | | 0 VA custom: Phenothiazines | Approved | 2012-02-06 09:00:04 | ONE_APPROVER | FIVE |
| 1132 | | 0 Thrombin Inhibitors (Non-Heparinoid) | Approved | 2012-06-01 15:33:52 | THREE_APPROVER | THRE |
| 1238 | | 0 Spectinomycin HCl | Approved | 2012-02-02 10:16:19 | ONE_APPROVER | UNA |
| 1338 | | 1 Antidiarrheal Formulations with Gut Flora Microorganisms | Approved | 2012-05-07 10:15:54 | ONE_APPROVER | ONE |
| 1344 | | 1 Glucagon | Approved | 2011-11-15 14:56:45 | SIX_APPROVER | UNA |
| 1519 | | 1 Saw Palmetto | Approved | 2011-11-07 08:29:10 | FOUR_APPROVER | FOUR |
| 1522 | | 1 Agents to Treat Erectile Dysfunction,Adrenergic Blocking-Type | Approved | 2011-10-18 14:16:30 | TWO_APPROVER | UNA |
| 220 | | 0 Lead Poisoning Agents | Approved | 2012-05-03 15:30:02 | TWO_APPROVER | TWO |

Figure 16: FDB Custom Duplicate Therapy Report

Table 18: FDB Custom Duplicate Therapy Report Details

| Report Column | Data Source (TableName.FieldName) |
|-----------------------|---|
| Dtcid | CTSTAGING.PECS_DUPL_THERAPY_VA.DTCID |
| Custom Dup Allowance | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.CUSTOM_DUP_ALLOWANCE |
| Description | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.CUSTOM_STRING |
| Action Status | CTSTAGING.PECS_STATE.CODE |
| Action Date | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.VERSION_DATE |
| Action Performed By | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.VERSION_USER |
| Request Assigned To | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.ASSIGNED_USER |
| Request Submitted By | CTSTAGING.PECS_DUPL_THERAPY_VA.REQUESTOR |
| Reference Text | CTSTAGING.PECS_DUPL_THERAPY_VA.REFERENCE_TEXT |
| Current Action Reason | CTSTAGING.PECS_DUPL_THERAPY_VA.VERSION_COMMENT |
| Dtcid | FDB_DIF.FDB_DUPLICATETHERAPY.DTCID |

| Report Column | Data Source (TableName.FieldName) |
|----------------------|---|
| Custom Dup Allowance | FDB_DIF.FDB_DUPLICATETHERAPY.DUPLICATIONALLOWANCE |
| Description | FDB_DIF.FDB_DUPLICATETHERAPY.DESCRPTION1 |

3.4.4 FDB Custom Professional Monograph Report

The FDB Custom Professional Monograph Report contains active VA custom Professional Monograph records in an Approved status along with their corresponding FDB record data.

| Monograph Title | Monograph ID | Action Status | Action Date | Action Performed By | Corresponding FDB Monograph ID | Request Assigned To |
|---|--------------|---------------|---------------------|---------------------|--------------------------------|---------------------|
| 3 VA customized - Solid Oral Potassium Tablets/Anticholinergics | 151164 | Approved | 2012-03-26 09:30:55 | THREE_APPROVER | | 1604 UNASSIGNED |
| 4 Cyclosporine/Selected Androgens | 151129 | Approved | 2012-05-03 15:03:27 | TWO_APPROVER | | 348 UNASSIGNED |
| 5 Live Vaccines/Belatacept | 151082 | Approved | 2012-05-03 08:20:01 | ONE_APPROVER | | 2160 FIVE_APPROVER |
| 6 Rubella Vaccine/Rho Immunoglobulin | 151081 | Approved | 2012-02-02 10:09:53 | SIX_APPROVER | | 2119 TWO_APPROVER |
| 7 Sulfonyleureas/Diazoxide | 151004 | Approved | 2011-10-20 20:28:58 | TWO_APPROVER | | 280 UNASSIGNED |
| 8 VA custom: Ergotamine Derivatives/Selected Macrolide Antibiotics | 151001 | Approved | 2012-02-02 10:02:34 | FOUR_APPROVER | | 336 FIVE_APPROVER |
| 9 VA Customized: Avoid concurrent use when possible (Significant) (AVD2) | 151101 | Approved | 2012-02-02 08:57:30 | TWO_APPROVER | | 0 FIVE_APPROVER |
| 10 VA Customized: Mixed Effects of the Former Drug (Significant) (MXF2) | 150043 | Approved | 2010-12-03 09:14:56 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 11 VA Customized: Increased Effects (Significant) (INL2) | 150041 | Approved | 2011-11-05 21:36:46 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 12 VA Customized: Labeling Conflicts Between Countries or Products (Significant) (LBL2) | 150039 | Approved | 2010-12-03 09:26:14 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 13 VA Customized: Labeling Conflicts between Countries or Products (Critical) (LBL1) | 150038 | Approved | 2010-12-03 09:26:40 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 14 VA Customized: Increased Effects (Significant) (INL2) | 150037 | Approved | 2010-12-03 09:23:28 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 15 VA Customized: Increased Effects (Critical) (INL1) | 150036 | Approved | 2010-12-03 09:21:54 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 16 VA Customized: Increased Effects (Significant) (INF2) | 150035 | Approved | 2012-05-08 14:45:15 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 17 VA Customized: Increased Effects (Critical) (INF1) | 150034 | Approved | 2010-12-03 09:21:21 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 18 VA Customized: Decreased Effects (Significant) (DEL2) | 150033 | Approved | 2010-12-03 09:19:54 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 19 VA Customized: Decreased Effects (Critical) (DEL1) | 150032 | Approved | 2010-12-03 09:18:21 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 20 VA Customized: Decreased Effects (Significant) (DEF2) | 150031 | Approved | 2010-12-03 09:18:50 | FOUR_APPROVER | | 0 FIVE_APPROVER |
| 21 VA Customized: Decreased Effects (Critical) (DEF1) | 150030 | Approved | 2010-12-03 09:17:35 | FOUR_APPROVER | | 0 FIVE_APPROVER |

Figure 17: FDB Custom Professional Monograph Report

Table 19: FDB Custom Professional Monograph Report Database Details

| Report Column | Data Source (TableName.FieldName) |
|--------------------------------|---|
| Monograph Title | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.TITLE |
| Monograph ID | CTSTAGING.PECS_MONOGRAPH_VA.MONOGRAPH_ID |
| Action Status | CTSTAGING.PECS_STATE.CODE |
| Action Date | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.VERSION_DATE |
| Action Performed By | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.VERSION_USER |
| Corresponding FDB Monograph ID | CTSTAGING.PECS_MONOGRAPH_VA.VA_MONOGRAPH_ID |
| Request Assigned To | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.ASSIGNED_USER |
| Request Submitted By | CTSTAGING.PECS_MONOGRAPH_VA.REQUESTOR |
| Reference Text | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.REFERENCE_TEXT |
| Current Action Reason | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.VERSION_COMMENT |
| Monograph Title | FDB_DIF.FDB_MONOGRAPH_DDIM.LINETEXT |
| Monograph ID | FDB_DIF.FDB_MONOGRAPH_DDIM.MONOGRAPHID |

3.4.5 Deleted Monograph Customization Report

The Deleted Monograph Customization Report contains active VA custom Drug-Drug interaction records in an Approved status that are associated with a deleted FDB Professional Monograph.

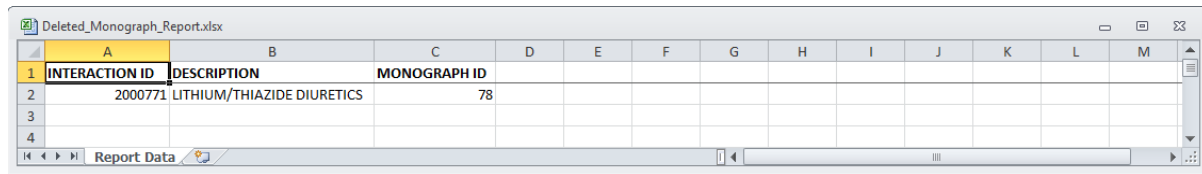
The screenshot shows an Excel spreadsheet titled 'Deleted_Monograph_Report.xlsx'. The spreadsheet has columns A through M. Row 1 contains headers: A1 is 'INTERACTION ID', B1 is 'DESCRIPTION', and C1 is 'MONOGRAPH ID'. Row 2 contains data: A2 is '2000771', B2 is 'LITHIUM/THIAZIDE DIURETICS', and C2 is '78'. The status bar at the bottom indicates 'Report Data'.

Figure 18: Deleted Monograph Customization Report

Table 20: Deleted Monograph Customization Report Database Details

| Report Column | Data Source (TableName.FieldName) |
|----------------|--|
| INTERACTION_ID | CTSTAGING.PECS_DDI_VA.INTERACTION_ID |
| DESCRIPTION | CTSTAGING.PECS_DDI_VERSION_VA.DESCRPTION |
| MONOGRAPH_ID | CTSTAGING.PECS_DDI_VERSION_VA.MONOGRAPH_ID |

3.4.6 Null Drug Pairs Customization Report

The Null Drug Pairs Customization Report contains approved VA custom Drug-Drug Interactions that contain Drug Pairs with null Routed Generic #1 or Routed Generic #2 fields. If this report contains any entries, it is recommended that a user in the Administrator role initiate the Null Drug pair Removal Process.

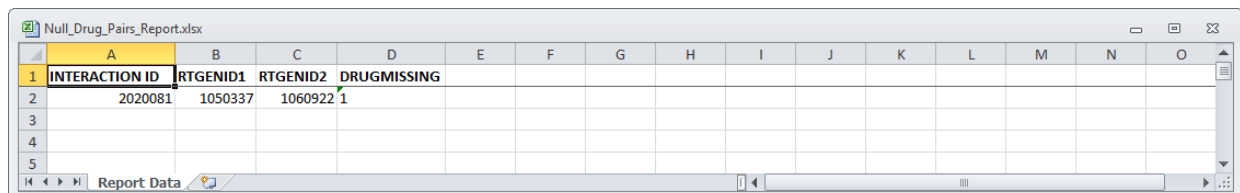
The screenshot shows an Excel spreadsheet titled 'Null_Drug_Pairs_Report.xlsx'. The spreadsheet has columns A through O. Row 1 contains headers: A1 is 'INTERACTION ID', B1 is 'RTGENID1', C1 is 'RTGENID2', and D1 is 'DRUGMISSING'. Row 2 contains data: A2 is '2020081', B2 is '1050337', C2 is '1060922', and D2 is '1'. The status bar at the bottom indicates 'Report Data'.

Figure 19: Null Drug Pairs Customization Report

Table 21: Null Drug Pairs Customization Report Database Details

| Report Column | Data Source (TableName.FieldName) |
|----------------|--|
| INTERACTION_ID | CTSTAGING.PECS_DDI_VA.INTERACTION_ID |
| RTGENID1 | CTSTAGING.PECS_DRUG_PAIR_VA.ROUTED_GENERIC_ID1 |
| RTGENID2 | CTSTAGING.PECS_DRUG_PAIR_VA.ROUTED_GENERIC_ID2 |
| DRUGMISSING | Calculated |

3.4.7 Drug-Drug Interaction/Drug Pair FDB Comparison Report

FDB comparison reports are generated by running a comparison of the latest FDB Update against the current FDB data stored in the FDB_DIF database. The output produce is stored in the PECS database as a binary object. The mappings below are for the database to the report. How the report is stored in the database is not described here. The FDB After Update and Drug Pair data come from a file sent from FDB because these values have not been applied to the database.

| DOIReport.xlsx | | | | | | | | | |
|----------------|------------------------------|----------------|--------------------------|-------------------|--------------------------|---------------------------|--|--|-----------------------------|
| | A | B | C | D | E | F | G | | |
| 1 | FDB Update Received: | 20120525 | | | | | Note: * indicates changed FDB data | | |
| 2 | | Action Status | Action Date | DATUP will delete | VA Interaction ID | FDB Interaction ID | Interaction Description | | Monograph ID |
| 46 | FDB Before Update | | | | | 31860 | QUININE/ANTICOAGULANTS | | Anticoagulants/Quinine - 14 |
| 48 | VA Custom | Not customized | | | | | | | |
| 49 | FDB After Update | | | | | 31585 | | | |
| 50 | FDB Before Update | | Yes | | | 31585 | SELECTED MACROLIDE ANTIBIOTICS/PIMOZIDE | | Pimozide/Selected Macrolic |
| 52 | VA Custom | Not customized | | | | | | | |
| 53 | FDB After Update | | | | | 1623 | POSACONAZOLE/CIMETIDINE HI * | | Theraphyllines/Quinolones |
| 54 | FDB Before Update | | | | | 1623 | POSACONAZOLE/CIMETIDINE * | | Posaconazole/Cimetidine - |
| 56 | VA Custom | Rejected | 2010-05-17 | | 2015651 | 1565 | RANOLAZINE/QT PROLONGING AGENTS | | Ranolazine/QT Prolonging A |
| 57 | VA Custom | Rejected | 2010-05-17 | | 2015652 | 1565 | RANOLAZINE/QT PROLONGING AGENTS | | Ranolazine/QT Prolonging A |
| 58 | FDB After Update | | | | | 1565 | RANOLAZINE/QT PROLONGING AGENTS-Today * | | Ranolazine/QT Prolonging A |
| 59 | FDB Before Update | | | | | 1565 | RANOLAZINE/QT PROLONGING AGENTS * | | Ranolazine/QT Prolonging A |
| 61 | VA Custom | Rejected | 2010-05-04 | | 2019797 | 1156 | INTERLEUKIN-1 BLOCKER/TUMOR NECROSIS FACTOR (TNF) INHIBITORS | | Interleukin-1 Blocker/Tumo |
| 62 | VA Custom | Approved | 2010-05-04 | | 2011561 | 1156 | INTERLEUKIN-1 BLOCKER/TUMOR NECROSIS FACTOR (TNF) INHIBITORS | | Interleukin-1 Blocker/Tumo |
| 63 | FDB After Update | | | | | 1156 | INTERLEUKIN-1 BLOCKER/TUMOR NECROSIS FACTOR (TNF) INHIBITORS | | Interleukin-1 Blocker/Tumo |
| 64 | FDB Before Update | | | | | 1156 | INTERLEUKIN-1 BLOCKER/TUMOR NECROSIS FACTOR (TNF) INHIBITORS | | Interleukin-1 Blocker/Tumo |
| 66 | VA Custom | Modified | 2012-03-09 | | 2020866 | 1581 | DROSPIRENONE/ACE INHIBITORS; ARBS | | Drosiprenone/Ace Inhibitor |
| 67 | FDB After Update | | | | | 1581 | DROSPIRENONE/ACE INHIBITORS; ARBS | | Cyclosporine/Calcium Chan |
| 68 | FDB Before Update | | | | | 1581 | DROSPIRENONE/ACE INHIBITORS; ARBS | | Drosiprenone/Ace Inhibi |
| 70 | VA Custom | New | 2012-03-09 | | 2020864 | 30786 | SELECTED MACROLIDE ANTIBIOTICS/EPLERENONE (MONO DELETED) | | Eplerenone/Selected Macro |
| 71 | DOI-EP FDB Comparison Report | | FDB Interaction ID 16-OP | | FDB Interaction ID 81-OP | FDB Interaction ID 112-OP | FDB Interaction ID 112-OP | | |

Figure 20: Drug-Drug Interaction/Drug Pair FDB Comparison Report

[illegible]

Figure 21: Drug-Drug Interaction/Drug Pair FDB Comparison Report - Associated FDB Interaction

Table 22: Drug-Drug Interaction/Drug Pair FDB Comparison Report Database Details

| Report Column | VA Custom Data Source | FDB Before Update Data Source |
|-------------------|--|-------------------------------|
| Action Status | CTSTAGING.PECS_STATE.CODE | N/A |
| Action Date | CTSTAGING.PECS_DDI_VERSION_VA.VERSION_DATE | N/A |
| DATUP Will Delete | N/A | N/A |

| Report Column | VA Custom Data Source | FDB Before Update Data Source |
|-------------------------|--|---|
| VA Interaction ID | CTSTAGING.PECS_DDI_VA.INTERACTION_ID | N/A |
| FDB Interaction ID | CTSTAGING.PECS_DDI_VA.FDB_ID | FDB_DIF.FDB_DDIMINTERACTION.INTERACTIONID |
| Interaction Description | CTSTAGING.PECS_DDI_VERSION_VA.DESCRPTION | FDB_DIF.FDB_DDIMINTERACTION.DESCRPTION1 |
| Monograph ID | CTSTAGING.PECS_DDI_VERSION_VA.MONOGRAPH_ID | FDB_DIF.FDB_DDIMINTERACTION.MONOGRAPHID |
| Severity Level | CTSTAGING.SEVERITY_LEVEL.CODE | FDB_DIF.FDB_DDIMINTERACTION.SEVERITYLEVELCODE |
| Clinical Effect 1 | CTSTAGING.CLINICAL_EFFECT.CODE | FDB_DIF.FDB_DDIMINTERACTION.CLINICALEFFECTCODE1 |
| Clinical Effect 2 | CTSTAGING.CLINICAL_EFFECT_CODE | FDB_DIF.FDB_DDIMINTERACTION.CLINICALEFFECTCODE2 |

3.4.8 Duplicate Therapy FDB Comparison Report

FDB comparison reports are generated by running a comparison of the latest FDB Update against the current FDB data stored in the FDB_DIF database. The output produce is stored in the PECS database as a binary object. The mappings below are for the actual report. The FDB After Update row comes from a flat file as these values have not been applied to the database.

| | A | B | C | D | E | F | G |
|----|-------------------------------|---------------|-------------|-------------------|-------|---------------|--|
| 1 | FDB Update Received: 20120525 | | | | | | Note: * indicates changed FDB data |
| 2 | | Action Status | Action Date | DATUP will delete | DTCID | Dup Allowance | Description |
| 3 | VA Custom | Approved | 2012-05-07 | | 1338 | | 1 Antidiarrheal Formulations with Gut Flora Microorganisms |
| 4 | FDB After Update | | | Yes | 1338 | | |
| 5 | FDB Before Update | | | | 1338 | | 0 Antidiarrheal Formulations with Gut Flora Microorganisms |
| 7 | VA Custom | Approved | 2012-04-16 | | 376 | | 1 Stimulant Laxatives |
| 8 | FDB After Update | | | Yes | 376 | | |
| 9 | FDB Before Update | | | | 376 | | 0 Stimulant Laxatives |
| 11 | VA Custom | Reviewed | 2012-02-23 | | 375 | | 0 Steroids - Mouth |
| 12 | FDB After Update | | | Yes | 375 | | |
| 13 | FDB Before Update | | | | 375 | | 0 Steroids - Mouth |
| 15 | VA Custom | Modified | 2012-02-23 | | 378 | | 1 Sulfonamides |
| 16 | FDB After Update | | | Yes | 378 | | |
| 17 | FDB Before Update | | | | 378 | | 0 Sulfonamides |
| 19 | VA Custom | Reviewed | 2012-04-13 | | 1132 | | 0 Thrombin Inhibitors (Non-Heparinoid) |
| 20 | FDB After Update | | | Yes | 1132 | | |
| 21 | FDB Before Update | | | | 1132 | | 0 Thrombin Inhibitors (Non-Heparinoid) |
| 23 | VA Custom | Modified | 2012-02-23 | | 1213 | | 1 Dantrolene |
| 24 | FDB After Update | | | Yes | 1213 | | |
| 25 | FDB Before Update | | | | 1213 | | 0 Dantrolene |

Figure 22: Duplicate Therapy FDB Comparison Report

Table 23: Duplicate Therapy FDB Comparison Report Data Tables

| Report Column | VA Custom Data Source | FDB BEFORE UPDATE |
|---------------|---------------------------|-------------------|
| Action Status | CTSTAGING.PECS_STATE.CODE | N/A |

| Report Column | VA Custom Data Source | FDB BEFORE UPDATE |
|-------------------|---|---|
| Action Date | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.VERSION_DATE | N/A |
| DATUP Will Delete | N/A | N/A |
| DTCID | CTSTAGING.PECS_DUPL_THERAPY_VA.DTCID | FDB_DIF.FDB_DUPLICATETHERAPY.DTCID |
| Dup Allowance | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.CUSTOM_DUP_ALLOWANCE | FDB_DIF.FDB_DUPLICATETHERAPY.DUPLICATIONALLOWANCE |
| Description | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.CUSTOM_STRING | FDB_DIF.FDB_DUPLICATETHERAPY.DESCRPTION21 |

3.4.9 Duplicate Therapy History of Changes Report

A Duplicate Therapy History of Changes Report will show all of the changes made to a Custom Duplicate Therapy over time as well as the FDB Duplicate Therapy that the Custom Duplicate Therapy overrides.

| | A | B | C | D | E | F | G | H | I |
|----|---------------|---|----------------------|-------|----------------|---------------------|---------------------|---------------------|-------------------|
| | Action Status | Description | Custom Dup Allowance | DTCID | Reference Text | Action Date | Action Performed By | Request Assigned To | Request Submitted |
| 2 | Modified | Immunosuppressants - Calcineurin Inhibitors!!!!!!!!!!!! | | 2 | 1360 2 * | 2012-11-09 15:36:01 | ONE_APPROVER | UNASSIGNED | FIVE_REQUEST |
| 3 | Modified | Immunosuppressants - Calcineurin Inhibitors!!!!!!!!!!!! | | 2 | 1360 1 | 2012-11-09 15:25:56 | ONE_APPROVER | UNASSIGNED | FIVE_REQUEST |
| 4 | Modified | Immunosuppressants - Calcineurin Inhibitors!!!!!!!!!!!! | | 2 | 1360 1 * | 2012-11-09 15:25:38 | ONE_APPROVER | UNASSIGNED | FIVE_REQUEST |
| 5 | Modified | Immunosuppressants - Calcineurin Inhibitors!!!!!!!!!!!! * | | 2 | 1360 | 2012-11-08 11:42:25 | ONE_APPROVER | UNASSIGNED | FIVE_REQUEST |
| 6 | Modified | Immunosuppressants - Calcineurin Inhibitors | 2 * | | 1360 | 2012-03-22 12:16:12 | ONE_APPROVER | UNASSIGNED | FIVE_REQUEST |
| 7 | New | Immunosuppressants - Calcineurin Inhibitors | | 0 | 1360 | 2012-02-28 14:01:27 | FIVE_REQUESTOR | UNASSIGNED | FIVE_REQUEST |
| 8 | | Immunosuppressants - Calcineurin Inhibitors | | 0 | 1360 | | | | |
| 9 | | | | | | | | | |
| 10 | | | | | | | | | |
| 11 | | | | | | | | | |
| 12 | | | | | | | | | |
| 13 | | | | | | | | | |
| 14 | | | | | | | | | |

Figure 23: Duplicate Therapy History of Changes Report

Table 24: Duplicate Therapy History Report Data Tables

| Report Column | VA Custom Table and Column | FDB Table and Column |
|----------------------|---|---|
| Action Status | CTSTAGING.PECS_STATE.CODE | N/A |
| Description | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.CUSTOM_STRING | FDB_DIF.FDB_DUPLICATETHERAPY.DESCRPTION21 |
| Custom Dup Allowance | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.CUSTOM_DUP_ALLOWANCE | FDB_DIF.FDB_DUPLICATETHERAPY.DUPLICATIONALLOWANCE |
| DTCID | CTSTAGING.PECS_DUPL_THERAPY_VA.DTCID | FDB_DIF.FDB_DUPLICATETHERAPY.DTCID |

| Report Column | VA Custom Table and Column | FDB Table and Column |
|-----------------------|--|----------------------|
| Action Date | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.VERSION_DATE | N/A |
| Action Performed By | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.VERSION_USER | N/A |
| Request Assigned To | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.ASSIGNED_USER | N/A |
| Request Submitted By | CTSTAGING.PECS_DUPL_THERAPY_VA.REQUESTOR | N/A |
| Reference Text | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.REFERENCE_TEXT | N/A |
| Action Effective Date | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.VERSION_DATE | N/A |
| Current Action Reason | CTSTAGING.PECS_DUPL_THERAPY_VERSION_VA.VERSION_COMMENT | N/A |

3.4.10 Professional Monograph History of Changes Report

A Professional Monograph History of Changes Report will show all of the changes made to a Professional Monograph over time as well as the Monograph FDB that the Professional Monograph overrides.

| Action Status | Language ID | Monograph ID | Corresponding FDB Monograph ID | Monograph Title |
|---------------|-------------|--------------|--------------------------------|---|
| Modified | 1 | 151105 | 1814 | VA custom - Rivaroxaban/Protease Inhibitors (mono deleted 07/07/2011) |
| Modified | 1 | 151105 | 1814 | VA custom - Rivaroxaban/Protease Inhibitors (mono deleted 07/07/2011) |
| Modified | 1 | 151105 | 1814 | VA custom - Rivaroxaban/Protease Inhibitors (mono deleted 07/07/2011) |
| Modified | 1 | 151105 | 1814 | VA custom - Rivaroxaban/Protease Inhibitors (mono deleted 07/07/2011) |
| Reviewed | 1 | 151105 | 1814 | VA custom - Rivaroxaban/Protease Inhibitors (mono deleted 07/07/2011) |
| Modified | 1 | 151105 | 1814 | VA custom - Rivaroxaban/Protease Inhibitors (mono deleted 07/07/2011) * |
| New | 1 | 151105 | 1814 | Rivaroxaban/Protease Inhibitors (mono deleted 07/07/2011) |

Figure 24: Professional Monograph History of Changes Report

Table 25: Professional Monograph History of Changes Report Table

| Report Column | VA Custom Table and Column | FDB Table and Columns |
|--------------------------------|---|--|
| Action Status | CTSTAGING.PECS_STATE.CODE | N/A |
| Language ID | CTSTAGING.PECS_MONOGRAPH_VA.LANGUAGE_ID | |
| Monograph ID | CTSTAGING.PECS_MONOGRAPH_VA.MONOGRAPH_ID | FDBDIF.FDB_CUSTOM_MONOGRAPH.MONOGRAPH_ID |
| Corresponding FDB Monograph ID | CTSTAGING.PECS_MONOGRAPH_VA.VA_MONOGRAPH_ID | N/A |
| Monograph Title | CTSTAGING.PECS_MONOGRAPH_VA.TITLE | N/A |
| Mechanism Of Action | CTSTAGING.PECS_MONOGRAPH_SECTION_LINE_VA.SECTION_CODE | N/A |
| Discussion | CTSTAGING.PECS_MONOGRAPH_SECTION_LINE_VA.SECTION_CODE | N/A |
| Clinical Effects | CTSTAGING.PECS_MONOGRAPH_SECTION_LINE_VA.SECTION_CODE | N/A |
| Severity Level | CTSTAGING.SEVERITY_LEVEL.SEVERITY_LEVEL_ID | N/A |
| Patient Management | CTSTAGING.PECS_MONOGRAPH_SECTION_LINE_VA.SECTION_CODE | N/A |
| Predisposing Factors | CTSTAGING.PECS_MONOGRAPH_SECTION_LINE_VA.SECTION_CODE | N/A |
| Reference | CTSTAGING.PECS_MONOGRAPH_SECTION_LINE_VA.SECTION_CODE | N/A |
| Disclaimer | CTSTAGING.PECS_MONOGRAPH_SECTION_LINE_VA.SECTION_CODE | N/A |
| Reference Text | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.REFERENCE_TEXT | N/A |
| Action Date | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.VERSION_DATE | N/A |
| Action Performed By | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.ACTION_BY | N/A |
| Request Assigned To | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.ASSIGNED_USER | N/A |
| Request Submitted By | CTSTAGING.PECS_MONOGRAPH_VA.REQUESTOR | N/A |
| Action Effective Date | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.VERSION_DATE | N/A |
| Current Action Reason | CTSTAGING.PECS_MONOGRAPH_VERSION_VA.VERSION_COMMENT | N/A |

3.4.11 Dose Range FDB Comparison Report

FDB comparison reports are generated by running a comparison of the latest FDB Update against the current FDB data stored in the FDB_DIF database. The output produce is stored in the PECS database as a binary object. The mappings below are for the actual report. The FDB After Update row comes from a flat file as these values have not been applied to the database.

| Action Status | Concept ID Number | Concept ID Description | Concept Type | Age Low In Days | Age High In Days | Dose Route | Dose Route Description | Dose Type | Dose Type |
|---------------|-------------------|------------------------|--------------|-----------------|------------------|------------|------------------------|-----------|-----------|
| Approved | 41567 30 MG | LISINOPRIL ORAL TABLET | | 6 | 6205 | 23724 064 | ORAL | 02 | MAINTEN |
| Reviewed | 41567 30 MG | LISINOPRIL ORAL TABLET | | 6 | 6205 | 23724 064 | ORAL | 02 | MAINTEN |
| New | 41567 30 MG | LISINOPRIL ORAL TABLET | | 6 | 6205 | 23724 064 | ORAL | 02 | MAINTEN |

Figure 25: Dose Range FDB Comparison Report**Table 26: Dose Range FDB Comparison Report Table**

| Report Column | VA Custom Data Source | FDB BEFORE UPDATE |
|-------------------|---|-------------------|
| Action Status | CTSTAGING.PECS_STATUS.NAME | N/A |
| Action Date | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.VERS ION_DATE | N/A |
| DATUP Will Delete | N/A | N/A |

| Report Column | VA Custom Data Source | FDB BEFORE UPDATE |
|---------------------------|--|--|
| Concept ID Number | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CONCEPTID | FDB_DIF.FDB_DOSING.CONCEPTID |
| Concept ID Description | N/A | FDB_DIF.FDB_GENERIC_ROUTEDDRUG.DESCRPTION1 |
| Concept Type | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CONCEPTTYPE | FDB_DIF.FDB_DOSING.CONCEPTTYPE |
| Age Low In Days | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.AGELOWINDAYS | FDB_DIF.FDB_DOSING.AGELOWINDAYS |
| Age High In Days | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.AGEHIGHINDAYS | FDB_DIF.FDB_DOSING.AGEHIGHINDAYS |
| Action Effective Date | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.VERSION_DATE | N/A |
| Dose Route | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSE_ROUTE_ID | FDB_DIF.FDB_DOSING.DOSEROUTEID |
| Dose Route Description | CTSTAGING.DOSE_ROUTE.NAME | FDB_DIF.FDB_DOSEROUTE.DESCRPTION1 |
| Dose Type | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSE_TYPE_ID | FDB_DIF.FDB_DOSING.DOSETYPEID |
| Dose Type Description | CTSTAGING.DOSE_TYPE.NAME | FDB_DIF.FDB_DOSETYPE.DESCRPTION1 |
| FDBDX | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FDBDX | FDB_DIF.FDB_DOSING.FDBDX |
| HIT TYPE | CTSTAGING.FDB_DOSE_RANGE_XREF.HITTYPE | FDB_DIF.FDB_DOSING.HITTYPE |
| DXID | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DXID | FDB_DIF.FDB_DOSING.DXID |
| Dose Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSELOW | FDB_DIF.FDB_DOSING.DOSELOW |
| Dose Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSELOWUNITS | FDB_DIF.FDB_DOSING.DOSELOWUNITS |
| Dose High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEHIGH | FDB_DIF.FDB_DOSING.DOSEHIGH |
| Dose High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEHIGHUNITS | FDB_DIF.FDB_DOSING.DOSEHIGHUNITS |
| Dose Form Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMLOW | FDB_DIF.FDB_DOSING.DOSEFORMLOW |
| Dose Form Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMLOWUNITS | FDB_DIF.FDB_DOSING.DOSEFORMLOWUNITS |
| Dose Form High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMHIGH | FDB_DIF.FDB_DOSING.DOSEFORMHIGH |
| Dose Form High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMHIGHUNITS | FDB_DIF.FDB_DOSING.DOSEFORMHIGHUNITS |
| Maximum Single Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOS | FDB_DIF.FDB_DOSING.MAXSINGLEDOS |
| Maximum Single Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSUNITS | FDB_DIF.FDB_DOSING.MAXSINGLEDOSUNITS |
| Maximum Single Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSFORM | FDB_DIF.FDB_DOSING.MAXSINGLEDOSFORM |

| Report Column | VA Custom Data Source | FDB BEFORE UPDATE |
|----------------------------------|---|---|
| Maximum Single Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSEFORMUNITS | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORMUNITS |
| Maximum Daily Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSE | FDB_DIF.FDB_DOSING.MAXDAILYDOSE |
| Maximum Daily Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEUNITS | FDB_DIF.FDB_DOSING.MAXDAILYDOSEUNITS |
| Maximum Daily Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEFORM | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORM |
| Maximum Daily Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEFORMUNITS | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORMUNITS |
| Maximum Lifetime Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOSE | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSE |
| Maximum Lifetime Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOSEUNITS | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEUNITS |
| Maximum Lifetime Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOSEFORM | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEFORM |
| Maximum Lifetime Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOSEFORMUNITS | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEFORMUNITS |
| Low Elimination Half Life | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.LOWELIMINATIONHALFLIFE | FDB_DIF.FDB_DOSING.LOWELIMINATIONHALFLIFE |
| High Elimination Half Life | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HIGHELIMINATIONHALFLIFE | FDB_DIF.FDB_DOSING.HIGHELIMINATIONHALFLIFE |
| Half Life Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HALFLIFEUNITS | FDB_DIF.FDB_DOSING.HALFLIFEUNITS |
| Frequency Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FREQUENCYLOW | FDB_DIF.FDB_DOSING.FREQUENCYLOW |
| Frequency High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FREQUENCYHIGH | FDB_DIF.FDB_DOSING.FREQUENCYHIGH |
| Duration Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DURATIONLOW | FDB_DIF.FDB_DOSING.DURATIONLOW |
| Duration High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DURATIONHIGH | FDB_DIF.FDB_DOSING.DURATIONHIGH |
| Maximum Duration | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDURATION | FDB_DIF.FDB_DOSING.MAXDURATION |
| Hepatic Impairment Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HEPATICIMPAIRMENTIND | FDB_DIF.FDB_DOSING.HEPATICIMPAIRMENTIND |
| Renal Impairment Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.RENALIMPAIRMENTIND | FDB_DIF.FDB_DOSING.RENALIMPAIRMENTIND |
| CRCL Threshold | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CRCLTHRESHOLD | FDB_DIF.FDB_DOSING.CRCLTHRESHOLD |
| CRCL Threshold Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CRCLTHRESHOLDUNITS | FDB_DIF.FDB_DOSING.CRCLTHRESHOLDUNITS |

| Report Column | VA Custom Data Source | FDB BEFORE UPDATE |
|-------------------------------------|---|---|
| Weight Required Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.WEIGHTREQUIREDIND | FDB_DIF.FDB_DOSING.WEIGHTREQUIREDIND |
| BSA Required Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.BSAREQUIREDIND | FDB_DIF.FDB_DOSING.BSAREQUIREDIND |
| Dose Rate Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATELOW | FDB_DIF.FDB_DOSING.DOSERATELOW |
| Dose Rate Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATELOWUNITS | FDB_DIF.FDB_DOSING.DOSERATELOWUNITS |
| Dose Rate High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATEHIGH | FDB_DIF.FDB_DOSING.DOSERATEHIGH |
| Dose Rate High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATEHIGHUNITS | FDB_DIF.FDB_DOSING.DOSERATEHIGHUNITS |
| Dose Form Rate Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATELOW | FDB_DIF.FDB_DOSING.DOSEFORMRATELOW |
| Dose Form Rate Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATELOWUNITS | FDB_DIF.FDB_DOSING.DOSEFORMRATELOWUNITS |
| Dose Form Rate High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATEHIGH | FDB_DIF.FDB_DOSING.DOSEFORMRATEHIGH |
| Dose Form Rate High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATEHIGHUNITS | FDB_DIF.FDB_DOSING.DOSEFORMRATEHIGHUNITS |
| Maximum Single Dose Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSERATE | FDB_DIF.FDB_DOSING.MAXSINGLEDOSERATE |
| Maximum Single Dose Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSERATEUNITS | FDB_DIF.FDB_DOSING.MAXSINGLEDOSERATEUNITS |
| Maximum Single Dose Form Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSEFORMRATE | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORMRATE |
| Maximum Single Dose Form Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSEFORMRATEUNITS | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORMRATEUNITS |
| Maximum Daily Dose Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSERATE | FDB_DIF.FDB_DOSING.MAXDAILYDOSERATE |
| Maximum Daily Dose Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSERATEUNITS | FDB_DIF.FDB_DOSING.MAXDAILYDOSERATEUNITS |
| Maximum Daily Dose Form Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEFORMRATE | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORMRATE |
| Maximum Daily Dose Form Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEFORMRATEUNITS | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORMRATEUNITS |
| Max Single NTE Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOSE | FDB_DIF.FDB_DOSING.NTESINGLEDOSE |
| Max Single NTE Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOSEUNITS | FDB_DIF.FDB_DOSING.NTESINGLEDOSEUNITS |

| Report Column | VA Custom Data Source | FDB BEFORE UPDATE |
|--------------------------------|---|---|
| Max Single NTE Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOSEFORM | FDB_DIF.FDB_DOSING.NTESINGLEDOSEFORM |
| Max Single NTE Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOSEFORMUNITS | FDB_DIF.FDB_DOSING.NTESINGLEDOSEFORMUNITS |

3.4.12 Dose Range History of Changes Report

A Dose Range History of Changes Report will show all of the changes made to a Dose Range over time as well as the FDB Dose Range that Dose Range overrides.

Figure 26: Dose Range History of Changes Report

Table 27: Dose Range History of Changes Report Table

| Report Column | VA Custom Table and Column | FDB Table and Column |
|------------------------|--|--|
| Action Status | CTSTAGING.PECS_STATUS.NAME | N/A |
| Concept ID Number | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CONCEPTID | FDB_DIF.FDB_DOSING.CONCEPTID |
| Concept ID Description | N/A | FDB_DIF.FDB_GENERIC_ROUTEDDRUG.DESCRPTION1 |
| Concept Type | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CONCEPTTYPE | FDB_DIF.FDB_DOSING.CONCEPTTYPE |
| Age Low In Days | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.AGELOWINDAYS | FDB_DIF.FDB_DOSING.AGELOWINDAYS |
| Age High In Days | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.AGEHIGHINDAYS | FDB_DIF.FDB_DOSING.AGEHIGHINDAYS |
| Action Effective Date | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.VEERSION_DATE | N/A |
| Dose Route | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSE_ROUTE_ID | FDB_DIF.FDB_DOSING.DOSEROUTEID |
| Dose Route Description | CTSTAGING.DOSE_ROUTE.NAME | FDB_DIF.FDB_DOSEROUTE.DESCRPTION1 |
| Dose Type | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSE_TYPE_ID | FDB_DIF.FDB_DOSING.DOSETYPEID |

| Report Column | VA Custom Table and Column | FDB Table and Column |
|--------------------------------|---|---|
| Dose Type Description | CTSTAGING.DOSE_TYPE.NAME | FDB_DIF.FDB_DOSETYPE.DESCRPTION1 |
| FDBDX | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FDBDX | FDB_DIF.FDB_DOSING.FDBDX |
| DXID | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DXID | FDB_DIF.FDB_DOSING.DXID |
| Dose Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSELOW | FDB_DIF.FDB_DOSING.DOSELOW |
| Dose Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSELOWUNITS | FDB_DIF.FDB_DOSING.DOSELOWUNITS |
| Dose High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEHIGH | FDB_DIF.FDB_DOSING.DOSEHIGH |
| Dose High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEHIGHUNITS | FDB_DIF.FDB_DOSING.DOSEHIGHUNITS |
| Dose Form Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMLOW | FDB_DIF.FDB_DOSING.DOSEFORMLOW |
| Dose Form Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMLOWUNITS | FDB_DIF.FDB_DOSING.DOSEFORMLOWUNITS |
| Dose Form High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMHIGH | FDB_DIF.FDB_DOSING.DOSEFORMHIGH |
| Dose Form High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMHIGHUNITS | FDB_DIF.FDB_DOSING.DOSEFORMHIGHUNITS |
| Maximum Single Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSE | FDB_DIF.FDB_DOSING.MAXSINGLEDOSE |
| Maximum Single Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSEUNITS | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEUNITS |
| Maximum Single Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSEFORM | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORM |
| Maximum Single Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXSINGLEDOSEFORMUNITS | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORMUNITS |
| Maximum Daily Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSE | FDB_DIF.FDB_DOSING.MAXDAILYDOSE |
| Maximum Daily Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEUNITS | FDB_DIF.FDB_DOSING.MAXDAILYDOSEUNITS |
| Maximum Daily Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEFORM | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORM |
| Maximum Daily Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDAILYDOSEFORMUNITS | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORMUNITS |
| Maximum Lifetime Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOSE | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSE |
| Maximum Lifetime Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOSEUNITS | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEUNITS |
| Maximum Lifetime Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOSEFORM | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEFORM |

| Report Column | VA Custom Table and Column | FDB Table and Column |
|----------------------------------|---|---|
| Maximum Lifetime Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXLIFETIMEDOSEFORMUNITS | FDB_DIF.FDB_DOSING.MAXLIFETIMEDOSEFORMUNITS |
| Low Elimination Half Life | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.LOWELIMINATIONHALFLIFE | FDB_DIF.FDB_DOSING.LOWELIMINATIONHALFLIFE |
| High Elimination Half Life | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HIGHELIMINATIONHALFLIFE | FDB_DIF.FDB_DOSING.HIGHELIMINATIONHALFLIFE |
| Half Life Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HALFLIFEUNITS | FDB_DIF.FDB_DOSING.HALFLIFEUNITS |
| Frequency Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FREQUENCYLOW | FDB_DIF.FDB_DOSING.FREQUENCYLOW |
| Frequency High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.FREQUENCYHIGH | FDB_DIF.FDB_DOSING.FREQUENCYHIGH |
| Duration Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DURATIONLOW | FDB_DIF.FDB_DOSING.DURATIONLOW |
| Duration High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DURATIONHIGH | FDB_DIF.FDB_DOSING.DURATIONHIGH |
| Maximum Duration | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAXDURATION | FDB_DIF.FDB_DOSING.MAXDURATION |
| Hepatic Impairment Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.HEPATICIMPAIRMENTIND | FDB_DIF.FDB_DOSING.HEPATICIMPAIRMENTIND |
| Renal Impairment Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.RENALIMPAIRMENTIND | FDB_DIF.FDB_DOSING.RENALIMPAIRMENTIND |
| CRCL Threshold | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CRCLTHRESHHOLD | FDB_DIF.FDB_DOSING.CRCLTHRESHHOLD |
| CRCL Threshold Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.CRCLTHRESHHOLDUNITS | FDB_DIF.FDB_DOSING.CRCLTHRESHHOLDUNITS |
| Weight Required Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.WEIGHTREQUIREDIND | FDB_DIF.FDB_DOSING.WEIGHTREQUIREDIND |
| BSA Required Indicator | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.BSAREQUIREDIND | FDB_DIF.FDB_DOSING.BSAREQUIREDIND |
| Dose Rate Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATELOW | FDB_DIF.FDB_DOSING.DOSERATELOW |
| Dose Rate Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATELOWUNITS | FDB_DIF.FDB_DOSING.DOSERATELOWUNITS |
| Dose Rate High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATEHIGH | FDB_DIF.FDB_DOSING.DOSERATEHIGH |
| Dose Rate High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSERATEHIGHUNITS | FDB_DIF.FDB_DOSING.DOSERATEHIGHUNITS |
| Dose Form Rate Low | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATELOW | FDB_DIF.FDB_DOSING.DOSEFORMRATELOW |
| Dose Form Rate Low Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATELOWUNITS | FDB_DIF.FDB_DOSING.DOSEFORMRATELOWUNITS |
| Dose Form Rate High | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATEHIGH | FDB_DIF.FDB_DOSING.DOSEFORMRATEHIGH |
| Dose Form Rate High Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.DOSEFORMRATEHIGHUNITS | FDB_DIF.FDB_DOSING.DOSEFORMRATEHIGHUNITS |

| Report Column | VA Custom Table and Column | FDB Table and Column |
|-------------------------------------|--|---|
| Maximum Single Dose Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAX SINGLEDOSERATE | FDB_DIF.FDB_DOSING.MAXSINGLEDOSERATE |
| Maximum Single Dose Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAX SINGLEDOSERATEUNITS | FDB_DIF.FDB_DOSING.MAXSINGLEDOSERATEUNITS |
| Maximum Single Dose Form Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAX SINGLEDOSEFORMRATE | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORMRATE |
| Maximum Single Dose Form Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAX SINGLEDOSEFORMRATEUNITS | FDB_DIF.FDB_DOSING.MAXSINGLEDOSEFORMRATEUNITS |
| Maximum Daily Dose Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAX DAILYDOSERATE | FDB_DIF.FDB_DOSING.MAXDAILYDOSERATE |
| Maximum Daily Dose Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAX DAILYDOSERATEUNITS | FDB_DIF.FDB_DOSING.MAXDAILYDOSERATEUNITS |
| Maximum Daily Dose Form Rate | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAX DAILYDOSEFORMRATE | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORMRATE |
| Maximum Daily Dose Form Rate Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.MAX DAILYDOSEFORMRATEUNITS | FDB_DIF.FDB_DOSING.MAXDAILYDOSEFORMRATEUNITS |
| Action Date | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.VERSION_DATE | N/A |
| Action Performed By | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.ACTION_BY | N/A |
| Request Assigned To | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.ASSIGNED_USER | N/A |
| Request Submitted By | CTSTAGING.PECS_DOSE_RANGE_VA.REQUESTOR | N/A |
| Reference Text | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.REFERENCE_TEXT | N/A |
| Max Single NTE Dose | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOSE | FDB_DIF.FDB_DOSING.NTESINGLEDOSE |
| Max Single NTE Dose Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOSEUNITS | FDB_DIF.FDB_DOSING.NTESINGLEDOSEUNITS |
| Max Single NTE Dose Form | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOSEFORM | FDB_DIF.FDB_DOSING.NTESINGLEDOSEFORM |
| Max Single NTE Dose Form Units | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.NTESINGLEDOSEFORMUNITS | FDB_DIF.FDB_DOSING.NTESINGLEDOSEFORMUNITS |
| Current Action Reason | CTSTAGING.PECS_DOSE_RANGE_VERSION_VA.VERSION_COMMENT | N/A |

3.4.13 Drug-Drug Interaction History of Changes Report

A Drug-Drug Interaction History of Changes Report will show all of the changes made to a Custom Drug-Drug Interaction over time as well as the FDB Drug-Drug Interaction that the Custom Drug-Drug Interaction overrides.

| A | B | C | D | E | F | G | H | I | J | K |
|---------------|-------------------------|----------------|--------------|------------------------|------------------------|------------------------|---|-------------------------------|-------------------------------------|---------------|
| Action Status | Interaction Description | Interaction ID | Monograph ID | Severity Level Code | Clinical Effect Code 1 | Clinical Effect Code 2 | Group Discussion | Corresponding FDB Interaction | EDI Number | EDI Text |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |
| Approved | LOVASTATIN/DANA ZOL | 2020276 | 1512 | 2 - Severe Interaction | ARF | INF | JUNE 2011: REMOVE SIMVASTATIN DP'S. NOW FOUND IN FDB 2018 AT LEVEL 1. PER FDA SAFETY ANNOUNCEMENT http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm | 1512 | 3: Minimally Clinically Significant | test edi test |

Figure 27: Drug-Drug Interaction History of Changes Report -- Top Left Sample

Figure 28: Drug-Drug Interaction History of Changes -- Bottom Left Sample

| Report Column | VA Custom Table and Column | FDB Table and Column |
|----------------------------------|--|----------------------|
| Action Status | CTSTAGING.PECS_STATE.CODE | N/A |
| Interaction Description | CTSTAGING. PECS_DDI_VERSION_VA.DESRIPTION | N/A |
| Interaction ID | CTSTAGING. PECS_DDI_VA.INTERACTION_ID | N/A |
| Monograph ID | CTSTAGING. PECS_DDI_VERSION_VA.MONOGRAPH_ID | N/A |
| Severity Level Code | CTSTAGING. PECS_DDI_VERSION_VA. SEVERITY_LEVEL_ID | N/A |
| Clinical Effect Code 1 | CTSTAGING. PECS_DDI_VERSION_VA. CLINICAL_EFFECT1_ID | N/A |
| Clinical Effect Code 2 | CTSTAGING. PECS_DDI_VERSION_VA. CLINICAL_EFFECT2_ID | N/A |
| Group Discussion | CTSTAGING. PECS_DDI_VERSION_VA. GROUP_DISCUSSION | N/A |
| Corresponding FDB Interaction ID | CTSTAGING. PECS_DDI_VA.FDB_ID | N/A |
| EDI Number | CTSTAGING. PECS_DDI_VERSION_VA. EDI_NUMBER_ID | N/A |
| EDI Text | CTSTAGING. PECS_DDI_VERSION_VA. EDI_TEXT | N/A |

| Report Column | VA Custom Table and Column | FDB Table and Column |
|---------------------------|---|----------------------|
| Micromedex Severity | CTSTAGING. PECS_DDI_VERSION_VA. MICROMEDEX_SEVERITY_ID | N/A |
| Micromedex Onset | CTSTAGING. PECS_DDI_VERSION_VA. MICROMEDEX_ONSET_ID | N/A |
| Micromedex Substantiation | CTSTAGING. PECS_DDI_VERSION_VA. MICROMEDEX_SUBSTANTIATION_ID | N/A |
| Micromedex Text | CTSTAGING. PECS_DDI_VERSION_VA. MICROMEDEX_TEXT | N/A |
| DI Facts Number | CTSTAGING. PECS_DDI_VERSION_VA. DI_FACT_NUMBER_ID | N/A |
| DI Facts Onset | CTSTAGING. PECS_DDI_VERSION_VA. DI_FACT_ONSET_ID | N/A |
| DI Facts Severity | CTSTAGING. PECS_DDI_VERSION_VA. DI_FACT_SEVERITY_ID | N/A |
| DI Facts Documentation | CTSTAGING. PECS_DDI_VERSION_VA. DI_FACT_DOCUMENTATION_ID | N/A |
| DI Facts Text | CTSTAGING. PECS_DDI_VERSION_VA. DI_FACT_TEXT | N/A |
| Medline Hits | CTSTAGING. PECS_DDI_VERSION_VA. MEDLINE_HIT_ID | N/A |
| Medline Text | CTSTAGING. PECS_DDI_VERSION_VA. MEDLINE_TEXT | N/A |
| Package Insert | CTSTAGING. PECS_DDI_VERSION_VA. PACKAGE_INSERT_ID | N/A |
| Package Insert Text | CTSTAGING. PECS_DDI_VERSION_VA. PACKAGE_INSERT_TEXT | N/A |
| PBM Criteria | CTSTAGING. PECS_DDI_VERSION_VA. PBM_CRITERIA_ID | N/A |
| PBM Criteria Text | CTSTAGING. PECS_DDI_VERSION_VA. PBM_CRITERIA_TEXT | N/A |
| AIDS Guidelines | CTSTAGING. PECS_DDI_VERSION_VA. AIDS_GUIDELINE_ID | N/A |
| AIDS Guidelines Text | CTSTAGING. PECS_DDI_VERSION_VA. AIDS_GUIDELINE_TEXT | N/A |
| Interaction Source | CTSTAGING. PECS_DDI_VERSION_VA. INTERACTION_SOURCE_ID | N/A |
| Interaction Type | CTSTAGING. PECS_DDI_VERSION_VA. INTERACTION_TYPE_ID | N/A |
| Highest Level of Evidence | CTSTAGING. PECS_DDI_VERSION_VA. LEVEL_OF_EVIDENCE_ID | N/A |
| Action Date | CTSTAGING. PECS_DDI_VERSION_VA.VERSION_DATE | N/A |
| Action Performed By | CTSTAGING. PECS_DDI_VERSION_VA. ACTION_BY | N/A |
| Request Assigned To | CTSTAGING. PECS_DDI_VERSION_VA. ASSIGNED_USER | N/A |
| Request Submitted By | CTSTAGING. PECS_DDI_VA.REQUESTOR | N/A |
| Action Effective Date | CTSTAGING. PECS_DDI_VERSION_VA.VERSION_DATE | N/A |
| Current Action Reason | CTSTAGING. PECS_DDI_VERSION_VA.VERSION_COMMENT | N/A |

3.5 Conceptual Infrastructure Design

The PECS application is a web-based application accessible from behind the VA network via a client workstation with a VA approved Internet browser. The deployment architecture implements a three-tiered model consisting of an Internet browser based graphical user interface serviced by a WebLogic 10.x application server, a JEE based business logic service processing layer, and an Oracle 11g based data access tier.

The PECS application has two components, the National Component containing the application and database servers, and the Local Component that represents the client workstation capable of Internet browser connections.

PECS is deployed at the national level as a single application server node connected to a database server. It interfaces with local VistA sites through VistALink.(KAAJEE).

PECS is deployed in 2 environments Pre-Production and Production environment at ITC - Austin, TX. The new PECS build, database changes (updates), Security Patches etc. are first applied to PECS Pre-Production and then on successful deployment promoted to PECS Production.

The Hardware/Software components and deployment architecture of Pre-Production and Production are the same. The PECS Application and database are kept in synchronization for both the environments.

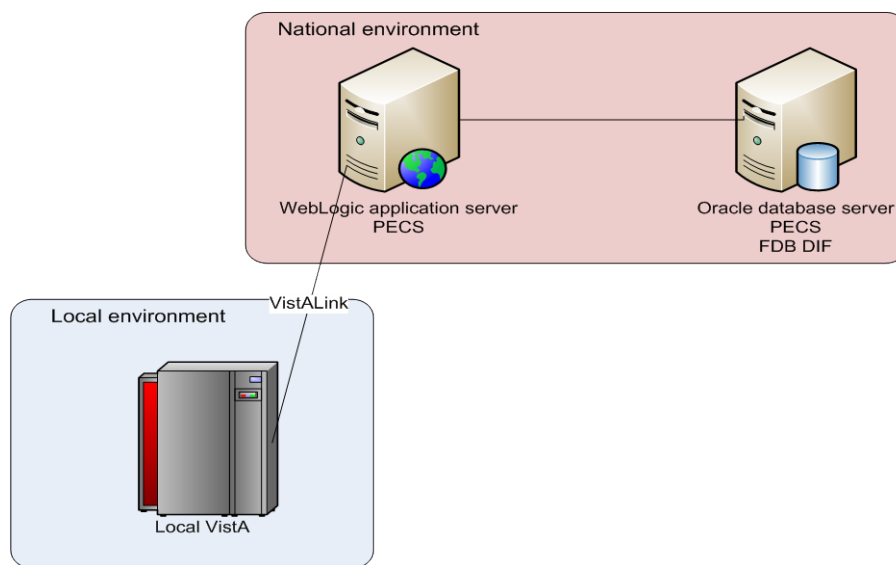


Figure 29: PECS High Level Deployment Design

3.5.1 System Criticality and High Availability

In line with the requirements established by Pharmacy Benefits Management (PBM) in the product's Requirements Specification Document (RSD), the system receives "essential support" as defined in the AITC Disaster Recovery Services. Please refer to the Application Contingency Plan maintained by CDCO for specifics on the Disaster Recovery (DR) procedures.

The system will inherit "High Availability" as defined in the High Availability Continuity of Operations through its deployment to a "Virtual Environment". Please refer to the Virtual Environment Continuity of Operations (COOP) Design Document Plan for additional information. Please contact the PRE Program Manager if you are unable to find the document.

3.5.2 Special Technology

No special technology is employed for the PECS application.

3.5.3 Technology Locations

The table below describes the various technology components used in the PECS application. The PECS Production environment will be hosted at the ITC, Austin, TX. For VA SQA testing, SQA servers are currently located at the Bay Pines OIFO and ITC. Plans to relocate/decommission the Bay Pines SQA servers are being evaluated due to the pending relocation of the Bay Pines OIFO.

Table 29: Technology Location

| Technology Component | Location | Usage |
|---------------------------|-----------------------|---|
| Production 1 | | |
| Workstations | VAMC | PECS users will log into the PECS application via browsers on these workstations |
| Special Hardware | N/A | |
| Interface Processors | N/A | |
| Legacy Mainframe | N/A | |
| Legacy Application Server | ITC- Austin -TX, VAMC | KAAJEE will use security keys for users located on their respective VAMC VistA Servers for successful login to PECS application |
| Legacy Databases | N/A | |
| Other | ITC | PECS Production Servers, will be hosted at the ITC Austin. |
| Production 2 | N/A | N/A |
| | | |
| Certification | N/A | N/A |
| | | |
| QAX | N/A | N/A |
| | | |
| Education | N/A | N/A |
| | | |
| Test | | |
| Workstations | Bay Pines | VA SQA personnel will log into the test PECS application via browsers on these testing workstations |
| Legacy Application Server | Albany | KAAJEE will use security keys for SQA users located on the Albany SQA Test VistA Servers for successful login to the PECS application |
| Development | | |
| Workstations | Developers Laptop | VA Developers will log into the Development environment for the PECS application via browsers on these workstations |
| Legacy Application Server | Albany | KAAJEE will use security keys for SQA users located on the Albany SQA Test VistA Servers for successful login to the PECS application |

3.5.4 Conceptual Infrastructure Diagram

Location of Environments and External Interfaces

The Figure below shows the Production environment that will be supported, and the local networks to which they will be attached for Local VAMCs, where PECS users are located.

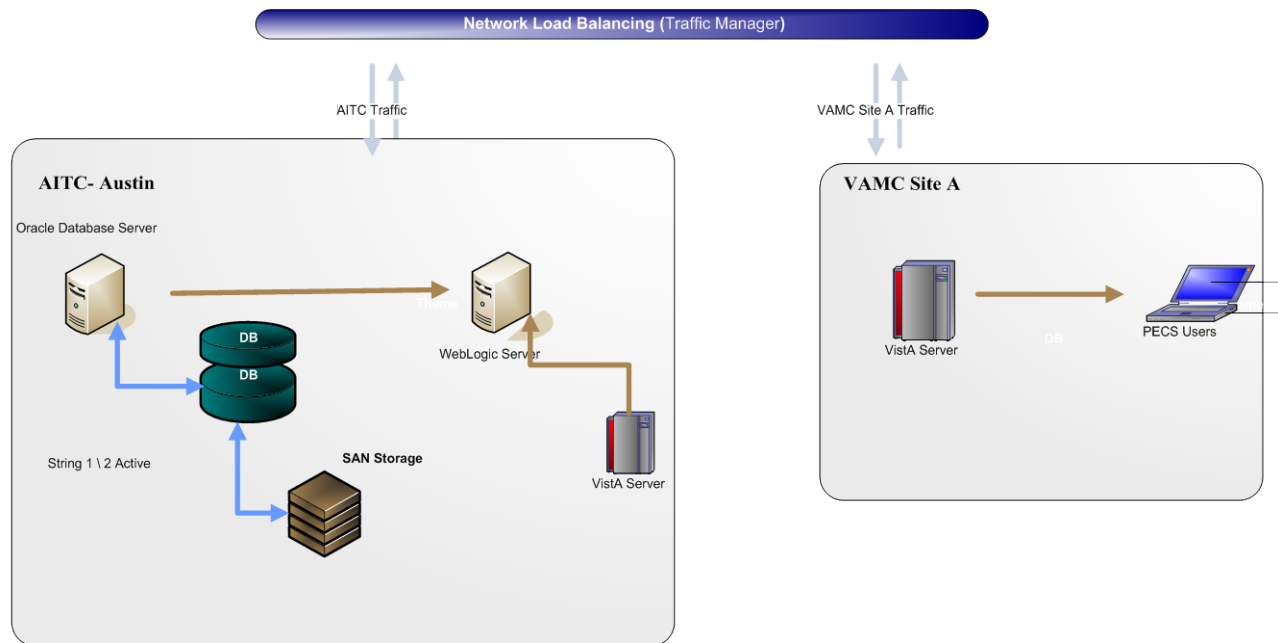


Figure 30: PECS Conceptual Networks and Environments

Conceptual Production String Diagram

The Figure below shows high level conceptual production configuration expected for the PECS application. The PECS application is deployed on a WebLogic server, and handles all external requests. This server communicates with an Oracle database server for persistence.

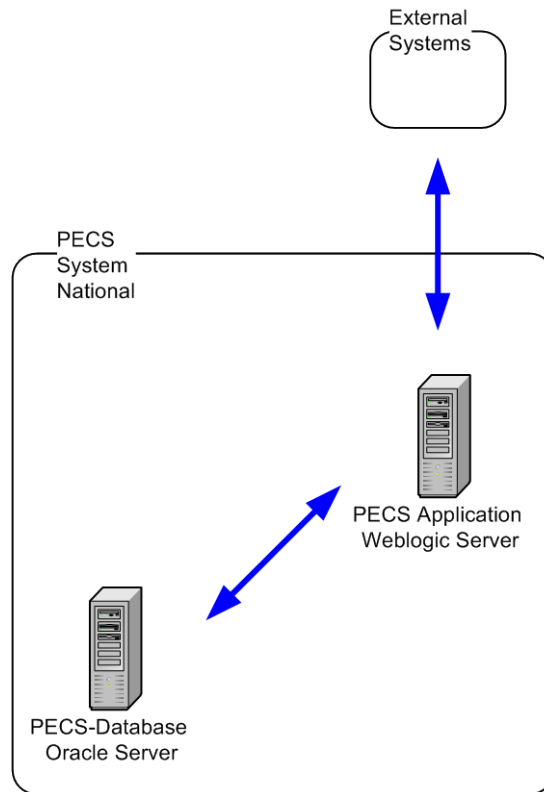


Figure 31: PECS Production String Diagram

4 System Architecture

The PECS architecture is comprised of the Software, Hardware, Communication, and Security architectures. The Software architecture describes the software components needed for PECS. The Hardware architecture describes the physical components needed for PECS and their relationship to one another. The Communication architecture describes the connections needed between the hardware components. The Security architectures describe the role-based security implemented for PECS using KAAJEE.

PECS is a 3-tier JEE application, deployed on a WebLogic Application Server, using Spring MVC as its presentation technology, Spring framework for the business services, and Hibernate to interface with an Oracle database.

4.1 Hardware Architecture

PECS is deployed at the national level on a two server architecture. The first server is a WebLogic application server and the second is an Oracle database server. The Production system will have two identical Application servers for Load Balancing. The servers will be configured as virtual machines on the AITC Virtual farm. Connections are made by standard TCP/IP protocols.

The following Figure represents the architecture for the Production and Pre-Production and Staging environments for PECS at AITC.

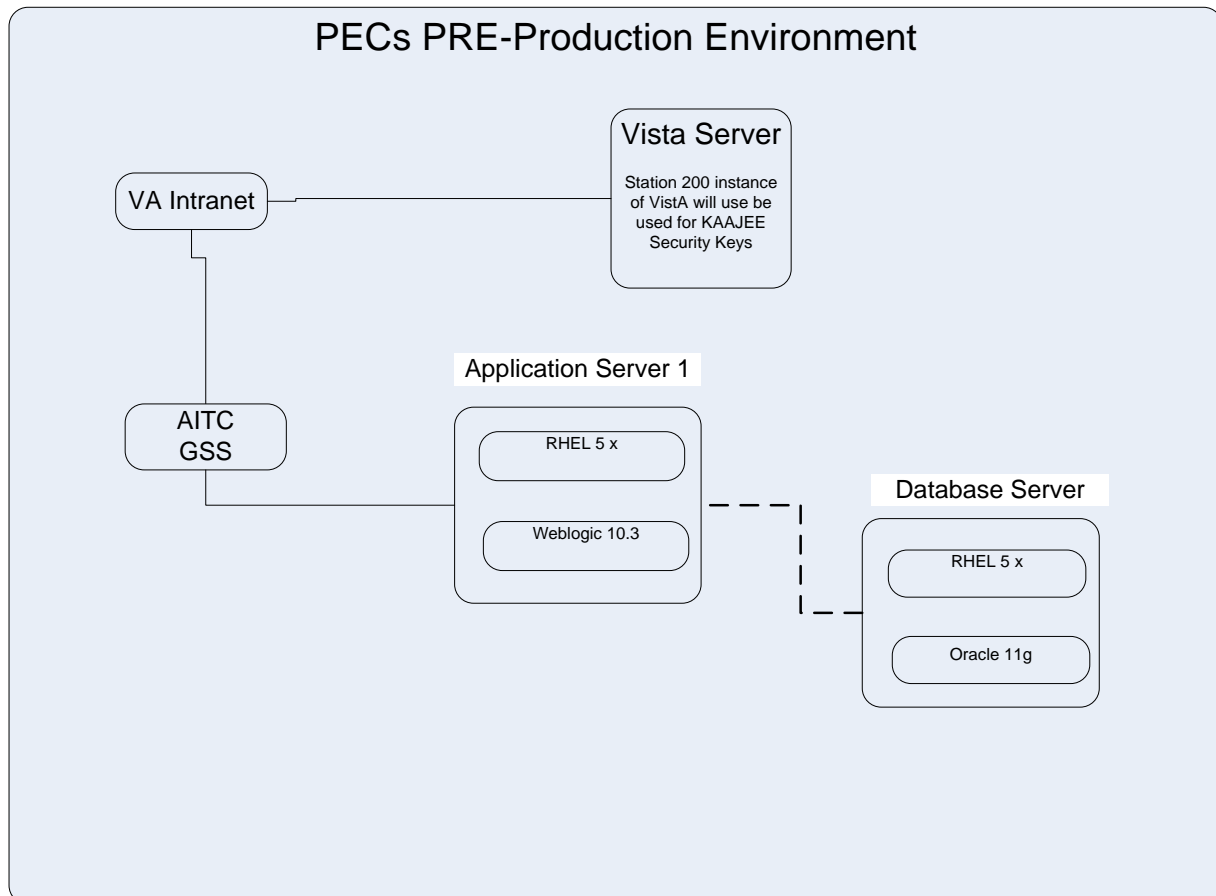


Figure 32: PECS Pre-Production System Diagram

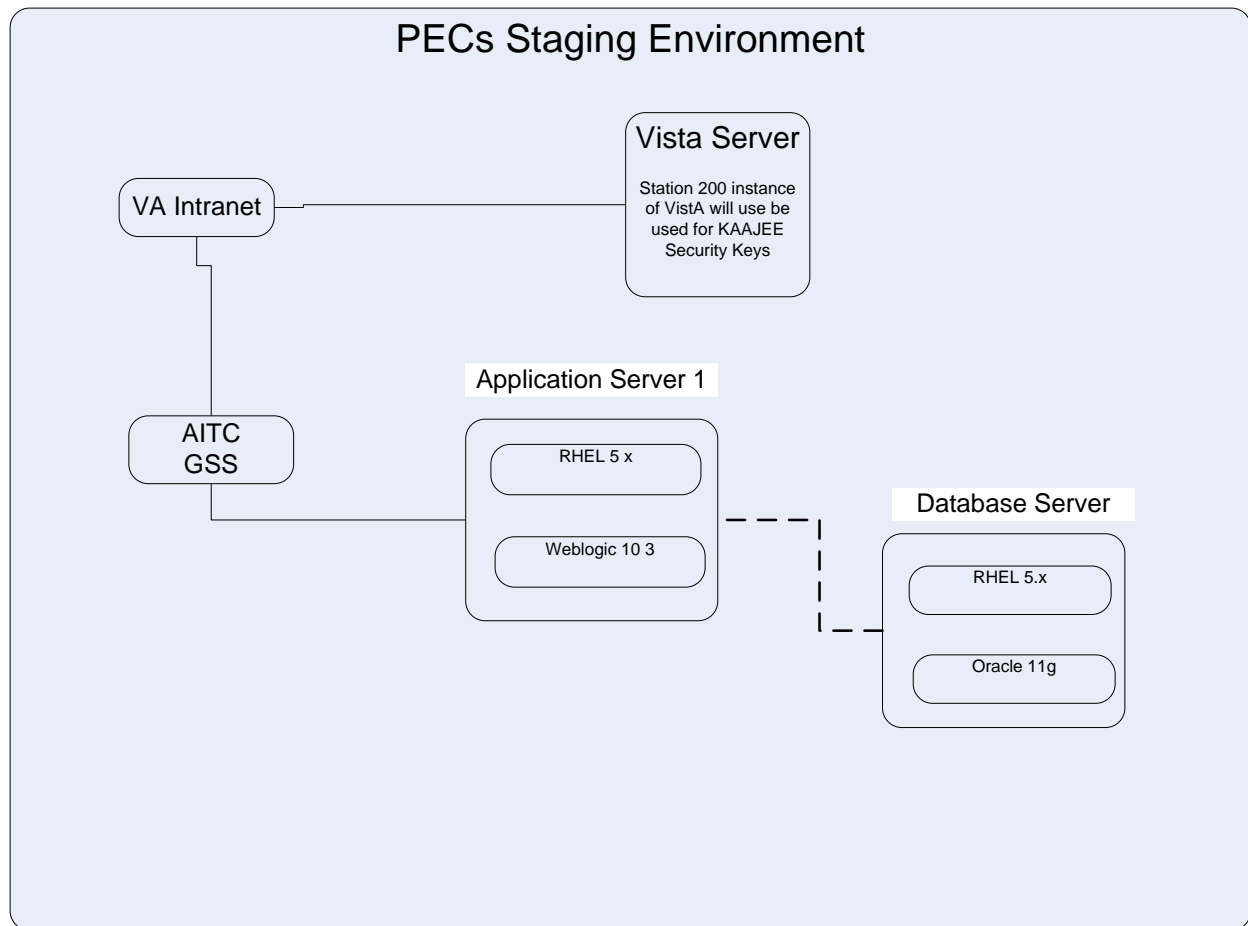


Figure 33: PECS Staging System Diagram

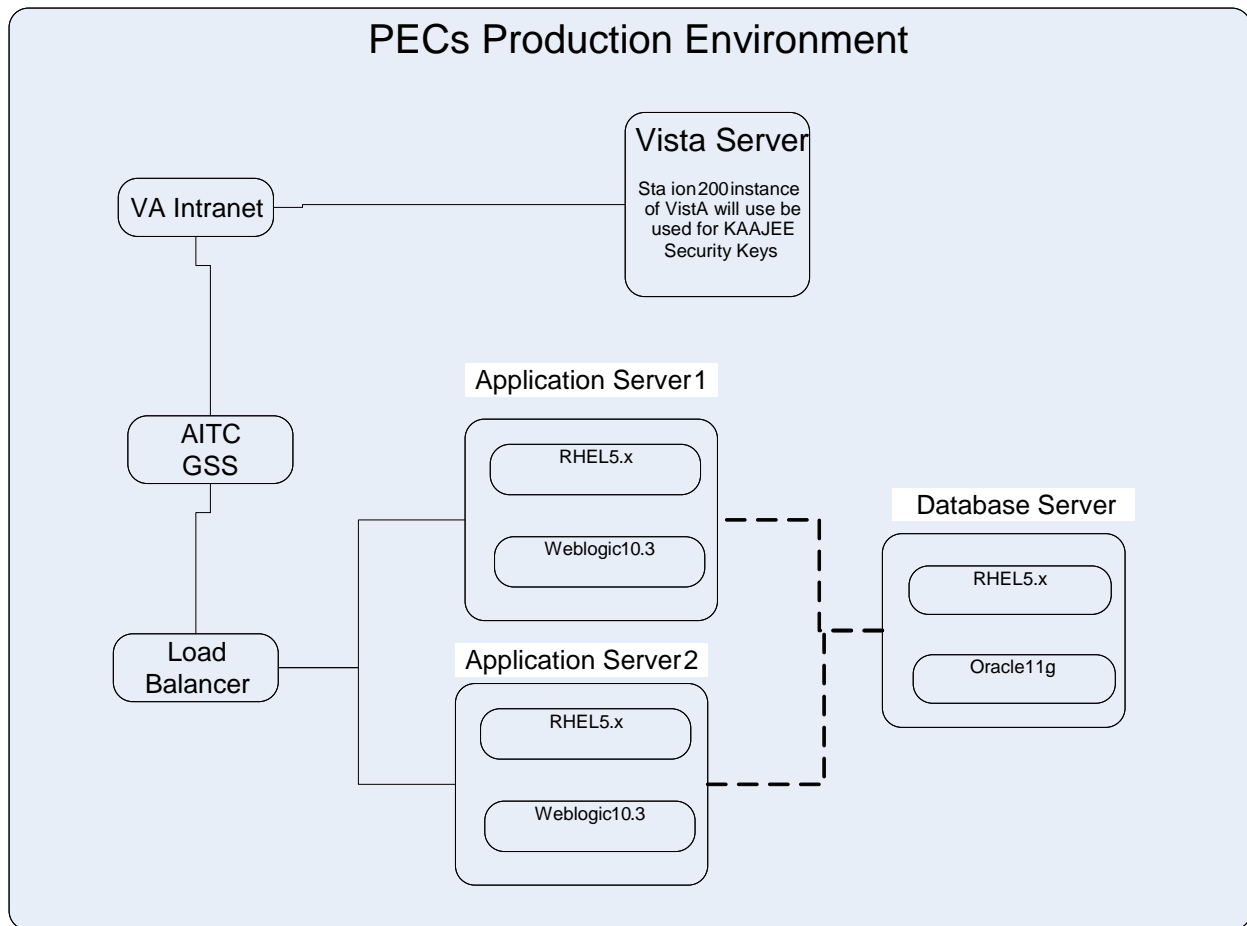


Figure 34: PECS Production System Diagram

4.2 Software Architecture

The PECS application is a web-based application accessible only from within the VA network via a client workstation with a VA approved Internet browser. The PECS application's architecture is designed and implemented according to VA architecture requirements using JEE framework. PECS is architected as an n-tier JEE application consisting of Presentation Tier, Business Logic Tier, and Data Persistence Tier. Each tier has its own design and implementation framework, and defined points of interaction with the other respective tiers.

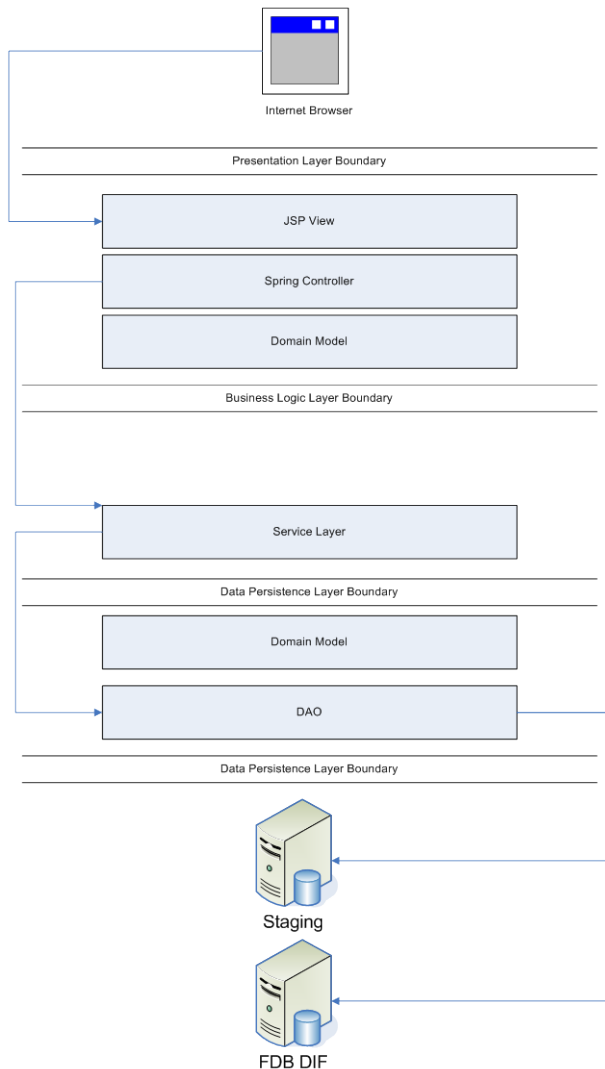


Figure 35: PECS Logical System Overview

4.2.1 Presentation Tier Overview

The presentation tier represents the GUI screens that allow the user to interact with the application, and the logic initiated by user interaction to execute screen functionality. Presentation Tier uses well known Model-View-Controller (MVC) design pattern implemented by the Spring MVC framework using Sun Microsystems JSP pages as the “View” portion of MVC. The MVC framework is used to manage the display screens and to dispatch and delegate requests initiated by the user to a business rule processing business logic tier. Non-navigational requests are handled by the MVC for querying Order Checks. The design of the MVC framework as it is used in the PECS application leverages an object hierarchy with commonly shared base classes.

4.2.2 Business Logic Tier Overview

The business logic tier is responsible for receiving business rule processing requests from the presentation tier, or other parts of the business logic tier. It is composed of services implemented as Spring beans. Transactional integrity is ensured by using Spring managed transactions.

The main services implemented deal with creation/modification/deletion of customization requests, workflow, queries and custom update generation.

The services encapsulate the business rules governing the creation/modification/deletion of customization requests and their workflow. The services are also responsible for interfacing and abstracting the data persistence tier from the rest of the application logic.

4.2.3 Data Persistence Tier Overview

The data persistence tier is designed and implemented with the open source Hibernate framework. The Hibernate framework is an object oriented abstraction for database CRUD operations (please see the Hibernate website for further information).

The data persistence tier interfaces with two logical Oracle databases. The first is the PECS database containing the tables and database objects necessary for the PECS application to perform Order Check customizations and track workflow status. The second is the FDB DIF database, which is the source of production Order Check data. The relevant tables in each of these databases have representative domain model objects and data access objects (DAOs) in the data persistence design.

4.3 Network Architecture

PECS communications architecture will use a combination of wide area networks (WAN) – VA Intranet coupled with local area networks (LAN) as depicted in the figure below. The LANs will use a star topology with transportation communication protocol and internet protocol (TCP/IP). The LAN will use gigabit or greater switches where required. All nodes within the confines of the ITC- Austin TX will be connected to the ITC- Austin TX LAN. All nodes within the confines of the Local VAMC facility will be connected to the Local LAN. A firewall is used to provide security and connect each LAN to the VA Intranet. Access to the PECS application is accomplished via a standalone laptop or workstation (on the VA Intranet) connected to PECS National using the appropriate browser.

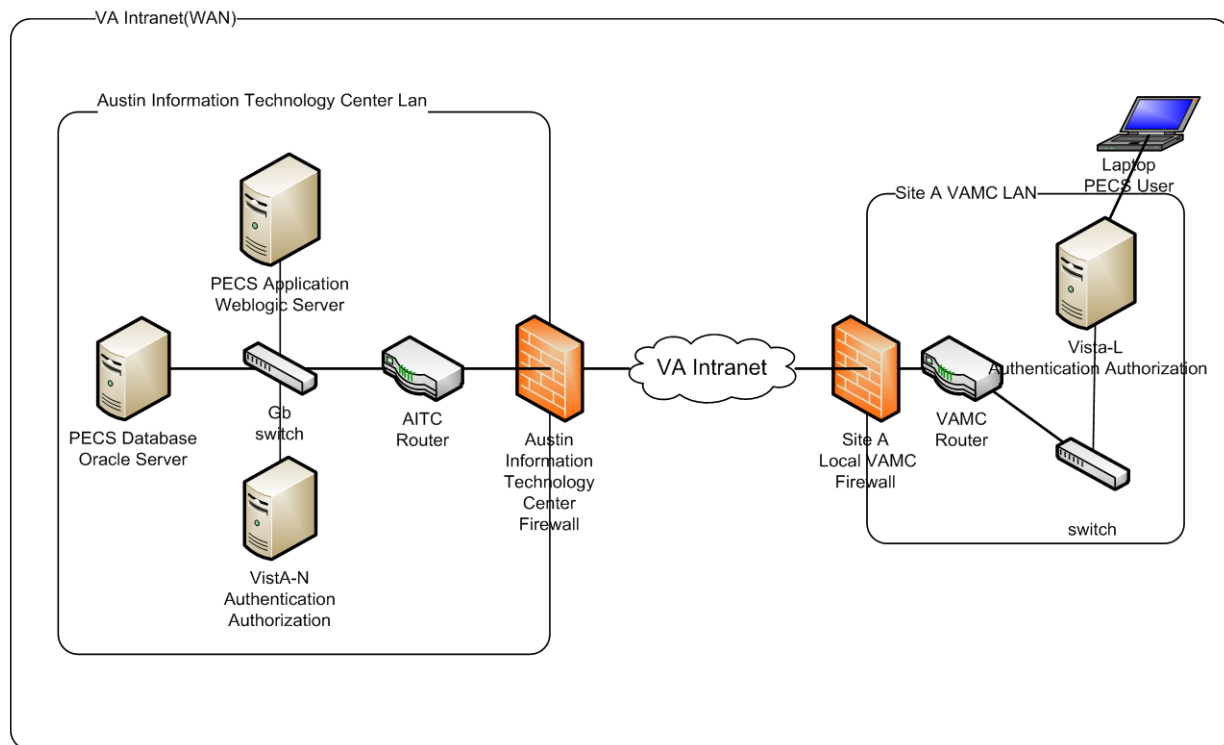


Figure 36: PECS Communication Architecture

4.4 Service Oriented Architecture / ESS

The PECS system is an established VHA Pharmacy system that has been in production for a number of years. The 6.0 version of PECS is being developed to provide for multiple functional and technical enhancements. Currently the PECS system does not expose any services for enterprise use and does not consume any ESS services. The scope of PECS 6.0 does not include any modifications for the inclusion or utilization of ESS services. To incorporate ESS into PECS requires a PRE program level effort that includes both MOCHA Server and PECS, and that effort is currently not funded.

4.5 Enterprise Architecture

The adherence to technical standards is established means to provide for a consistent enterprise architecture. PECS 6.0 is TRM compliant. TRM compliance is a major feature of the development plan and corrects the current deviancies from the TRM, the most significant of which is the replacement of

FTP with SFTP. An audit of the current technologies and tools used in the PECS systems is shown below. It lists the target TRM version that will be utilized as part of PECS 6.0.

Modification of the DATUP system is a central piece of the SFTP implementation. PECS 6.0 will modify and deploy DATUP as part of the release process. DATUP technologies are also included in the table below.

| Software Tools (include version number) | Description | PECS 6.0 Target |
|--|---|---------------------|
| antlr V. 2.7.6 | ANother Tool for Language Recognition (ANTLR) is a powerful parser generator for reading, processing, executing, or translating structured text or binary files. | 4.1 |
| aopalliance V 1.0 | The AOP Alliance project is a joint open-source project between several software engineering people who are interested in AOP and Java. | (Spring Dependency) |
| Apache Commons | <p>The Commons is an Apache project focused on all aspects of reusable Java components.</p> <ul style="list-style-type: none"> • beanutils-1.8.3 • codec-1.5 • collections • digester-2.1 • jexl-2.0.1 • lang-2.4 • logging-1.1.1 • net-2.0 • scxml-0.9commons-beanutils- 1.8.3.jar • commons-beanutils-bean-collections-1.8.3.jar • commons-beanutils-core-1.8.3.jar • commons-cli-1.0.jar • commons-codec-1.5.jar • commons-collections-3.2.1.jar • commons-digester-2.1.jar • commons-discovery-0.5.jar • commons-fileupload-1.2.2.jar • commons-io-1.4.jar • commons-lang-2.6.jar • commons-logging-1.1.1.jar • commons-logging-1.1.3.jar • commons-net-3.3.jar • commons-vfs2-2.0.jar | Under TRM review |

| Software Tools (include version) | Description | PECS 6.0 Target |
|---|---|--------------------|
| Apache FTP Server V. ftplet-api- 1.0.3.jar ftpserver- core-1.0.3.jar | An FTP server is a software.html application running the File Transfer Protocol (FTP), which is the protocol for exchanging files over the Internet. | No Change |
| Apache Mina v.2.0.0.M6 mina-core- 2.0.0-M6.jar | Apache MINA (Multipurpose Infrastructure for Network Application) is a network application framework for developing network applications. | No Change |
| Apache POI V. 3.7 | The Apache Poor Obfuscation Implementation (POI) project is a set of APIs (Application Programming Interface) for reading-writing Microsoft Office file formats using pure Java. | 3.9 |
| Apache Tiles V. 2.2.2 | Apache Tiles is a template based framework used to simplify the development of web application user interfaces. | No Change |
| Attachmate Reflection for UNIX and OpenVMS 14.0.687 SP6 | Attachmate Reflection allows connection to UNIX, OpenVMS, and HP host types. Reflection for IBM is terminal emulation software that connects Windows users to applications on IBM mainframe and AS/400 systems. | 15.6 |
| cglib-nodep | Code Generation Library (CGLIB) is used to extend JAVA classes and implements interfaces at runtime. It is an application for dynamic generation of classes. | 3.1 |
| CheckStyle V 5.5 | CheckStyle is a code auditing technology. The primary purpose of CheckStyle is to allow for automated checking of adherence to coding standards | 5.6 |
| DBUNIT V2.2.1 | DbUnit is a testing solution for database driven projects. | 2.49 |
| DOJO Toolkit V. 1.9.1 | Dojo Toolkit is an open source modular JavaScript library used to build web applications using Asynchronous JavaScript and XML (AJAX). | 1.1 |
| domj4 V. 1.6.1 | dom4j is an easy to use, open source library for working with XML, XPath and XSLT on the Java platform using the Java Collections Framework and with full support for DOM, SAX and JAXP. | No change |

| Software Tools (include version) | Description | PECS 6.0 Target |
|--|---|--------------------------|
| Eclipse EE (Juno) | Tools for Java developers creating Java EE and Web applications for Windows OS, including a Java IDE, tools for Java EE, JPA, JSF, Mylyn, EGit and others. | 4.3(Kepler) 4.4(Luna) |
| Ehcache V. 2.4 | Ehcache is a free open source, Java based cache used for database offloading and scalability. | 2.7 |
| FileZilla V. 3.8.x | FileZilla is an open source GUI based desktop file transfer utility for FTP, FTPS and SFTP. | No Change |
| Findbugs Eclipse Plugin | FindBugs looks for bugs in Java programs. It uses static analysis to inspect Java code or bytecode for occurrences of bug patterns. | No Change |
| FTP | FTP is a system utility that provides for the transmission of files from one system to another | SFTP |
| Geronimo V1.0 Component CXF | Apache Geronimo is an open source server runtime that integrates the best open source projects to create Java/OSGi server runtimes that meet the needs of enterprise developers and system administrators. | 2.7.7 |
| Hibernate Object/Relation al Mapping (ORM) V. 3.5.6 | Hibernate Object/Relational Mapping (ORM), formally known as Hibernate Core, is a foundational framework for mapping and persisting object state to a relational database, also referred to as Object/Relational Mapping (ORM). | 4.3 |
| Hibernate Validator V 4.2 | Hibernate Validator is the reference implementation of Java Specification (JSR-303) 303, which provides Java bean validation capabilities. | 5.1 |
| Jackson V. 1.8.2 | Jackson is an open source JavaScript Object Notation (JSON) parser and data binder. Jackson provides the capability to convert Java objects to JavaScript objects and to convert JavaScript objects to Java objects. | 2.3 |

| Software Tools (include version) | Description | PECS 6.0 Target |
|---|---|--------------------|
| Java Architecture for Extensible Markup Language V. 2.1.12 jaxb-xjc-2.1.12 jaxb-api-2.1.12 jaxb-impl- 2.1.12 | Java Architecture for Extensible Markup Language (JAXB RI) provides a reference implementation for Extensible Markup Language (XML) Binding JAXB specification | 2.2.7 |
| JAVA EE 6 | The Java Platform, Enterprise Edition, or Java EE (formerly known as J2EE) is a platform for large scale server programming in the Java programming language. | 1.7 |
| JAVA SE V 1.6 | Java Platform, Standard Edition (Java SE), formerly Java 2 Standard Edition (J2SE), is the specifications of a Java virtual machine and Java application programming interface (API | 1.7 |
| javassist | Javassist (Java Programming Assistant) is a class library for editing byte codes in Java; it enables Java programs to define a new class at runtime and to modify a class file when the JVM (Java Virtual Machine) loads it. | 3.18 |
| JAWS for Windows 14.0.9002 | Job Access With Speech (JAWS) is a Freedom Scientific technology product for users whose vision is lost. | 15 |
| JUnit V. 4.7 | JUnit is a Java unit test development and testing framework. It provides a framework for developers to rapidly develop and deploy unit tests for their Java development artifacts. | 4.11 |
| Log4J V. 1.2.15 | Log4J is a Java runtime logging framework that allows developers to include in their source code, the ability to generate logging output messages. The verbosity and output of the log can be controlled by configuration at runtime. | 1.2.17 |

| Software Tools (include version) | Description | PECS 6.0 Target |
|--|---|--------------------|
| Oracle Database V. 11.2.0.2 | Oracle Database, also known as Oracle RDBMS or Oracle Enterprise Database, is an object-relational database management system. There are several Oracle editions (Express, Personal, Standard, and Enterprise) that are supported on a variety of operating systems. This assessment is concerned with the Standard and Enterprise editions of Oracle as well as various optional components that are also listed in this assessment. | No Change |
| Quartz Enterprise Job Scheduler V 2.2.1 | Quartz Enterprise Job Scheduler is an open source job scheduling library that can be integrated with, or used alongside Java Enterprise Edition (Java EE) or Java Standard Edition (Java SE) applications.. | 2.2 |
| SLF4J V1.5.2 slf4j-api-1.5.2.jar slf4j-nop-1.5.2.jar | SLF4J - is a simple logging facade for java - an interface standard that allows a framework to include a level of abstraction to a desired logging implementation, such as Java simple logging, log4j, NCL, etc. | 1.7.0 |
| Spring Framework V 3.2.4 | Spring is an application framework based on Inversion of Control. It provides a lightweight Java Enterprise Edition (Java EE) container. Spring is a modular framework for Java applications that can be used in a stand-alone Java Virtual Machine (JVM) with the Java Standard Edition libraries, in servlet containers, and in Java EE servers. | 4.0.6 |
| WebLogic Server V. 10.3.2 | Oracle WebLogic Server is a Java Enterprise Edition application server platform designed to host distributed applications written using Java and the Java Enterprise Edition frameworks. WebLogic Server has Enterprise Service Bus (ESB) capabilities that can be configured to provide system connectivity and data transformation spanning IT environments. | 12c |
| Xalan V. 2.6.0 | Xalan-Java is an Extensible Stylesheet Language Transformations (XSLT) processor for transforming Extensible Markup Language (XML) documents into HyperText Markup Language (HTML), text, or other XML document types. | 2.7.2 |

| Software Tools (include version) | Description | PECS 6.0 Target |
|-------------------------------------|---|--------------------|
| XMLBeans V. 2.3.0 | XMLBeans provides a framework for accessing and manipulating XML (Extensible Markup Language) documents through Java Type binding. For Java applications that need to process or manipulate XML documents, XMLBeans support the traditional Document Object Model (DOM) approach to XML handling, but adds both a Java Type binding and cursor base approach to XML handling. | 2.6.0 |

4.6 Performance Requirements

Table 28: Functional Requirements provides an overview of the major functional requirements and associated Performance Requirements for the PECS system.

Table 30: Functional Requirements

| ID – Requirement Number from Functional Requirements Document | Specific Requirement/Synopsis | Requirement Text |
|---|-------------------------------|--|
| 1 | System | The system shall allow customization to the COTS information of Drug Interaction, Drug Pairs, Dose Range, Duplicate Therapy, and Professional Monograph. |
| 2 | System | The system shall provide a means to store all changes with access to view historical records. |
| 3 | Functional | The system shall provide a means to query records from the COTS table as well as those customized by the users. |
| 4 | Functional | The system shall provide a means to export VA Customized records. |
| 5 | System | The system shall provide access control based on the defined roles. |
| 6 | Functional | The system shall provide an overview of transactions by action status on the PECS home page. |
| 7 | System | The system shall provide wizard actions of retrieving and viewing selected FDB and/or VA customized records. |
| 8 | Functional | The system shall provide a means to easily customize field names, display and turning on or off of fields for query, reports, and data entry by a role allowed within the application. |

| ID – Requirement Number from Functional Requirements Document | Specific Requirement/ Synopsis | Requirement Text |
|---|--------------------------------|---|
| 9 | Functional | The system shall provide a means to run a query for DDI for up to 10 drugs and receive all the interactions with Duplicate Therapy and Professional Monographs if required. |
| 10 | Functional | The system shall provide a means to run a query with patient data and dose particular for a routed generic. |

4.6.1 Functional Workload and Functional Performance Requirements

TABLE shows the functional workload and performance requirements of PECS linked to the Requirement ID from the Functional Requirements document.

Table 31: Workload and Performance Requirements

| ID | Requirement |
|----------|---|
| SPEC838 | Total number of users by role: <ul style="list-style-type: none"> Administrator: five Approver: twenty Requestor: 10 per medical center (1280) (or potentially all VA clinical employees) Release Manager: five |
| SPEC839 | Number of concurrent users by role: <ul style="list-style-type: none"> Administrator: one Approver: Five Requestor: 3 per medical center (284) Release Manager: one |
| SPEC840 | Response time: <ul style="list-style-type: none"> Submitting / approving request: five seconds Running queries: five seconds or less Creating custom file: five minutes or less |
| SPEC841 | Usage peak times: Monday through Friday, 7:00 a.m. Eastern Time – 7:00 p.m. Eastern Time |
| SPEC842 | Maximum number of customization request (estimated): <ul style="list-style-type: none"> Daily: 3 Weekly: 15 |
| SPEC843 | The system shall allow 30 minutes idle time prior to time out of the application. |
| SPEC1120 | Number of users, worst case scenario 128 VMS facilities (defined as VistA instance) 10 users / facility 5 concurrent / facility Facilities are open from 7:00 am eastern to 7:00 pm eastern |

| ID | Requirement |
|----------|--|
| SPEC1125 | <p>Workload distribution on business functions:</p> <ul style="list-style-type: none"> • Querying for Drug-Drug Interactions (DDI) info (10/hour/site) • Querying for Drug Pairs (DP) (5/hour/site) • Drug Pair Lookup query (5/hour/site) • Querying for Professional Monograph (PM) info (5/hour/site) • Querying for Duplicate Therapy (DT) info (3/hour/site) • Querying for Dose Range info (3/hour/site) • Open a custom Drug-Drug Interaction record in the detail screen and open the list of associated drug pairs (4/hour/site). • Open an FDB VA Drug-Drug Interaction record in the detail screen (4/hour/site) • Open a custom Drug Pair record in the detail screen (4/hour/site) • Open an FDB Drug Pair record in the detail screen (4/hour/site) • Open a custom Professional Monograph record in the detail screen (2/hour/site) • Open an FDB Professional Monograph record in the detail screen (2/hour/site) • Open a custom Duplicate Therapy record in the detail screen (1.2/hour/site) • Open a FDB Duplicate Therapy record in the detail screen (1.2/hour/site) • Open a custom Dose Range record in the detail screen (1.2/hour/site) • Open an FDB Dose Range record in the detail screen (1.2/hour/site) |

5 Data Design

PECS data design consists of a set of tables used to store the customization requests and audit information related to them, as well as a set of tables that hold configuration data.

5.1 Database Management System (DBMS) Files

The PECS application uses a relational back-end database. It depends on two different databases. The FDB DIF database is used to retrieve reference data and lookup values on which to base Order Check customizations. PECS also uses its own database to stage and manage customizations that are going through the request and approval workflow process. This database is referred to as the “Staging” database. Since the FDB DIF database is a COTS application and is well documented, it will not be discussed here.

The architecturally significant elements of the Staging database are the tables that mirror the FDB DIF custom tables. In the Staging database, there is one table that includes all of the fields of the FDB DIF database table, for each of the custom Order Checks that are managed by the PECS application. These tables follow a naming convention similar to the FDB DIF tables, with a “_VA” suffix. These Staging tables also include additional metadata about the customization record that is used to manage the customization record as it is processed through the customization workflow.

5.1.1 Customization Tables

Each concept that can be customized is stored in its own tables. The data design for all concepts follows the same pattern. A ‘main’ table holds an entry for each customization request. These entries only store immutable data related to that customization request. The rationale is that those fields don’t need to be versioned for auditing purposes. Some of these data elements are concept-specific (represented in the diagram as IMMUTABLE_FIELD_1 and IMMUTABLE_FIELD_2), while some are common to all concepts (like an integer identifier and the requestor, i.e., the user who initiated the customization request).

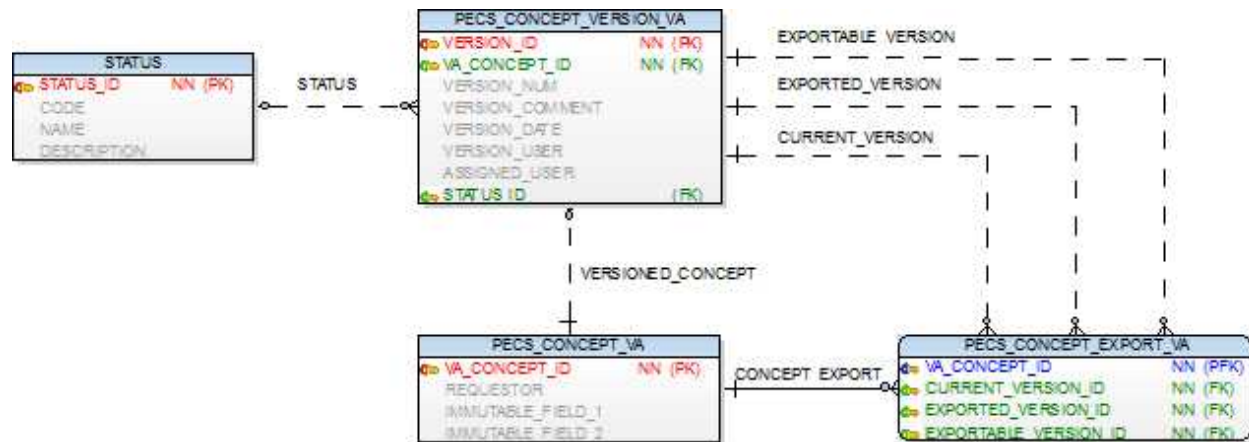


Figure 37: Concept of PECS Customization Tables

The remaining data for the concept is stored in an associated version table. All mutable data elements are recorded here. To maintain an audit trail, the application never overwrites data. Instead, any time a user makes a change to a customization request, a new record is created in this table and the old one is inactivated (it becomes historical). Along with concept-specific data (exemplified as MUTABLE_FIELD_1, MUTABLE_FIELD_2), the table stores information about the user performing the action, the date, as well as workflow related information.

Below is a brief explanation of the relationships between tables:

- **ACTIVE_VERSION:** The ACTIVE_VERSION_ID is a foreign key that references the most recent version record for a given concept record. As described before, each customization request has one or more associated version records that constitute its audit trail. The version with the highest number (VERSION_NUM) records the most up to date mutable data elements for that request. That record is called the *current or active* one and this foreign key maintains a reference to it. All other records associated with that customization request are called *historical*.
- **EXPORTABLE_VERSION:** The EXPORTABLE_VERSION_ID is a foreign key that references the version ready to be included in the next custom update file (if any).
- **EXPORTED_VERSION:** The EXPORTED_VERSION_ID is a foreign key that references the version included in the last custom update file (if any).
- **VERSIONED_CONCEPT:** The VA_CONCEPT_ID is a foreign key that relates a version record with its corresponding customization request.

The Data View will be developed as the design of the PECS 6.0 product design matures.

The PECS data schema has two parts – one part provided by the First Data Bank (FDB), the Drug Data Vendor, and one part created by the PECS team that supports the customization of data elements in the FDB schema. PECS 5.0 currently uses FDB's MedKnowledge Framework v3.3 (formerly known as FDB-DIF v3.3). It is likely that PECS 6.0 will include an upgrade to FDB Med Knowledge v4.0. This upgrade would impact both parts of the PECS data schema.

In addition, further discussions between FDB and the PECS Team are needed to understand how to properly satisfy documentation requirements, but not violate any agreements with FDB to protect their proprietary data schema.

This section will be updated during the PECS 6.0 UFT to reflect the results of any upgrade in a manner acceptable to the Drug Data Vendor.

6 Detailed Design

PECS Hardware and Software design elements are listed in the hardware and software detailed design sections, below respectively.

6.1 Hardware Detailed Design

PECS is installed in two environments, Pre-Production and Production, at ITC Austin, TX. The new PECS build, database changes (updates), Security Patches, etc., are first applied to PECS Pre-Production and then on successful deployment promoted to PECS Production.

The Hardware/Software components and deployment architecture of Pre-Production and Production are the same. The PECS application and database are kept in synchronization for both the environments.

6.1.1 Deployment Design – PECS

The figure below, Figure 37: PECS Deployment, shows the overview of Logical deployment design for the PRE PECS Application.

Application Server:

The WebLogic Application Server 10.3 will host PRE PECS and its business services.

Data Base Server:

The Database Server- Oracle 11g will have Red Hat Linux Enterprise version RHEL5 as its OS. It will host the Custom Table Staging database and FDB-DIF database.

Legacy Interface:

There will be an existing VistA server which will host legacy KAAJEE and VistALink interface.

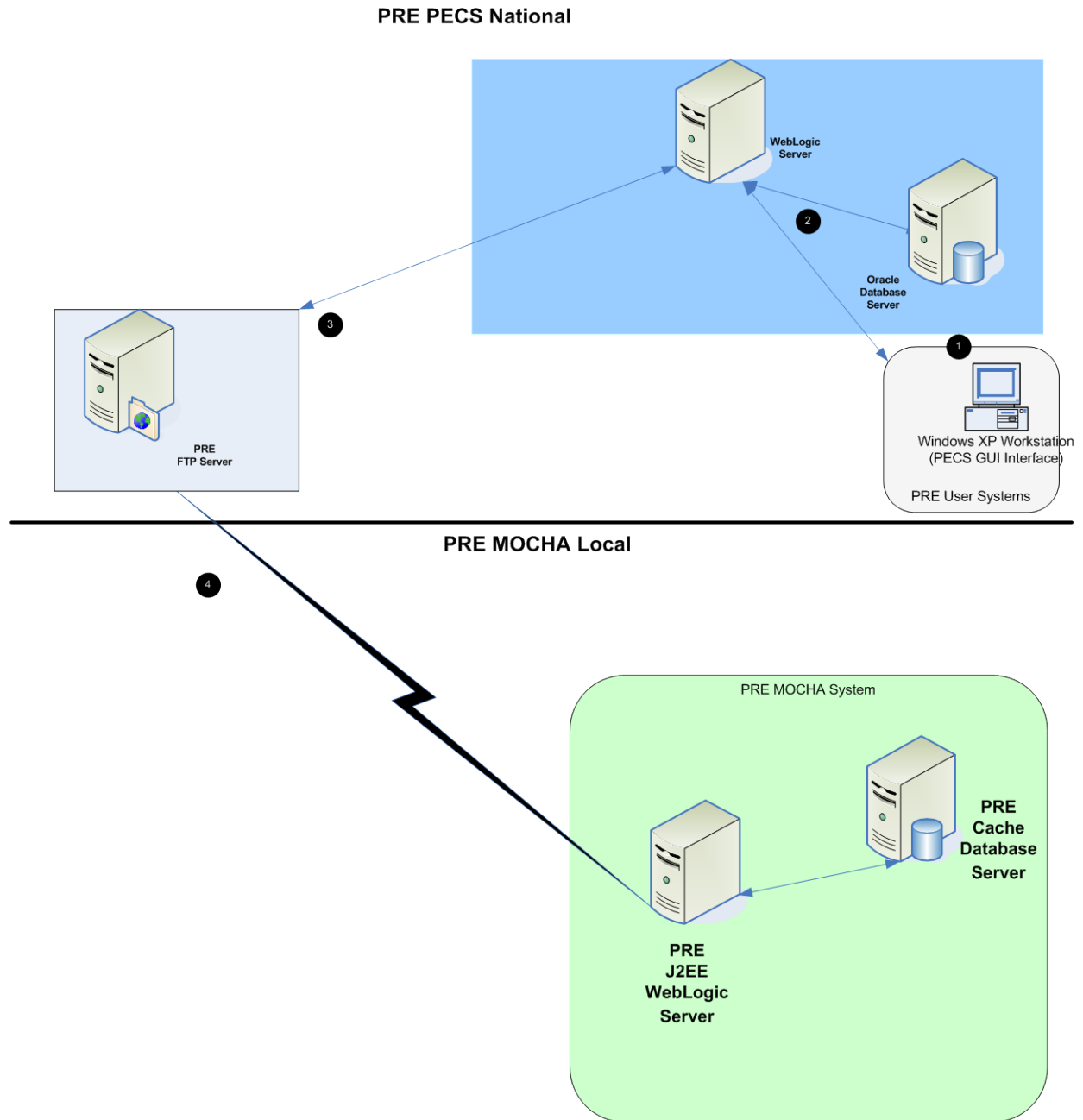


Figure 39: PECS Deployment

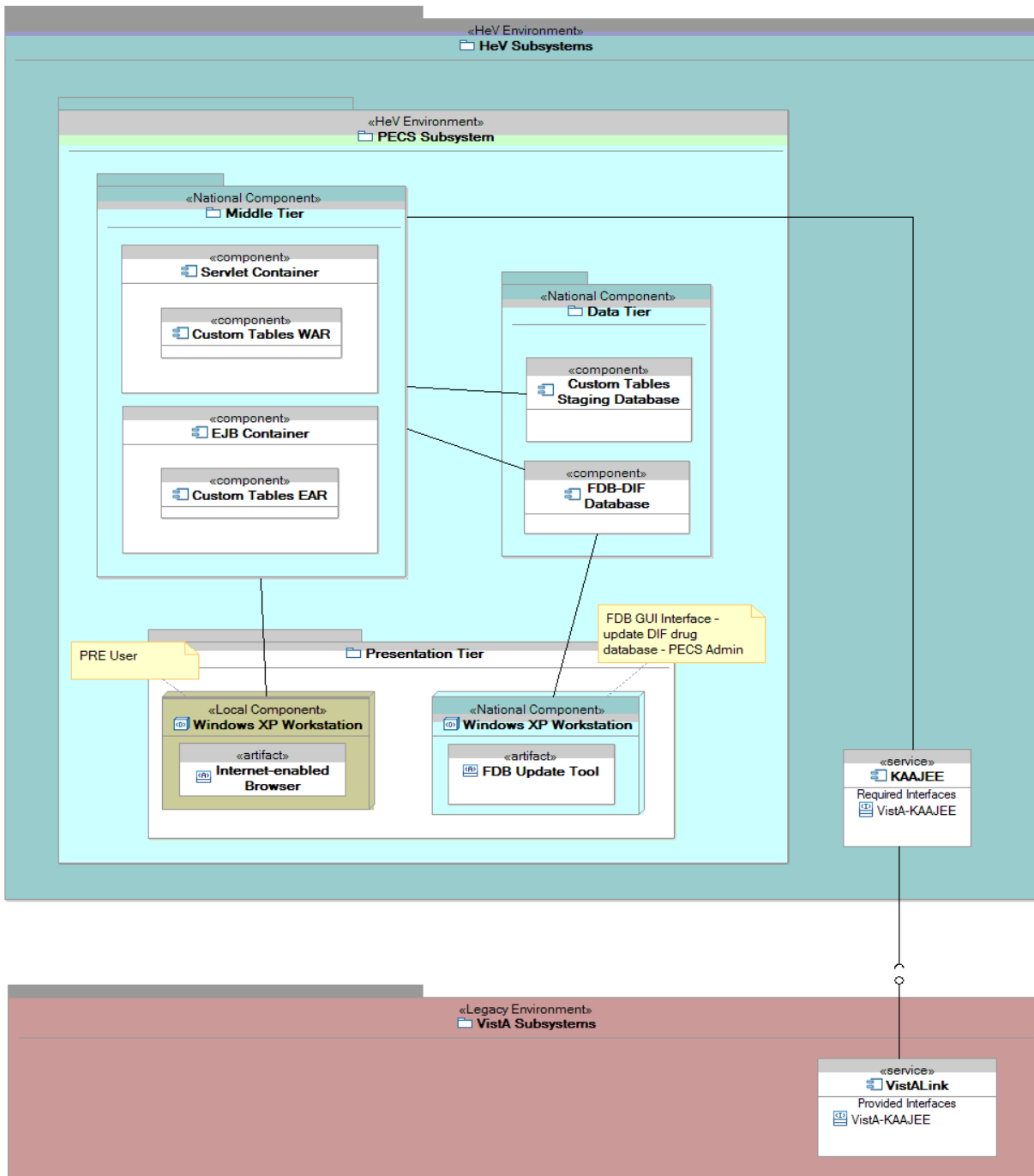


Figure 40: PECS Deployment, continued

6.2 PECS Software and Hardware

The tables below depict the PECS software and hardware located at the Information Technology Center - Austin:

Table 32: PECS Software

| Manufacturer | Software Name | Use (i.e., OS, Database) | Version Number | License Information |
|--------------|--------------------------|--------------------------|-----------------------------|---------------------------------|
| Red Hat | Red Hat Enterprise Linux | OS | 5.x x86_64 operating system | VA Enterprise License |
| Oracle | Oracle | Database | 11g | VA Enterprise License (generic) |
| Oracle | WebLogic | Application SW | 10.3.2 | VA Enterprise License (generic) |

Table 33: PECS Firmware/Hardware (for Virtual Environment)

| Manufacturer | Version Number | Device Installed On |
|--------------|----------------|---------------------|
| VMWare | VShpere | Application Server |
| VMWare | VShpere | Database Server |

Table 34: Client Hardware and Software Parameters

| Parameter | Value |
|-------------------------|--|
| Central Processing Unit | Standard VA issue Desktop or Laptop |
| Software Requirements | Internet Explorer 6 or higher to run PEPS WEB Application. |

Table 35: Middle Tier (Application) Hardware and Software Parameters (TRM Class C server)

| Parameter | Value |
|---------------------------------|--|
| Central Processing Unit | 2 CPU, x86-64 architecture (Intel x86-64 or equivalent), 2 GHz or faster |
| RAM | 24 GB (3x8GB for optimal DDR-3 performance) |
| Available Hard Disk Space (OS) | 70 GB |
| Available Hard Disk Space (App) | 75 GB |
| Operating System | Red Hat Linux – Enterprise Edition Version 5.x |
| Network Interface | dual 1000 Base T or higher |
| Out of Band Management | VMWare Console |
| Software | BEA WebLogic 10.3 |
| VA Mandated Software | Visibility to Servers Requirements |
| McAfee Enterprise/EPO | |
| Encase | |
| BigFix | |

Table 19: Data Tier Hardware and Software Parameters (TRM Class C server)

| Parameter | Value |
|-------------------------|--|
| Central Processing Unit | 2 Quad core CPU, x86-64 architecture (Intel x86-64 or equivalent 2 |

| Parameter | Value |
|--------------------------------|--|
| | GHz or faster) |
| RAM | 48 GB (6x8GB for optimal DDR-3 performance) |
| Available Hard Disk Space (OS) | 70 GB |
| Available Hard Disk Space (DB) | 150 GB |
| Operating System | Red Hat Linux – Enterprise Edition Version 5.x |
| Network Interface | 4 x 1000 Base T or higher |
| Out of Band Management | VMWare Console |
| Database | Oracle 11 g |
| VA Mandated Software | Visibility to Servers Requirements |
| McAfee Enterprise/EPO | |
| Encase | |
| BigFix | |

6.3 Physical Deployment

The figure below displays the physical layout of the PECS application.

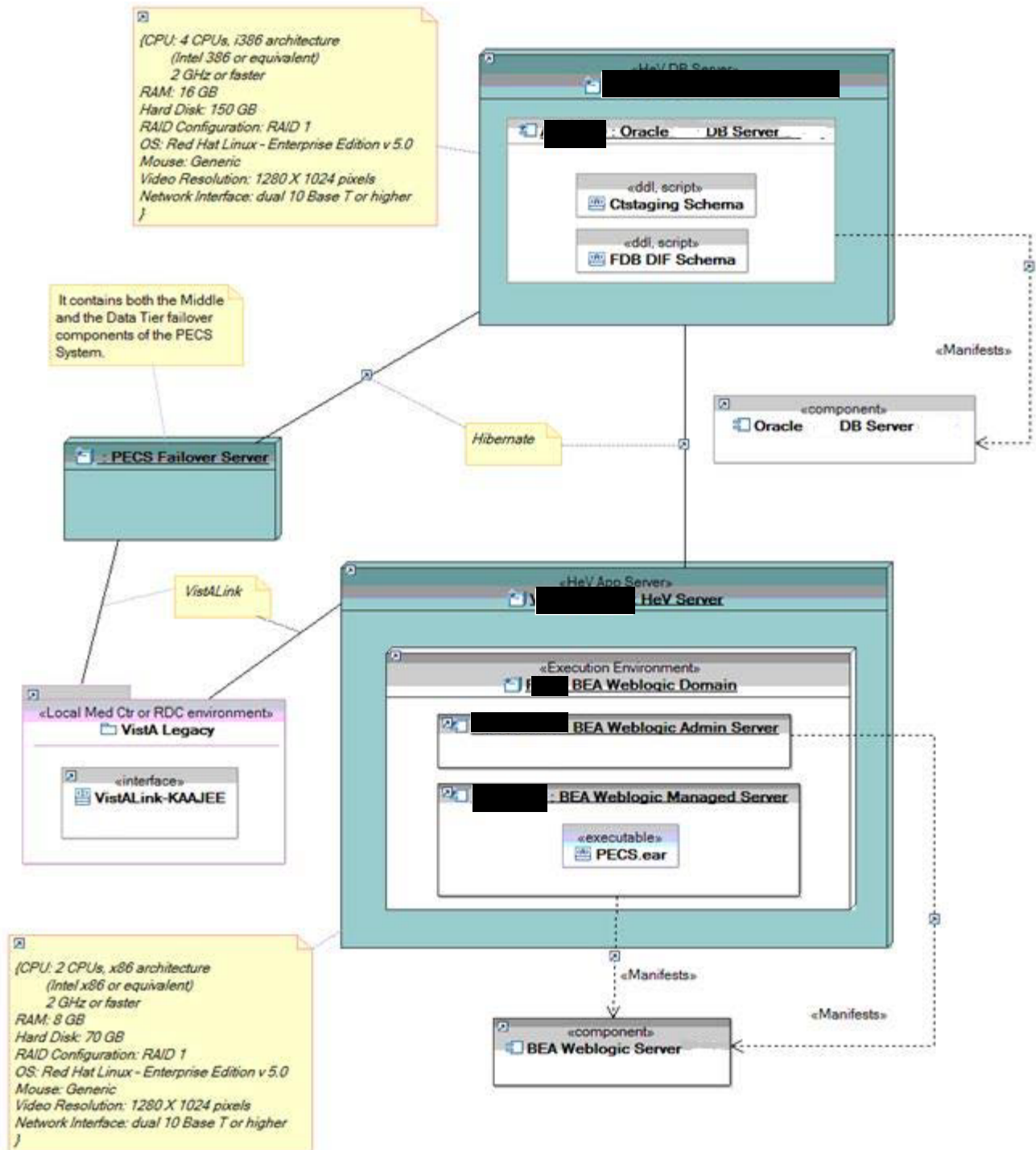


Figure 41: PECS Physical Deployment

6.4 Software Detailed Design

The PECS Software Architecture consists of six major subsystems as detailed below.

- **Query:** This module queries Drug Information from PECS and FDB-DIF Database. There are modules specific to each of the concepts PECS can Query (drug-drug interaction, drug pair, monograph, dose range, duplicate therapy). The design of these modules follows the same pattern, but there are some concept-specific differences.
- **Customization:** There are modules specific to each of the concepts PECS can customize (drug-drug interaction, drug pair, monograph, dose range, duplicate therapy). The design of these modules follows the same pattern, but there are some concept-specific differences. They deal with the entire life-cycle of the customization request and cut through all three application layers (presentation, business, and data).
- **Custom updates:** The ultimate purpose of PECS is to produce a full and incremental update file that can be imported into the COTS drug database to make the customizations available to the run-time drug order checks. The custom update module encapsulates the functionality for generating update files for each concept.
- **Reports:** This module is responsible for generating on-demand or displaying various reports.
- **Easy Search:** This module allows users to interrogate the combined FDB and custom drug data through FDB's APIs.
- **Metadata:** PECS uses metadata and is heavily driven by configuration data that can be, to some extent, altered by users. The metadata module facilitates the use of this configuration data in queries, display, reports, and business rule validation. The metadata module describes each field of significance to the user. Each field has attributes that determine where it should be visible, whether it should be included in query results or reports, whether it's an internal field or one that is exported to the FDB database.

The architecture for PECS is defined as an n-tiered system consisting of the following logical layers:

- **Presentation Layer** – has user interface components
- **Service Layer** – has business logic components
- **Domain Layer** – has data and database interfacing components
- **Interface Layer** – has interface components to systems external to the PECS application

6.4.1 Presentation Tier

The Presentation tier is architected using MVC design pattern implemented with the Spring MVC framework. This pattern is composed of a Model, a View, and a Controller. The Model aspect is implemented with a domain model design implemented in the data persistence tier. The View aspect is implemented with the JSP technology, which integrates with the Spring framework.

6.4.2 Service Tier

The Service tier is implemented on top of Spring Framework. It provides a lightweight Inversion of Control (IoC) container and a number of modules that address all aspects of an enterprise application.

Services are implemented as Spring beans and are wired with the presentation tier through dependency injection. They take advantage of the declarative transaction management capabilities provided by Spring.

The service tier encapsulates the business logic related to creating and managing customization requests. The workflow rules are encapsulated by a state machine and data rules are enforced by combining a small number of validators.

Services manage the domain objects that represent the concepts being customized by the application. They are also responsible for converting between the persistent domain model and the Data Transfer Objects (DTO) used to communicate between the service and the presentation tier.

Services, customizable concepts, and their version history are modeled through hierarchies having at their root abstract classes that implement much of the common functionality.

6.4.3 Data Tier

The Data tier interfaces with two logical databases. One stores the third party drug data (FDB DIF) and the other one is used to persist the customization requests created through the application.

Access to the persistent store is abstracted through a set of Data Access Objects (DAO). They are responsible for interfacing with Hibernate, the Object-Relational persistence tool that maps Java classes to relational data structures.

6.4.4 Customization Module

The section below provides a detailed description of each Drug Concept software module.

Drug-Drug Interaction Professional Monograph Customization Module

Processing: below are representative class diagrams.

Presentation Layer

Professional Monograph Presentation Layer

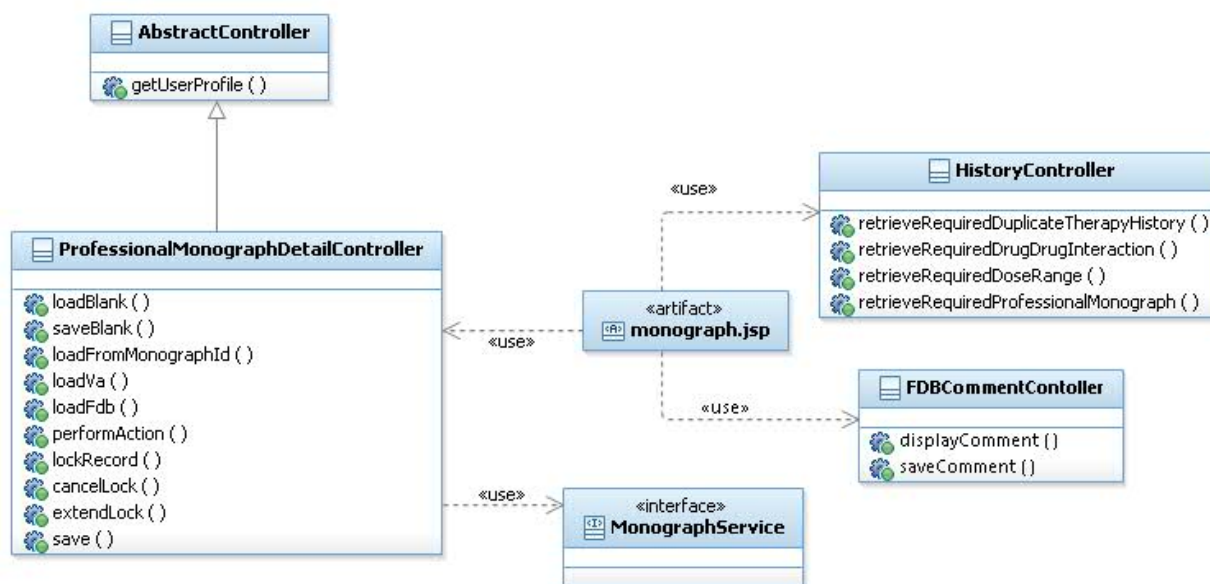


Figure 42: Professional Monograph Presentation Layer

The ProfessionalMonographDetailController allows a user to create a new custom Professional Monograph from a FDB Professional Monograph and provides the user the capability to create their own Professional Monograph using a blank form.

The ProfessionalMonographDetailController also allows a user to retrieve, create or update an existing Professional Monograph customization.

The ProfessionalMonographDetailController class utilizes the Professional Monograph Business Logic Hierarchy (defined below) to retrieve, create, or update Professional Monographs in PECS. All validation is accomplished using the Business Rules service.

Service Layer

Professional Monograph Business Logic Hierarchy

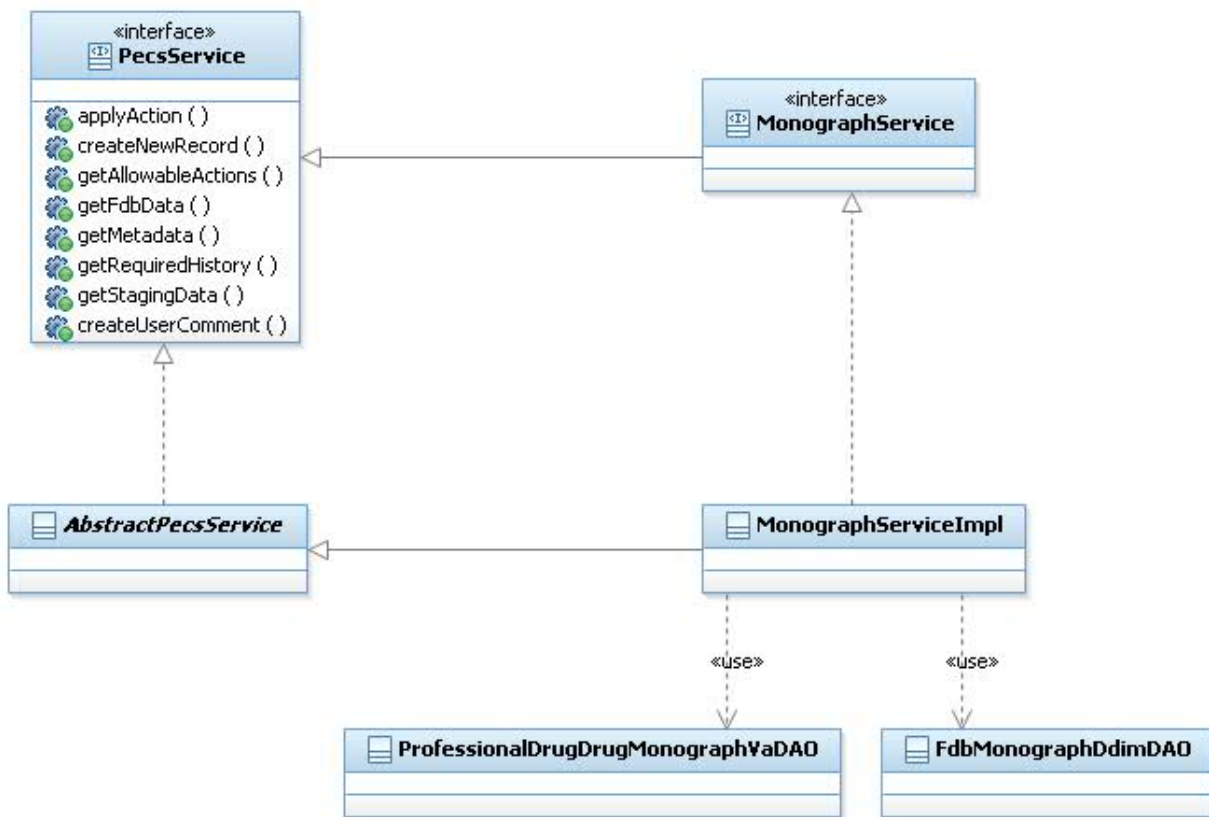
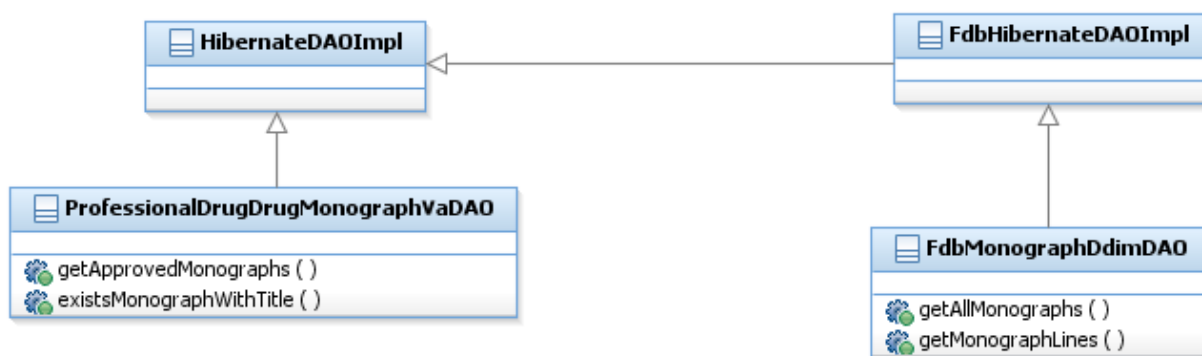


Figure 43: Professional Monograph Business Logic Hierarchy

Persistence Layer

In addition to the inherited functionality common to all concepts related to querying and processing customization requests, the monograph service also exposes a method for obtaining a list of all FDB and approved custom monographs.

Data Access



Domain

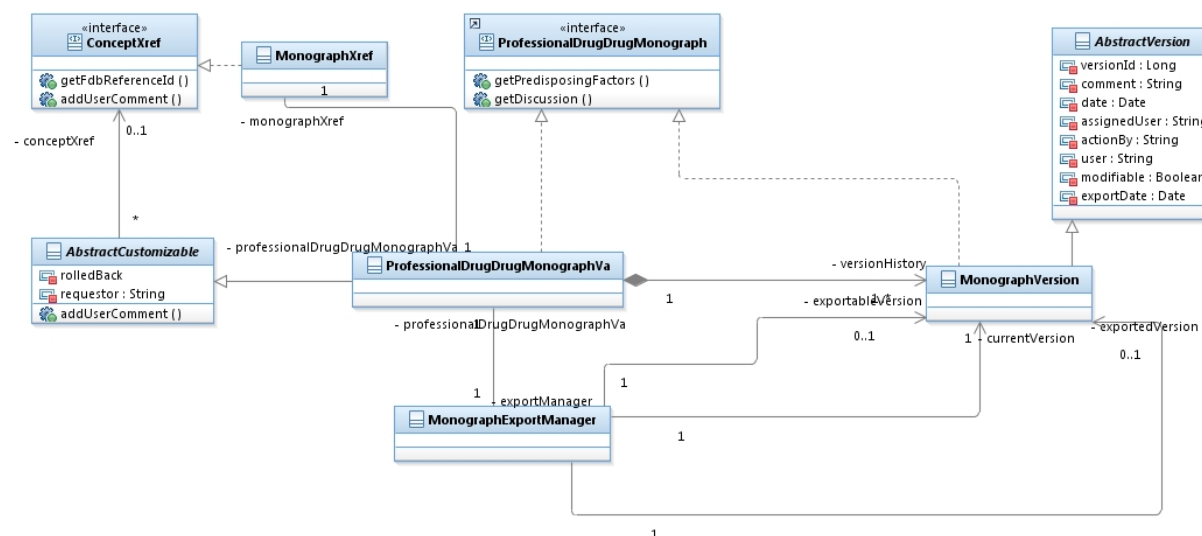


Figure 44: Drug-Drug Interaction Professional Monograph Domain Objects

Drug Pair Customization Module

Processing: below is a representative class diagram.

Presentation Layer

Within PECS, a Drug Pair can be viewed in one of two ways: view all Drug Pairs associated with a particular Drug-Drug Interaction, or view a single Drug Pair. The classes of the presentation layer that allow these two different views are depicted in the following diagram.

Drug Pair Presentation Layer Design Elements

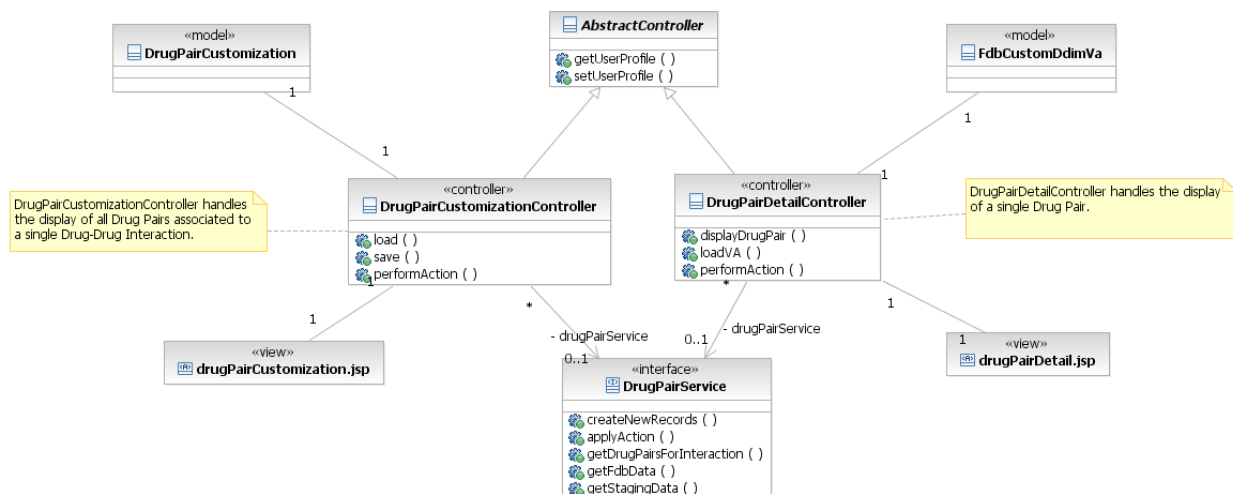


Figure 45: Drug Pair Presentation Layer

The **DrugPairCustomizationController** allows a user to operate on a batch of Drug Pairs associated with a single Drug-Drug Interaction at a time. This controller allows a user to create a new custom Drug Pair from a FDB Drug Pair, if the custom Drug-Drug Interaction is associated with a FDB Drug-Drug Interaction. The user also has the capability to create their own Drug Pair to associate with the Drug-Drug Interaction.

The **DrugPairDetailController** allows a user to retrieve, create or update a single Drug Pair that is associated to a Drug-Drug Interaction.

Both the **DrugPairCustomizationController** and **DrugPairDetailController** classes utilize the Drug Pair Business Logic Hierarchy (defined below) to retrieve, create, or update Drug Pairs in PECS.

There is no special validation logic for a Drug Pair coded in the Presentation Layer. All validation is accomplished using the Business Rules service defined later on.

Service Layer

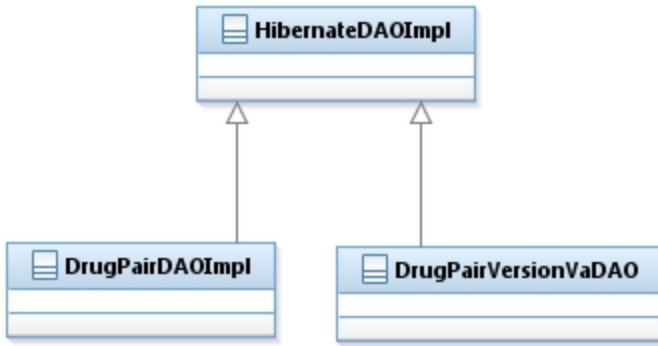
The drug pair service needs to provide functionality for processing sets of drug pairs (creating, applying actions). It also provides various ways to look up drug pairs, as well as functionality for obtaining all routed generic drugs present in the drug database.



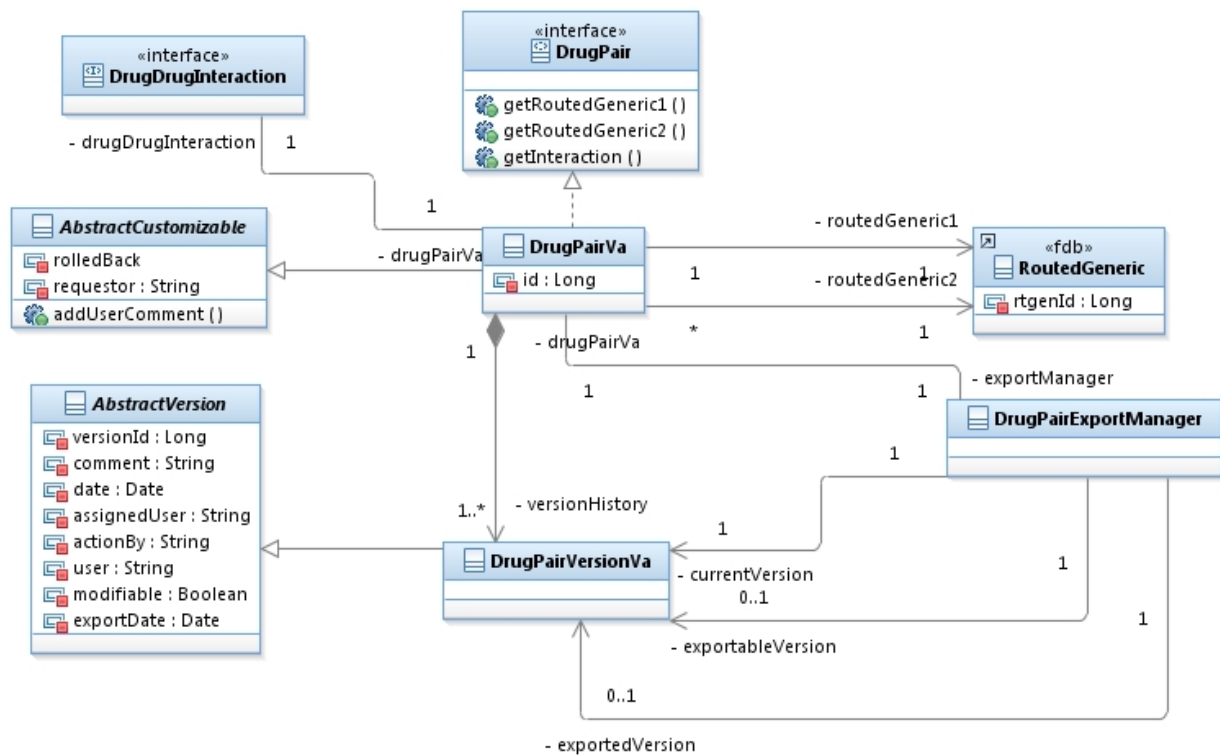
Figure 46: Drug Pairs Business Logic Hierarchy

Persistence Layer

Data Access



Domain



Duplicate Therapy Customization Module

Presentation Layer

The **DuplicateTherapyController** class allows the user to view a Duplicate Therapy Order Check. This class also allows the user to create and make state changes on Duplicate Therapy Objects. The **DoseRangeCustomztnController** inherits from the **AbstractController** class.

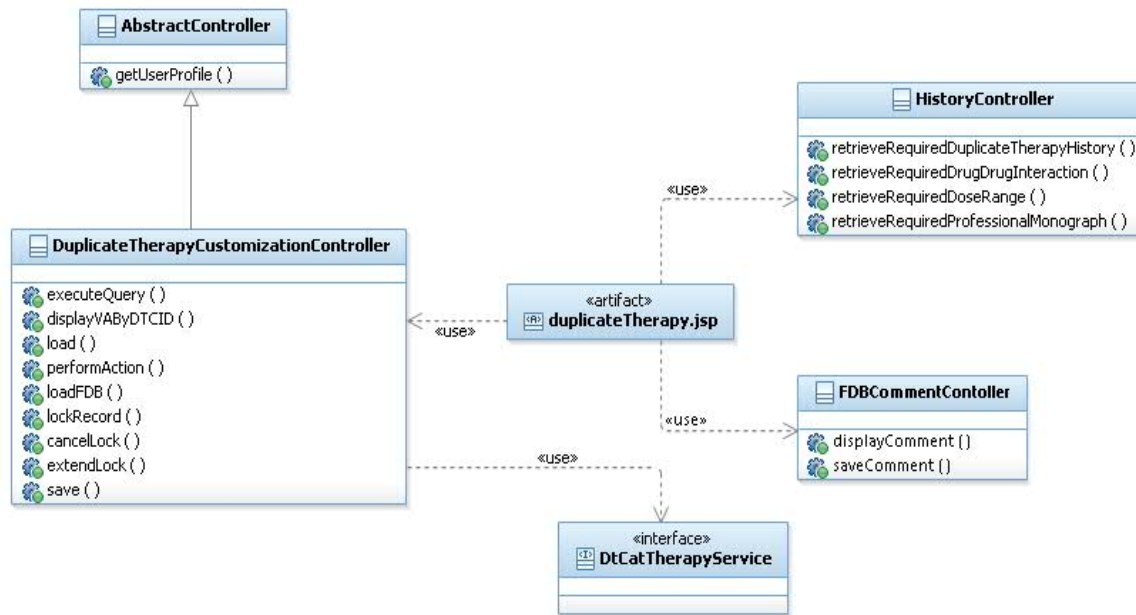


Figure 47: Duplicate Therapy Presentation

Service Layer

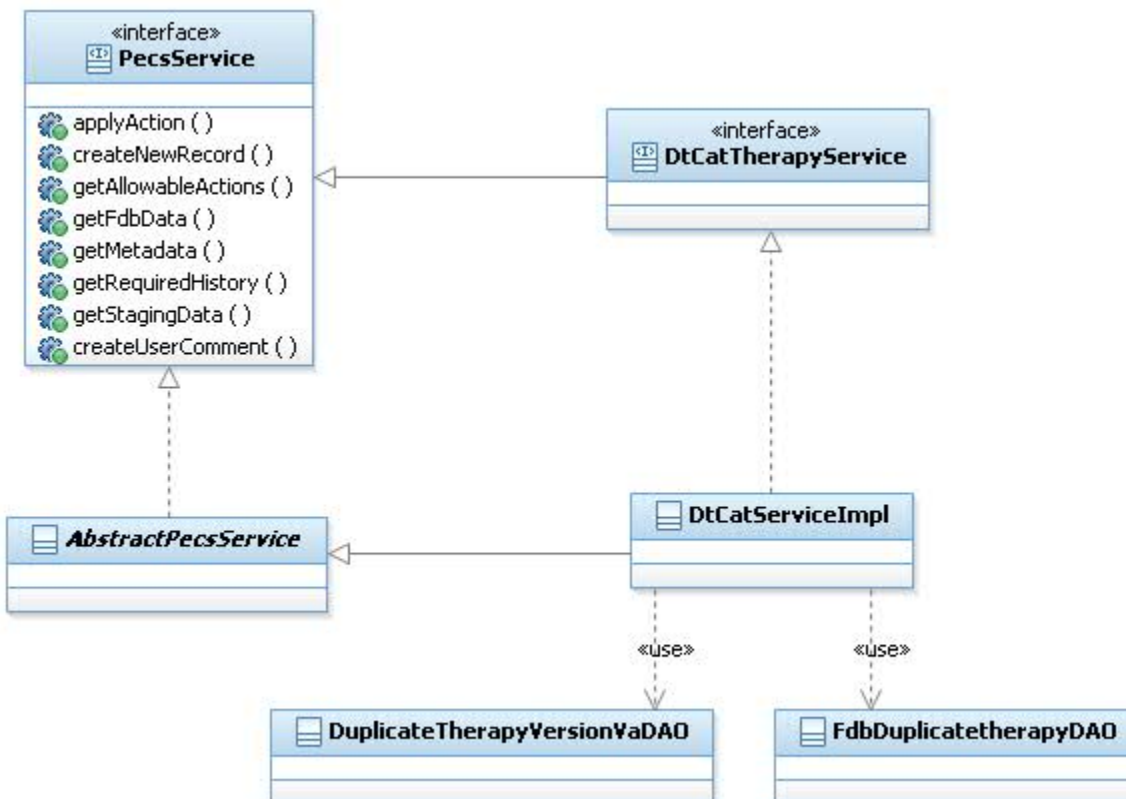
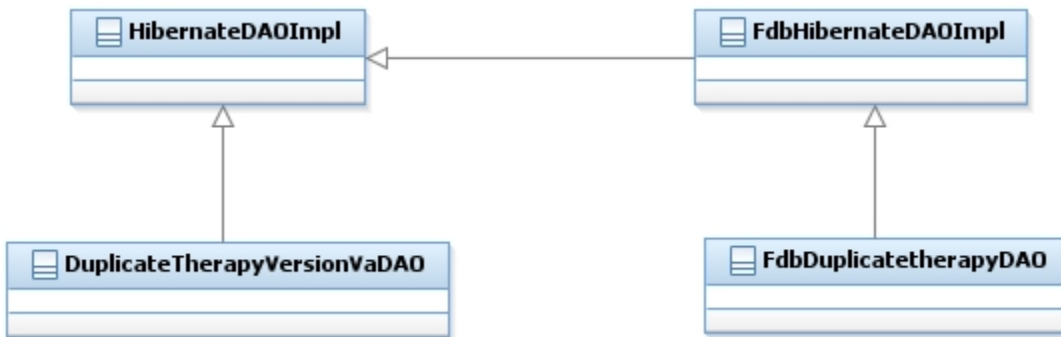


Figure 48: Duplicate Therapy Business Logic Hierarchy

Persistence Layer

Data Access



Domain

The Duplicate Therapy Interaction Domain objects are used internally by PECS to represent a Dose Range Custom Concept.

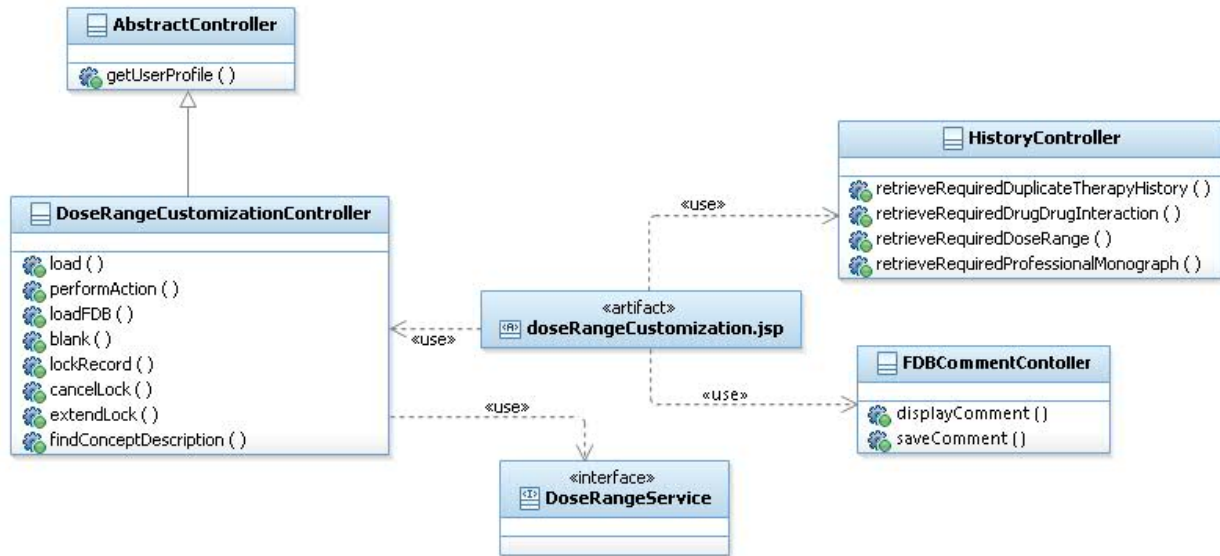


Figure 50: Dose Range Presentation Layer Hierarchy

Service Layer

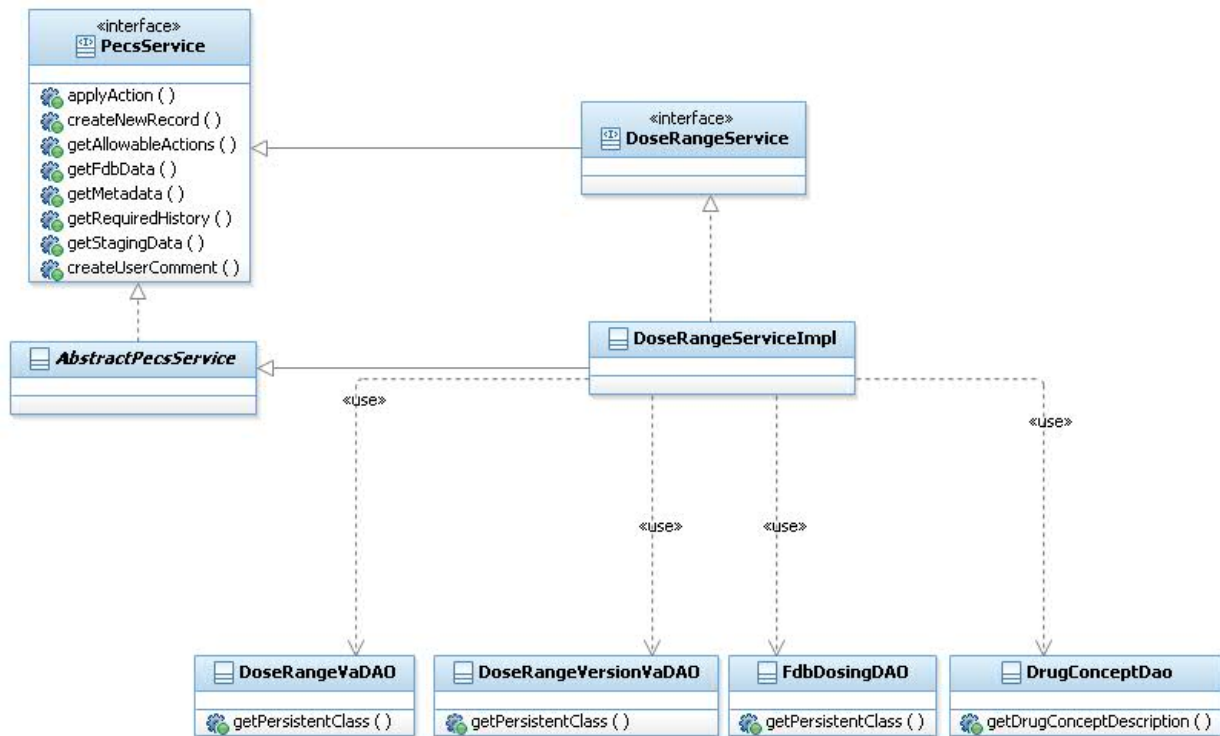
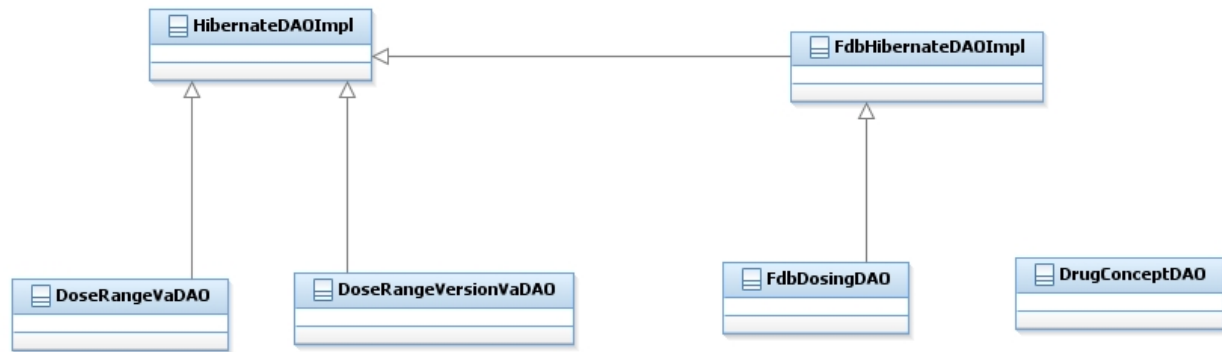


Figure 51: Dose Range Business Logic Hierarchy

Persistence Layer

Data Access



Domain

The Dose Range Domain objects are used internally by PECS to represent a Dose Range Custom Concept. New attributes for the PECS 2.2 release are: **MaxSingleNTEDose**, **MaxSingleNTEDoseUnit**, **MaxSingleNTEDoseForm**, and **MaxSingleNTEDoseFormUnit**. FDB Dose Range does support another attribute, **AgeSourceCode**, but PBM has decided they do not need to support this attribute.

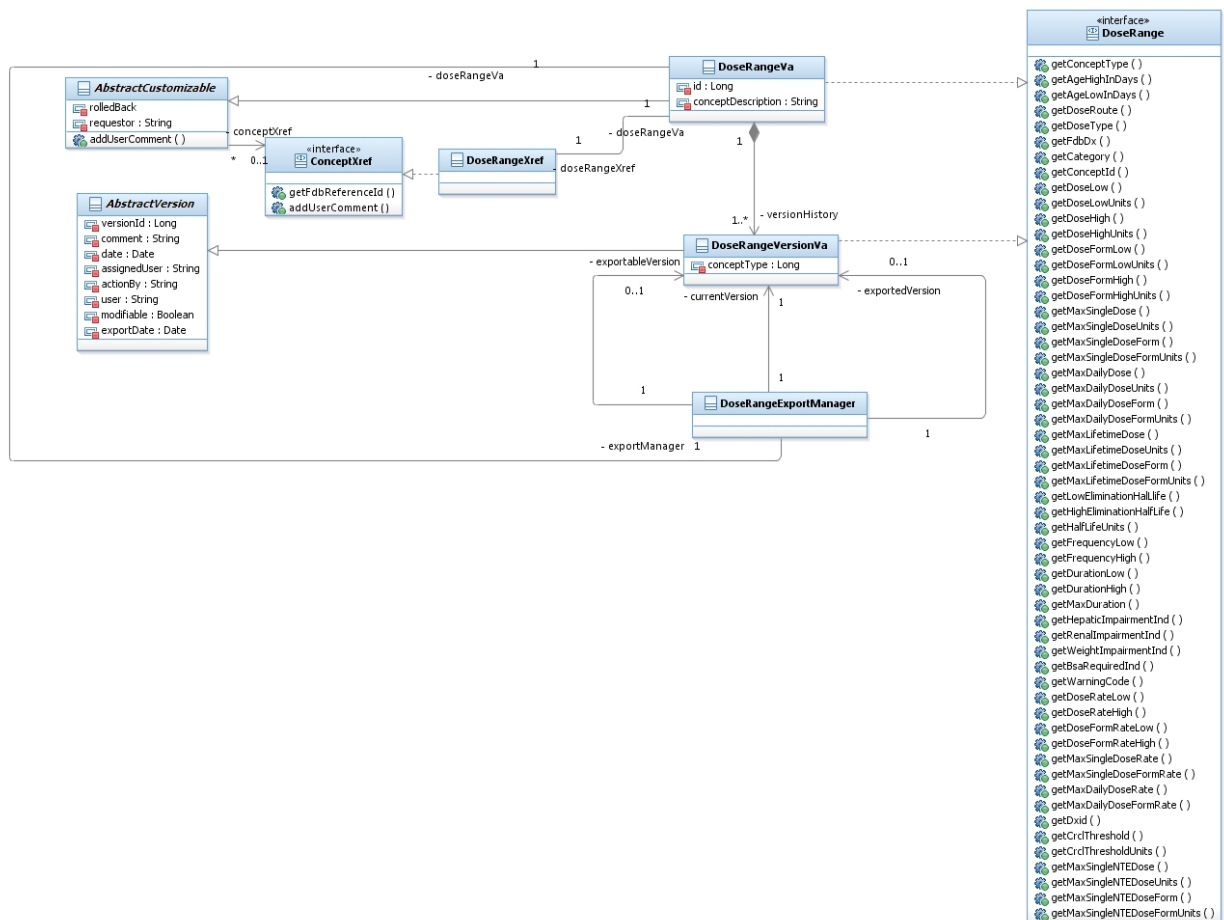


Figure 52: Dose Range Interaction Domain

Drug-Drug Interaction Customization Module

Processing:

Below is a representative class diagram.

Presentation Layer

The InteractionController class allows the user to view a Drug-Drug Interaction. This class also allows the user to create and make state changes on Drug-Drug Interactions. The InteractionController inherits from the AbstractController which supplies methods to retrieve the UserProfile object.

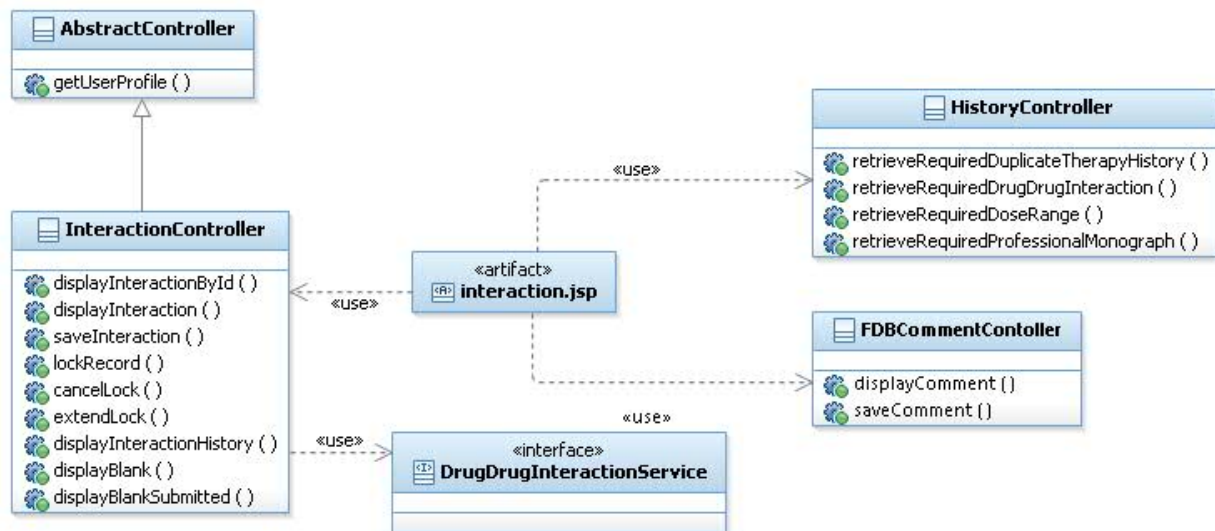


Figure 53: Drug-Drug Interaction Presentation Layer Hierarchy

Service Layer

The Drug-Drug Interaction Business Logic contains the implementation of the business rules that applies to a Drug-Drug Interaction. This layer also controls the access to the data layer which controls the retrieval and persisting of data.

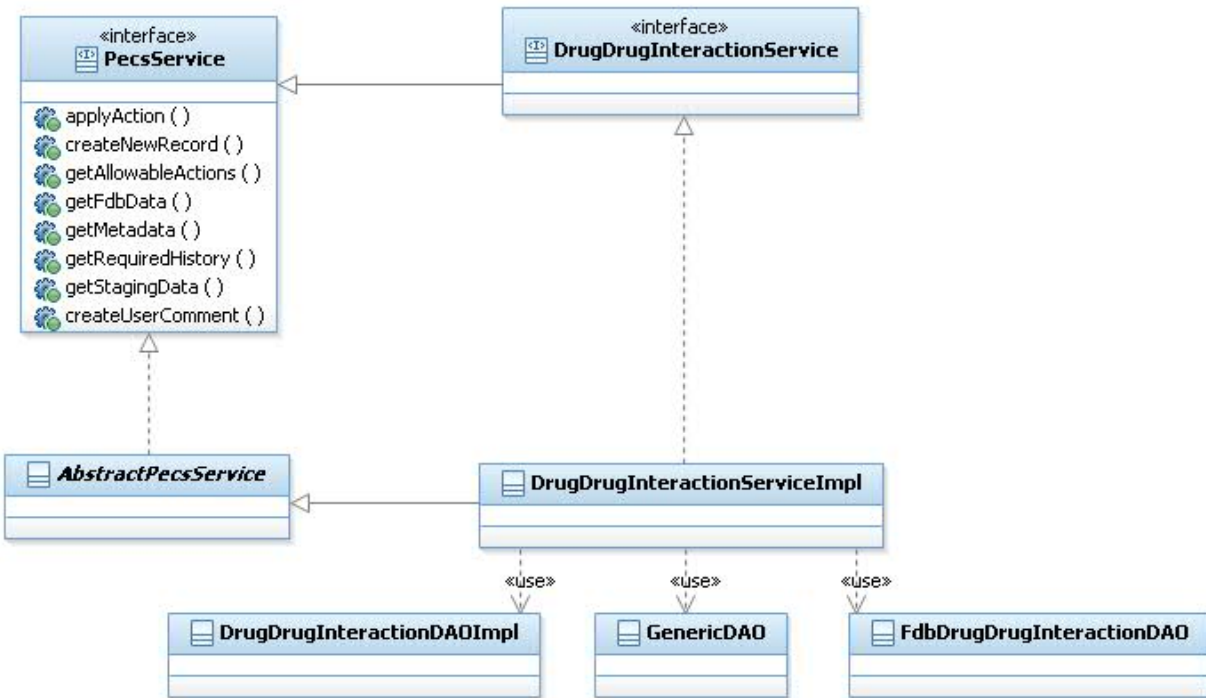
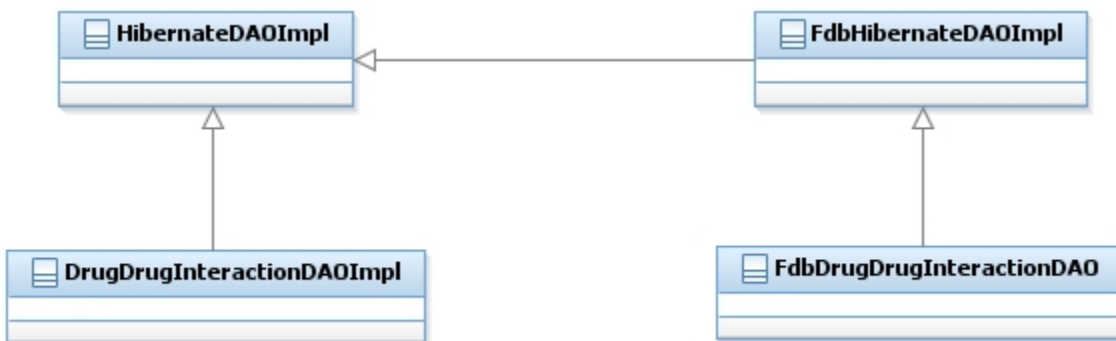


Figure 54: Drug-Drug Interaction Business Logic Hierarchy

Persistence Layer

Data Access



Domain

The Drug-Drug Interaction Domain objects are used internally by PECS to represent a Drug-Drug Interaction Custom Concept.

Drug-Drug Interaction Domain classes

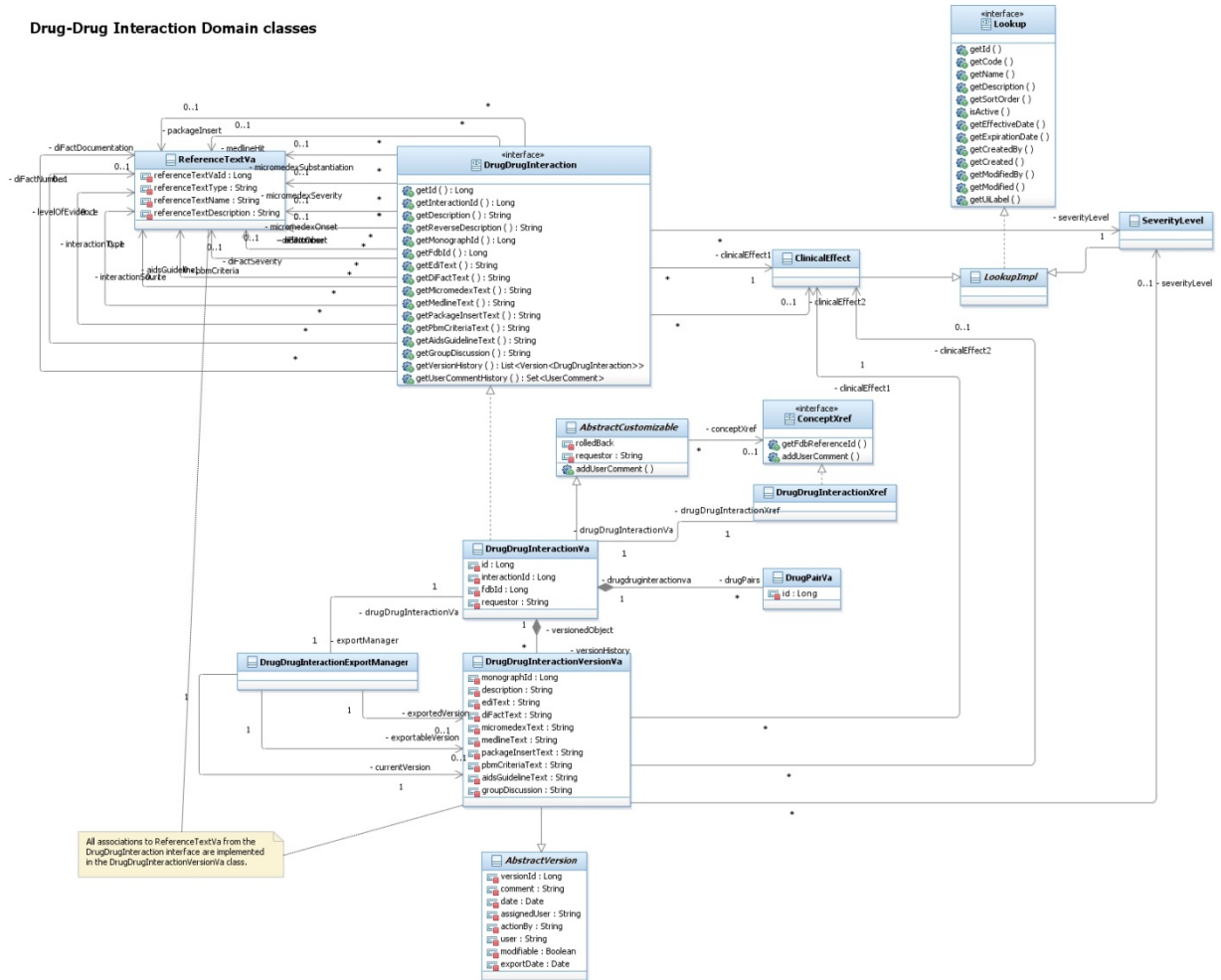


Figure 55: Drug-Drug Interaction Domain

6.4.5 Record Locking

Starting in PECS version 2.2, the functionality to lock a customization from being edited by two different users at the same time was added. When the current version of a customization is read by a user, it is presented to the user in a “read-only” mode. In order to modify any information, the user has to click the presented Edit button, which will do multiple things:

1. Check to see if the customization is locked by another user. If it is not, the customization is then locked.
2. The customization is opened for modification by the user.

To accomplish this, classes were added to keep track of what user has what customization locked.

The Record Locking is set to automatically expire in 15 minutes. If the user is still logged in and working on the customization, they are presented with a message box asking if they would like to keep the record locked.

Since there are so few classes involved in the Record Locking architecture, the domain and control layers are presented in the same diagram. There is no presentation layer dealing specifically with record locking.

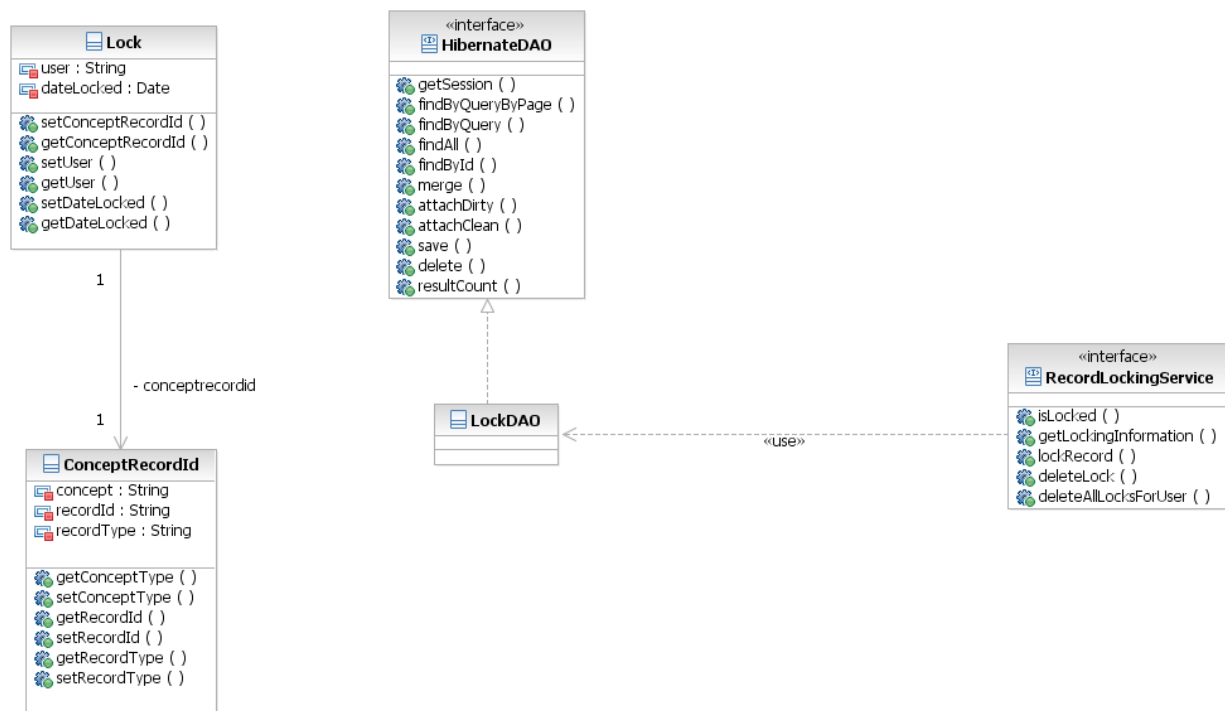


Figure 56: Record Locking

6.4.6 FDB Comparison Reports

Also starting with PECS version 2.2, the ability to compare incoming FDB update data against existing customizations was needed. This ability allows the users to determine if any changes to the currently customized data needs to be made.

FDB Comparison Report Domain

The FDB Comparison Report Domain was designed with the following into account:

- Reports for only 4 of the 5 customizable concepts have been request: Duplicate Therapy, Dose Range, Drug-Drug Interaction and Drug Pairs. The Drug-Drug Interaction and Drug Pairs should be shown on the same report.
- The last 8 weeks of reports should be kept in the database.

Comparison Reports Domain Objects

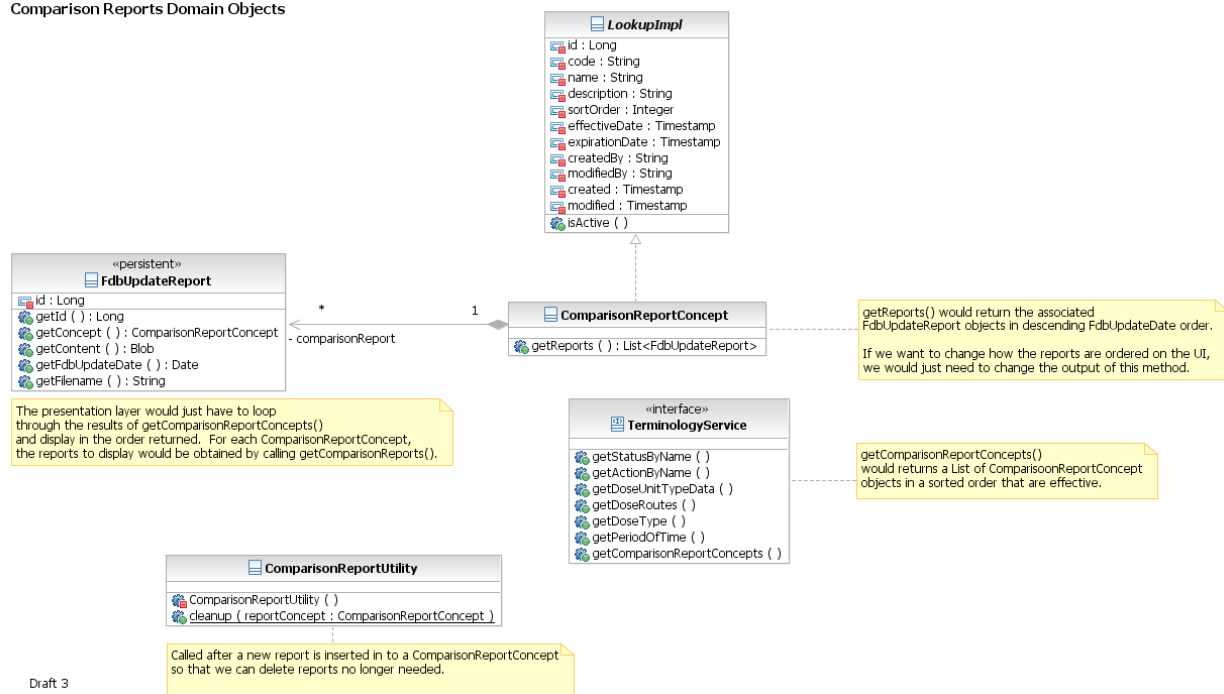


Figure 57: FDB Comparison Reports

FDB Comparison Reports Presentation Layer

The FDB Comparison Reports were added to the existing Reports page in PECS.

FDB Comparison Reports Business Logic Layer

The FDB Comparison Reports process is a scheduled process that is configured via a properties file in the file system. The properties file contains at what time the process should start, the FTP server to access for the FDP update files, the user to log in to the FTP server and the directories where the files will reside.

When examining the FTP update files on the FTP server, the process will check to make sure the FDB previous issue date from the update file matches the FDB Issue Date currently in the database. This check makes sure the FDB data is in a known state before generating reports against that data.

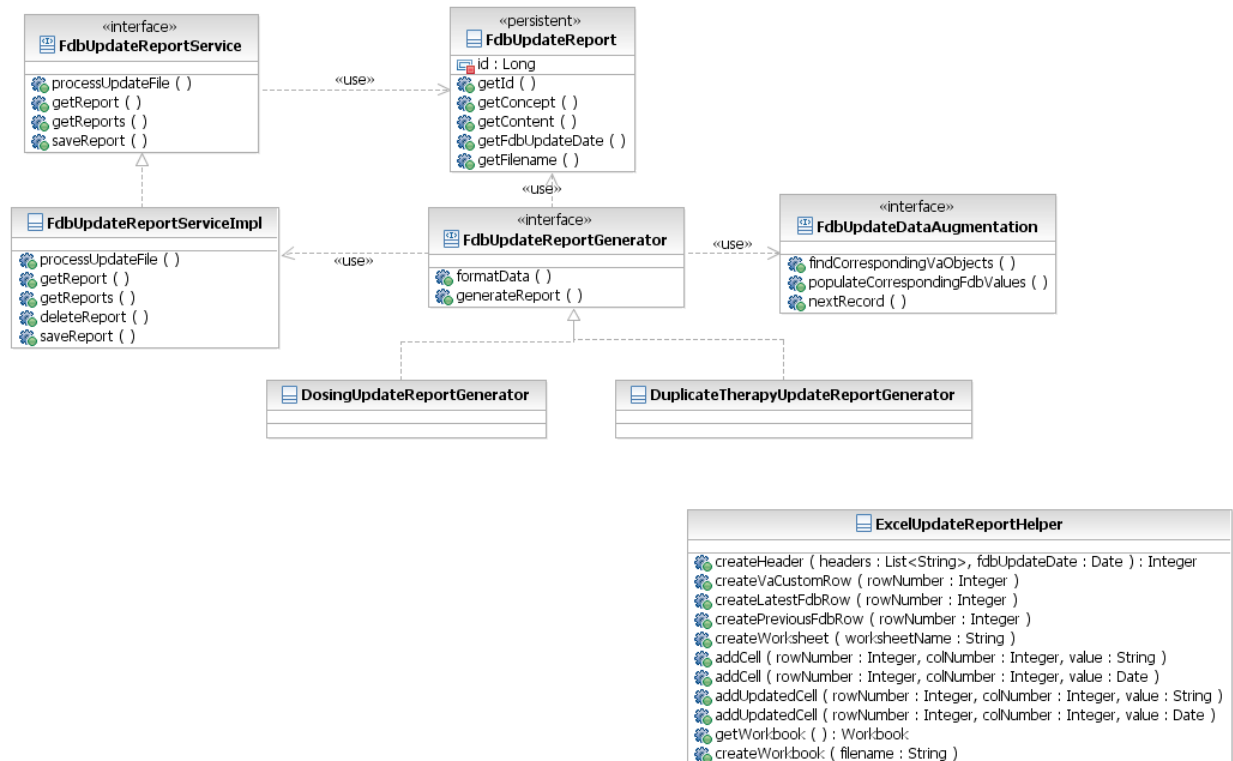


Figure 58: FDB Comparison Reports Business Layer Logic

6.4.7 Easy Search

Presentation Tier

Easy Search Action Controller Hierarchy

The presentation tier for Easy Search consists of two Spring controllers:

- **DrugSearchController** handles AJAX calls from the web interface (e.g. searching for drugs by names, finding appropriate dose routes and types etc.)
- **EasySearchController** handles form submissions (e.g. checking drug-drug interactions, duplicate therapy or dosing)
- Both controllers use the Easy Search service to perform business logic.

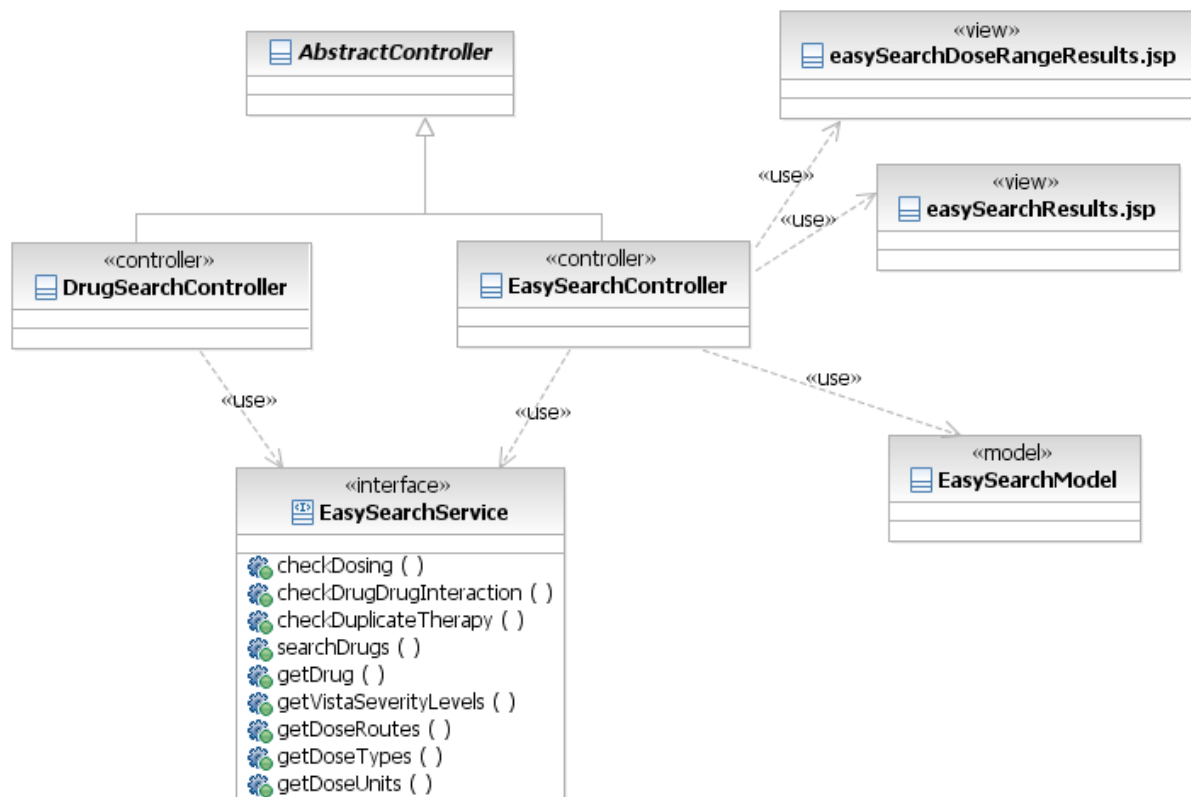


Figure 59: Easy Search Controller Hierarchy

6.4.7.1 Business Logic Tier

Easy Search Business Logic Hierarchy

The Easy Search implementation delegates the data access and clinical screening logic to the FDB-DIF API. In some cases, like drug searches, the API is invoked directly, while for clinical screening, the MOCHA libraries are used. The diagram below depicts this dependency.

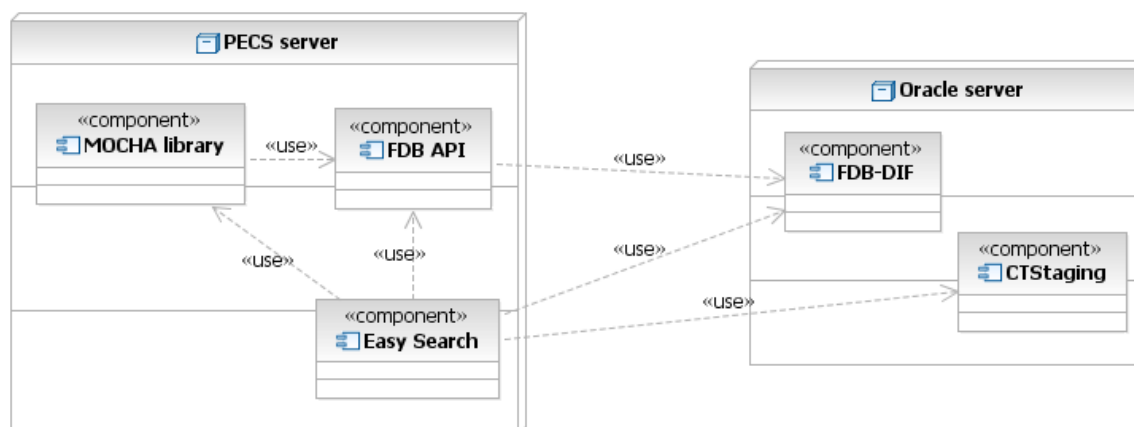


Figure 60: Easy Search Components Dependency

The diagram below shows the relationships between Easy Search Service and collaborating classes from PECS, MOCHA, and FDB.

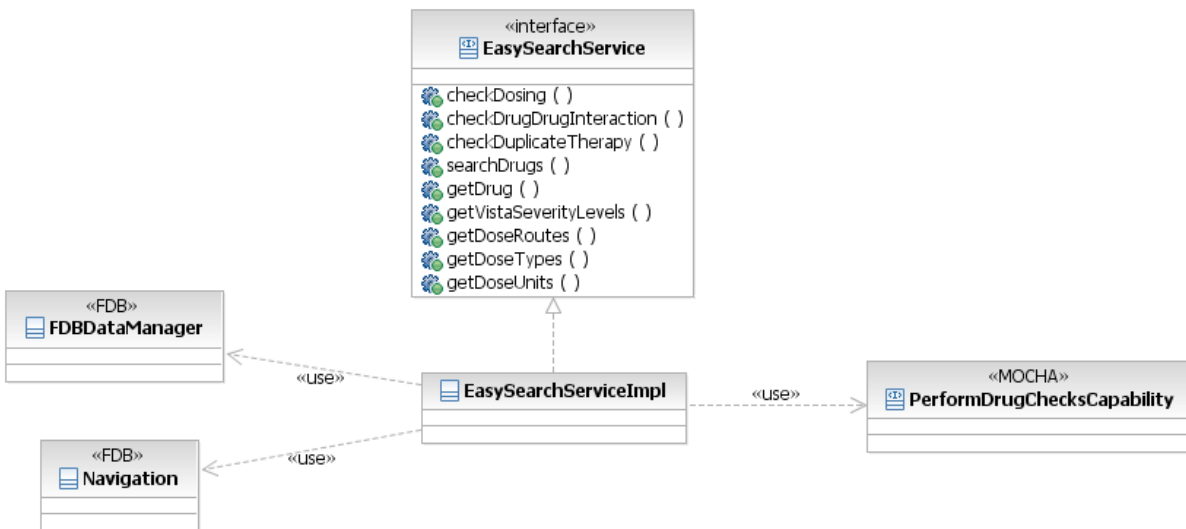


Figure 61: Easy Search Business Logic Hierarchy

Easy Search Domain

The Easy Search implementation delegates functionality to the FDB-DIF API, either directly or indirectly, through the MOCHA API. It only defines Data Transfer Objects used to exchange information with the presentation tier, not domain classes.

6.4.8 Metadata

The metadata module describes each field of significance to the user. Each field has attributes that determine where it should be visible, whether it should be included in query results or reports, whether it's an internal field or one that is exported to the FDB database.

Processing:

One of the uses of the metadata is in defining the validation rules specified by the requirements documentation. These rules consist of an assertion that must be true (validation), for example a certain field should not be null, and a condition that must be met (trigger) for the assertion to be checked, for example when a certain action is performed. These rules are built with a small set of classes that work across all concepts, because they are defined using metadata (for example, one can check whether only internal fields have been modified).

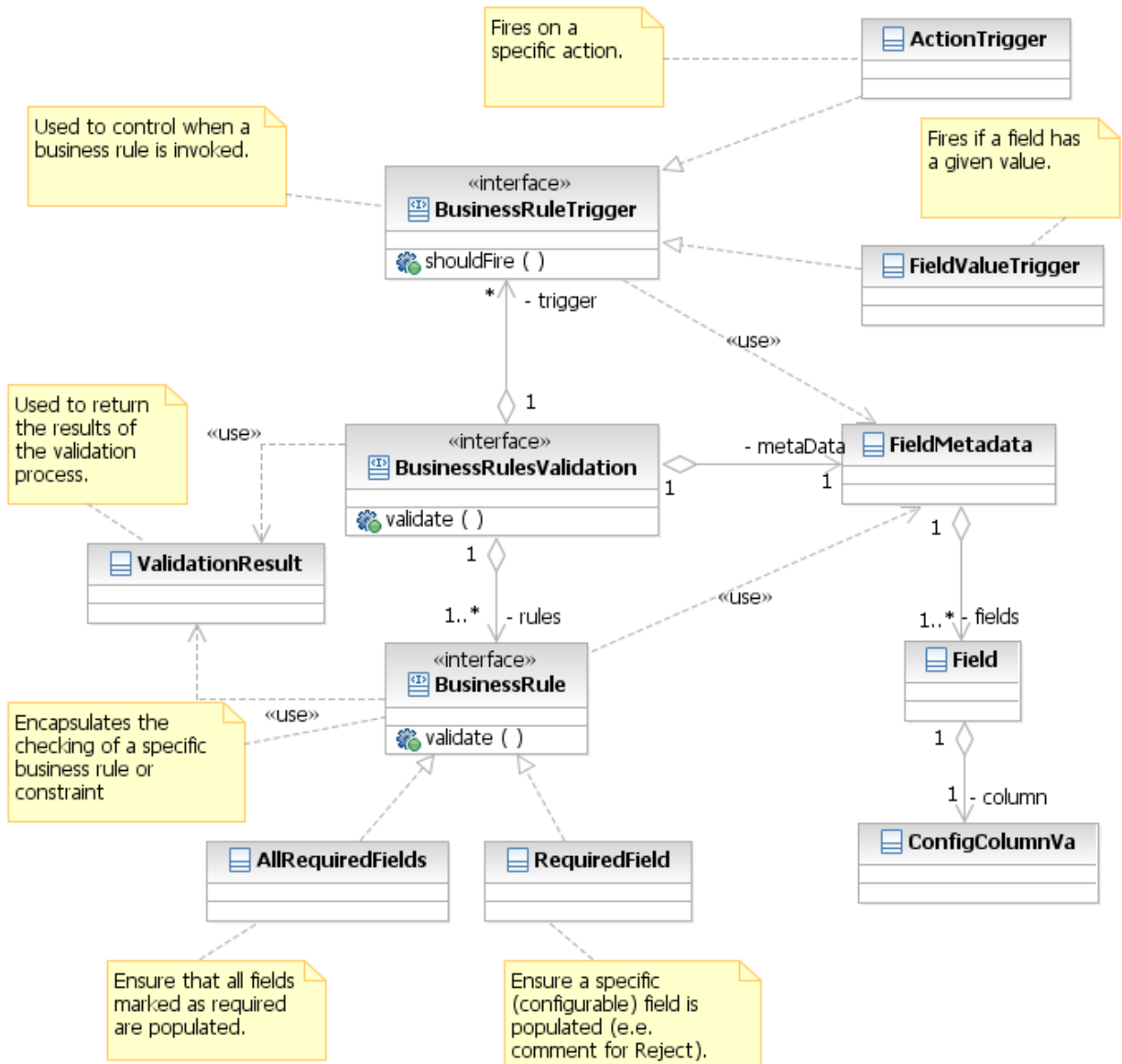


Figure 62: Metadata Processing

6.4.9 User Messages

PECS defines three different types of messages that can be displayed to the user. These message types are: Errors, Warning, and Informational.

The handling of Errors within PECS is through the Spring Validation support and through custom code since some validation is changeable by the users from within PECS. The Spring Validation support is built upon the JSR-303 Bean Validation API. Through the use of Validation annotations, data is validated and any errors are returned through Spring's BindingResult object.

Warning messages are handled through custom classes and interfaces defined in the following class diagram.

Warning Messages Implementation Classes

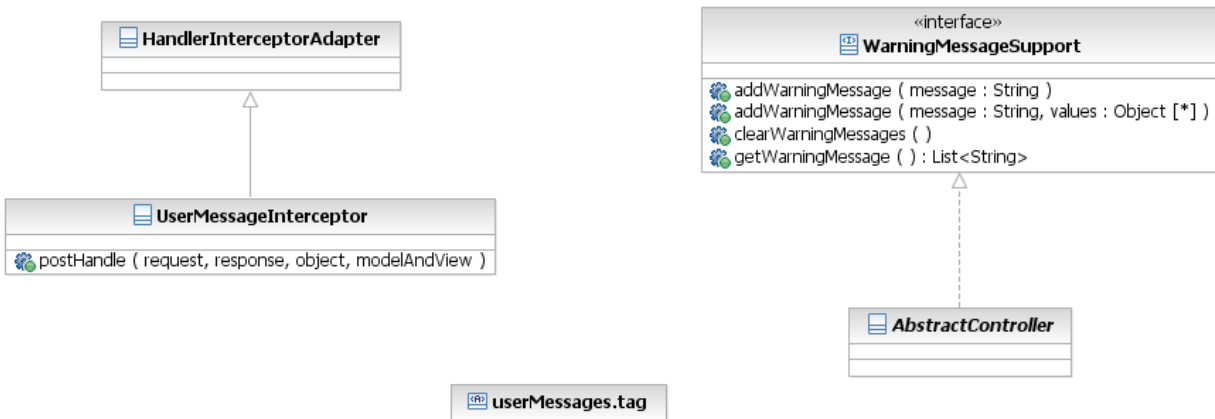


Figure 63: Warning Message Implementation

Warning messages can be set up for display to the user by any Controller that extends the **AbstractController** class. These messages are added to the view returned by the Controller using the **UserMessageInterceptor** class. Once a warning message is added to a view, the warning message is then deleted from the Controller.

Informational messages are handled using the same pattern as Warning Messages. The following diagram shows the classes and interfaces that are used to support the Informational Messages.

Information Messages Implementation Classes

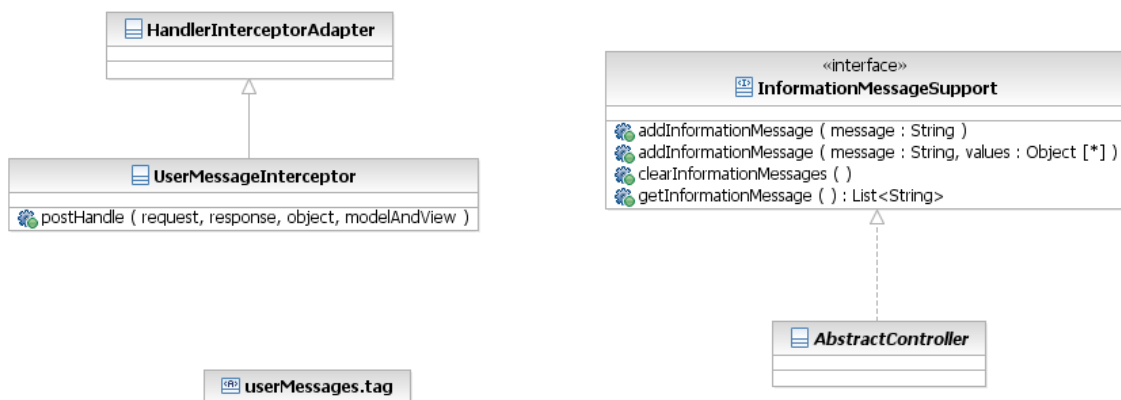


Figure 64: Information Message Implementation

The handling of Informational Messages is the same as the handling of Warning Messages.

The user interface code for displaying these messages is encapsulated in the **userMessages.tag** file. The UI code is set up to display any Error, Warning, or Informational Messages. A developer has the ability to

configure the displaying of All, Global, or Field error messages. The default is to display only Global errors, as field errors should be displayed next to the actual field.

6.4.10 History of Changes Report

The History of Changes functionality in PECS has been designed based on the Model-View-Controller (MVC) pattern. The controller for each concept will be updated to: call the concept service to collect the data that should be included on the report, build the model that will hold the data that the viewer needs and pass the processing off to a generic viewer that will build the report that will be downloaded to the user. The sequence diagram that lists the events that happen is below.

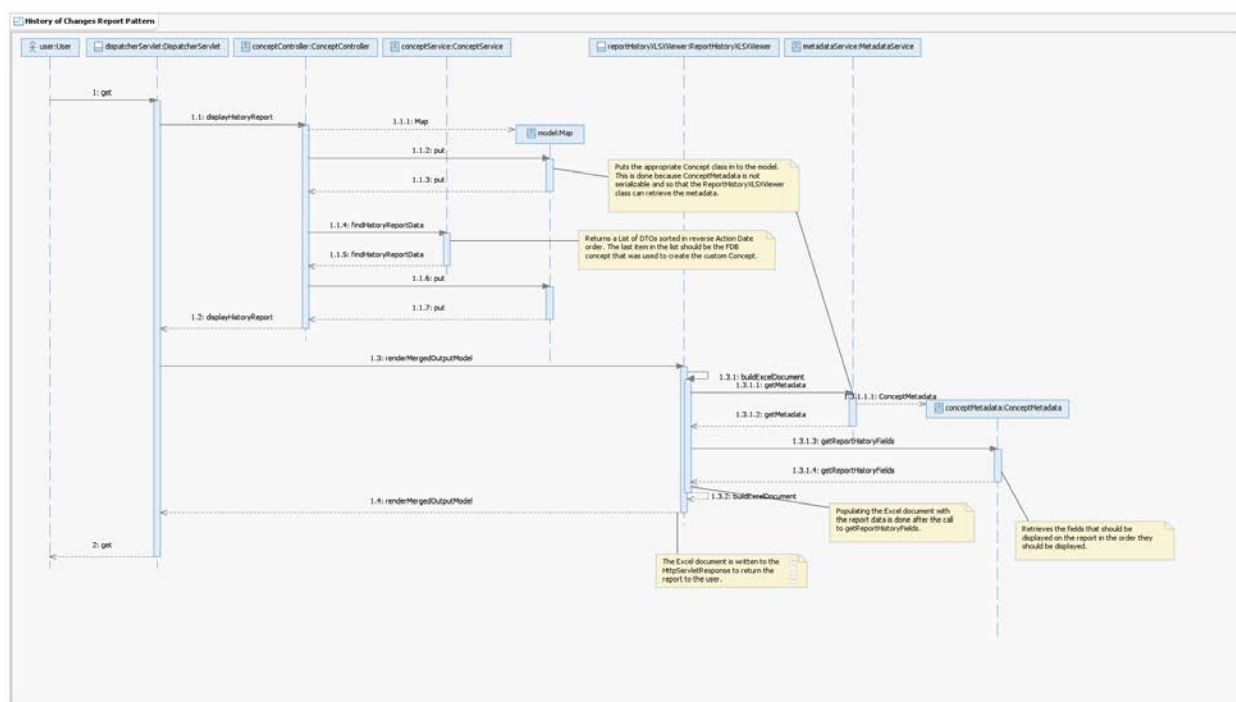


Figure 65: History of Changes Report Sequence Diagram

FDB User Comments

Since PECS 6.0 the FDB user Comments functionality for the PECS application been designed based on the Model-View-Controller (MVC) pattern. Functionality will allow PECS users to add a comments to a non-customized FDB record.

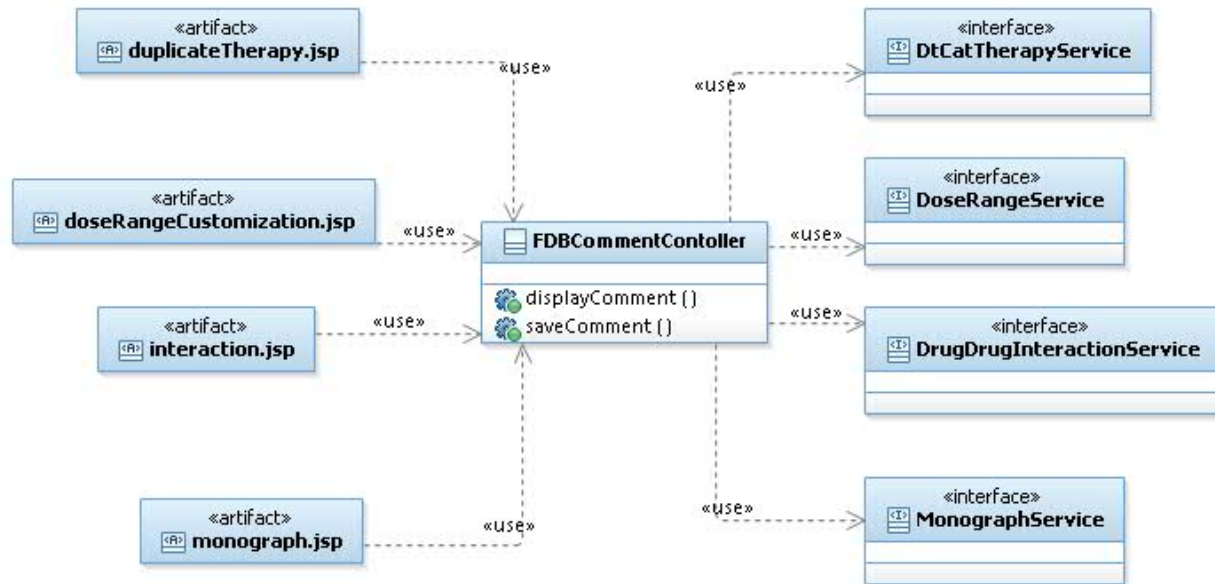


Figure 43: FDB User Comment diagram

6.5 Communications Detailed Design

The PECS system Communication design at the ITC Production environment is described in Section 4.3. The Local VAMCs and ITC facilities have pre-existing functional LANs, and servers installed. No additional hardware components are needed to make the PECS system functional.

7 External Interface Design

The external interface design describes the interfaces between pre-existing systems and the system being developed. The PECS application needs to externally interface with the legacy systems VistA-National and VistA Local (for authentication and authorization services). It will also interface with the DATUP application. The external interfaces are further described in the following sections and in the PECS Interface Control Document (ICD).

7.1 Interface Architecture

PECS interfaces with Local VistA sites in the authentication and authorization process, using KAAJEE.

PECS also interfaces with DATUP to send the custom update file that contains customizations performed in PECS. The following is a high level view of the process. The figure below illustrates the logical system components for the National and Local environments. The National components are responsible for verifying and publishing FDB-DIF and FDB-Custom updates to the Anonymous FTP Server. The Local components then consume and apply the verified updates in an automated manner.

1. DATUP – Implements the FDB-DIF update business logic.
2. Scheduler – Background process for scheduling DATUP.
3. WebLogic – Application server environment for DATUP and PECS.
4. Configuration Files – Define the configuration settings for PECS and DATUP.
5. Email Templates – Template emails for notifications sent to National/Local Managers.
6. Anonymous FTP Server – FTP Server that hosts the FDB-DIF update archives.
7. Email Server – Email relay server.
8. PECS – Implements the FDB-Custom drug business logic.
9. CT Staging Database – Stores PECS FDB-Custom modifications.
10. DATUP Database – Stores DATUP site update history.
11. FDB-DIF Database – Stores the FDB-DIF drug database.
12. Legacy VistA – Existing VistA Server for Security Interface.

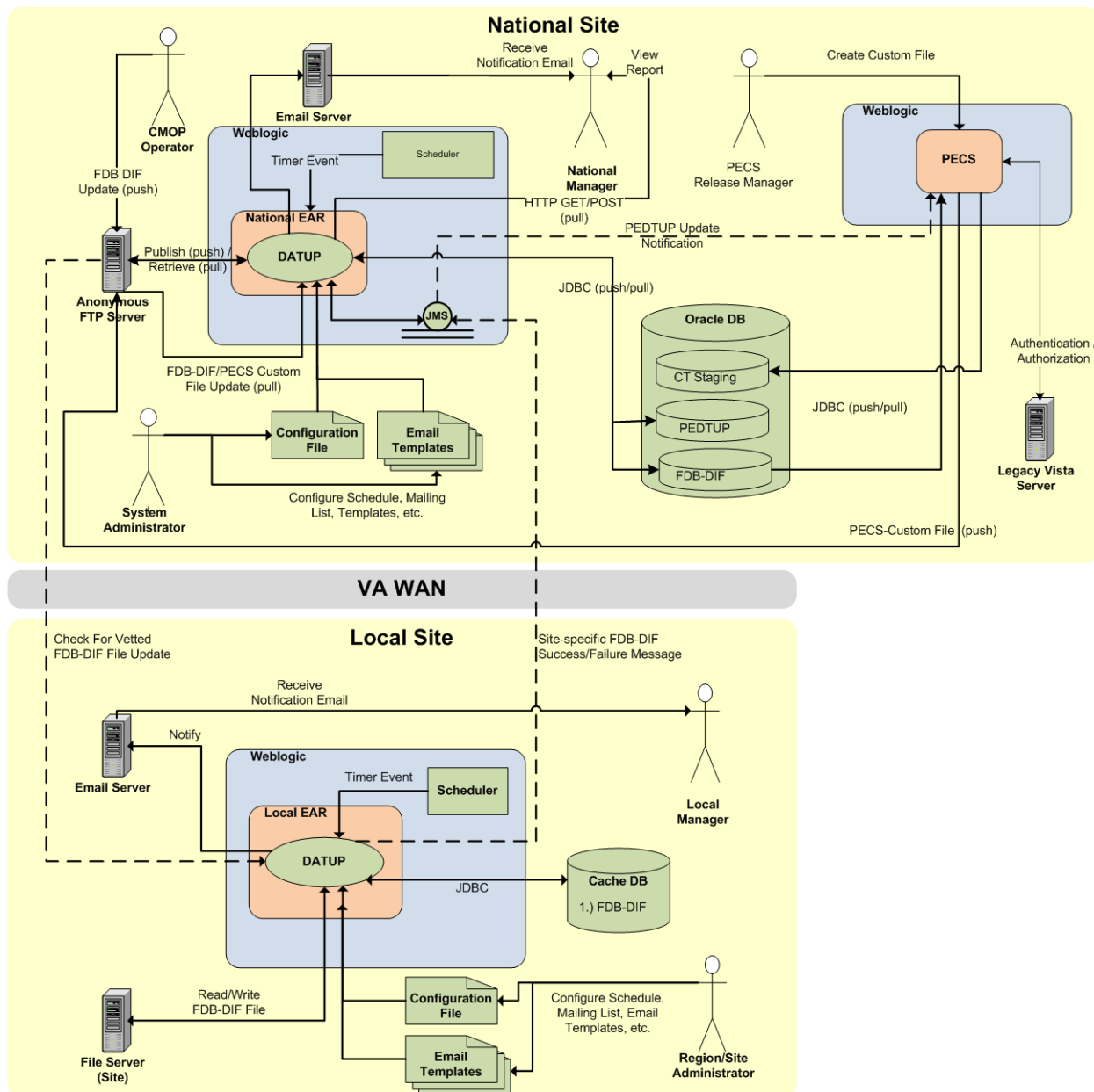


Figure 66: Combined DATUP/PECS Interface Architecture Diagram

7.2 Interface Detailed Design

DATUP is using the FDB Updater APIs to process the update file. As such, the file follows the structure defined by FDB.

7.2.1 Overview

The FDB Updater application is designed to read a control file and one or more update files from the same user-specified directory or zip file, and to apply the transactions from the update files to the customer database. Each update file must contain data for only one table in the database. If it is desired, the transactions for a table can be divided into multiple update files (e.g., for data bundling of the

product); however, transactions in one update file must not be dependent on the existence or order of execution of transactions in another update file.

There are two types of files required, typically bundled in a zip archive: a control file (named `fdbupdcontrol.dat`) and one or more update files, containing the actual data to be loaded (having a `.upd` extension).

7.2.2 Control File

The control file contains data that the application will use to verify that a matching set of update files is being applied to the customer database, and that the version of the customer database is the one to which the set of update files should be applied. It also contains transactions to update the version table in the customer database. The control file must be named `fdbupdcontrol.dat`.

Records in the control file must appear in the following sequence:

- 1 Version Control Record (record type V)
- 1 Field Definition Record (record type F)
- 1 Primary Key Definition Record (record type P)
- 1 Beginning Version Change Record (record type B)
- 1 Ending Version Change Record (record type E)

The Version Control Record specifies the name of the version table, and a list of field names, descriptions, and values for fields that determine if the state of the customer database is correct for the application of the set of update files. The application retrieves the values for the specified fields from the database and compares them to the values given in the Version Control Record. If any of the values do not match, an error message using the field description from the Version Control Record is displayed, and the update execution will be aborted. The field description should be worded so that it fits in this sentence: “Version control field: <control file field description> - value (<control file field value>) does not match value in database table (<database field value>).” The values should be in “raw” form – strings should not be enclosed in quotes, and embedded quotes should not be converted to two quotes.

The Field Definition Record defines all of the fields for the version table, assigning an integer Field ID to each field. The fields should appear in sequential Field ID order. Fields will be referenced by Field ID on the other records in the file.

The Primary Key Definition Record identifies which fields (if any) compose the primary key of the version table. The Field IDs defined on the Field Definition Record are referenced to indicate which fields are part of the primary key. The Field IDs should appear in the order the fields appear in the primary key. If there is no primary key for the table, the Primary Key Field Count should be 0 and no Field IDs should be listed. In such a case, the application will generate UPDATE statements for the version table that do not have a WHERE clause. Therefore, processing without a primary key may not yield the desired results if the table has more than one row.

The Beginning Version Change Record will generate an UPDATE statement for the version table that will be executed before any other tables are processed. This record makes it possible to place the version table in a state that indicates that the incremental update is in progress. If the incremental update does not complete successfully, the application would then be able to recognize that a database recovery is needed before another attempt can be made to apply the update files. The Primary Key Field Values should correspond to the sequence of the primary key fields in the Primary Key Definition Record. The Modified Field IDs and Values should appear following the Primary Key Values. The Primary Key Field Values and the Modified Field Values should be formatted so that they can be concatenated into the WHERE and SET clauses of an UPDATE statement with no further modification. Values for string fields must be enclosed in single quotes, and any embedded single quotes must be converted to two single quotes. To set

a field to null, the value should be a zero-length string with no quotes. It is recommended that the Modified Fields should include one or more of the validation fields specified on the Version Control Record.

The Ending Version Change Record will generate an UPDATE statement for the version table that will be executed after all other tables are processed. This record should place the version table in its final state, indicating that the incremental update was completed successfully. Other than the Record Type, the record is formatted in the same manner as the Beginning Version Change Record.

7.2.3 Update Files

The update files contain transactions that will be used to update the customer database so that it matches the current version of the product database. Each update file will contain transactions for only one table; however, a table can be updated from multiple files. There is no limit in the application to the number of update files in total, or for an individual table. The files may have any name as long as the file extension is upd (e.g., fdbdrugname.upd).

Records in an update file must appear in the following sequence:

- 1 Header Record (record type H)
- 0 or 1 Field Definition Records (record type F)
- 0 or 1 Primary Key Definition Records (record type P)
- 0 or more Add (record type A), Change (record type C), and Delete (record type D) Records

The Header Record specifies the name of the table, the number of add/change/delete transactions in the file, and a list of Version Field Values that determine if the state of the customer database is correct for the application of this update file. The Version Field Values should match those found in the Version Control Record from the control file. If any of the values do not match, an error message using the field description from the Version Control Record will be displayed, and the update execution will be aborted. The values should be in “raw” form – strings should not be enclosed in quotes, and embedded quotes should not be converted to two quotes. If there are no transactions in the file for the table (i.e., the add, change, and delete counts are all zero), then the Header Record should be the only record in the update file.

The Field Definition Record defines all of the fields for the table, assigning an integer Field ID to each field. The fields should appear in sequential Field ID order. Fields will be referenced by Field ID on the other records in the file.

The Primary Key Definition Record identifies which fields (if any) compose the primary key of the table. The Field IDs defined on the Field Definition Record are referenced to indicate which fields are part of the primary key. The Field IDs should appear in the order the fields appear in the primary key. If there is no primary key for the table, the Primary Key Field Count should be 0 and no Field IDs should be listed. In such a case, the application will generate SQL statements for the table that do not have a WHERE clause. Therefore, processing without a primary key may not yield the desired results if the table has more than one row.

The Add Record will generate an INSERT statement to add a row to the table. Each field in the table should be referenced by the Field ID assigned in the Field Definition Record. The Field Values should be formatted so that they can be concatenated into the VALUES clause of an INSERT statement with no further modification. Values for string fields must be enclosed in single quotes, and any embedded single quotes must be converted to two single quotes. To set a field to null, the value should be a zero-length string with no quotes.

The Change Record will generate an UPDATE statement to modify an existing row in the table. The Primary Key Field Values should correspond to the sequence of the primary key fields in the Primary Key

Definition Record. The Modified Field IDs and Values should appear following the Primary Key Values. The Primary Key Field Values and the Modified Field Values should be formatted so that they can be concatenated into the WHERE and SET clauses of an UPDATE statement with no further modification. Values for string fields must be enclosed in single quotes, and any embedded single quotes must be converted to two single quotes. To set a field to null, the value should be a zero-length string with no quotes.

The Delete Record will generate a DELETE statement to remove an existing row from the table. The Primary Key Field Values should correspond to the sequence of the primary key fields in the Primary Key Definition Record, and they should be formatted so that they can be concatenated into the WHERE clause of a DELETE statement with no further modification. Values for string fields must be enclosed in single quotes, and any embedded single quotes must be converted to two single quotes.

7.2.4 Record Layouts

This section presents the layouts for records that make up the control and update files. All fields are delimited by the pipe character (|).

Version Control Record (Control File Only)

| Field Name | Maximum Length | Data Type |
|------------------------------------|----------------|-----------|
| Record Type ("V") | 1 | String |
| Version Table Name | 32 | String |
| Version Field Count | 3 | Integer |
| Version Field 1 Name | 32 | String |
| Version Field 1 Description | 80 | String |
| Version Field 1 Value | 255 | String |
| ... | | |
| Version Field <i>n</i> Name | 32 | String |
| Version Field <i>n</i> Description | 80 | String |
| Version Field <i>n</i> Value | 255 | String |

Note: The value of *n* will match the Version Field Count value.

Field Definition Record (Control and Update Files)

| Field Name | Maximum Length | Data Type |
|---------------------|----------------|-----------|
| Record Type ("F") | 1 | String |
| Field Count | 3 | Integer |
| Field 1 ID | 3 | Integer |
| Field 1 Name | 32 | String |
| ... | | |
| Field <i>n</i> ID | 3 | Integer |
| Field <i>n</i> Name | 32 | String |

Note: The value of *n* will match the Field Count value.

Primary Key Definition Record (Control and Update Files)

| Field Name | Maximum Length | Data Type |
|--------------------------|----------------|-----------|
| Record Type ("P") | 1 | String |
| Primary Key Field Count | 3 | Integer |
| Primary Key Field 1 ID | 3 | Integer |
| ... | | |
| Primary Key Field k ID | 3 | Integer |

Note: The value of k will match the Primary Key Field Count value, which may be zero.

Beginning Version Change Record (Control File Only)

| Field Name | Maximum Length | Data Type |
|-----------------------------|----------------|-----------|
| Record Type ("B") | 1 | String |
| Primary Key Field 1 Value | 255 | String |
| ... | | |
| Primary Key Field k Value | 255 | String |
| Modified Field 1 ID | 3 | Integer |
| Modified Field 1 Value | 255 | String |
| ... | | |
| Modified Field n ID | 3 | Integer |
| Modified Field n Value | 255 | String |

Note: The value of k will match the Primary Key Field Count value from the Primary Key Definition Record.

Ending Version Change Record (Control File Only)

| Field Name | Maximum Length | Data Type |
|-----------------------------|----------------|-----------|
| Record Type ("E") | 1 | String |
| Primary Key Field 1 Value | 255 | String |
| ... | | |
| Primary Key Field k Value | 255 | String |
| Modified Field 1 ID | 3 | Integer |
| Modified Field 1 Value | 255 | String |
| ... | | |
| Modified Field n ID | 3 | Integer |
| Modified Field n Value | 255 | String |

Note: The value of k will match the Primary Key Field Count value from the Primary Key Definition Record.

Header Record (Update Files Only)

| <u>Field Name</u> | <u>Maximum Length</u> | <u>Data Type</u> |
|-------------------------|-----------------------|------------------|
| Record Type ("H") | 1 | String |
| Table Name | 32 | String |
| Add Count | 10 | Long |
| Change Count | 10 | Long |
| Delete Count | 10 | Long |
| Version Field 1 Value | 255 | String |
| ... | | |
| Version Field n Value | 255 | String |

Note: The value of n will match the Version Field Count value from the Control File Record.

Add Record (Update Files Only)

| <u>Field Name</u> | <u>Maximum Length</u> | <u>Data Type</u> |
|-------------------|-----------------------|------------------|
| Record Type ("A") | 1 | String |
| Field 1 Value | 255 | String |
| ... | | |
| Field n Value | 255 | String |

Note: The value of n will match the Field Count value from the Field Definition Record.

Change Record (Update Files Only)

| <u>Field Name</u> | <u>Maximum Length</u> | <u>Data Type</u> |
|-----------------------------|-----------------------|------------------|
| Record Type ("C") | 1 | String |
| Primary Key Field 1 Value | 255 | String |
| ... | | |
| Primary Key Field k Value | 255 | String |
| Modified Field 1 ID | 3 | Integer |
| Modified Field 1 Value | 255 | String |
| ... | | |
| Modified Field n ID | 3 | Integer |
| Modified Field n Value | 255 | String |

Note: The value of k will match the Primary Key Field Count value from the Primary Key Definition Record.

Delete Record (Update Files Only)

| Field Name | Maximum Length | Data Type |
|-----------------------------|----------------|-----------|
| Record Type ("D") | 1 | String |
| Primary Key Field 1 Value | 255 | String |
| ... | | |
| Primary Key Field k Value | 255 | String |

Note: The value of k will match the Primary Key Field Count value from the Primary Key Definition Record.

7.2.5 Field Definitions

Following are definitions of the fields that appear in the record definitions above.

Table 36: Field Definitions

| Field Name | Field Description |
|-------------------------------|--|
| Add Count | The total number of Add Records in an update file (Header Record). |
| Change Count | The total number of Change Records in an update file (Header Record). |
| Delete Count | The total number of Delete Records in an update file (Header Record). |
| Field Count | The total number of fields in a table (Field Definition Record). |
| Field n ID | A unique integer assigned to a field in a table (Field Definition Record). |
| Field n Name | The name of a field in a table (Field Definition Record). |
| Field n Value | The value to be assigned to a field (Add Record). |
| Modified Field n ID | A unique integer identifying a field to be modified (Beginning Version Change Record, Ending Version Change Record, Change Record). |
| Modified Field n Value | The value to be assigned to a field to be modified (Beginning Version Change Record, Ending Version Change Record, Change Record). |
| Primary Key Field Count | The total number of fields in the primary key for a table (Primary Key Definition Record). |
| Primary Key Field k ID | A unique integer identifying a field in the primary key (Primary Key Definition Record). |
| Primary Key Field k Value | The value of a field in the primary key (Beginning Version Change Record, Ending Version Change Record, Change Record, Delete Record). |
| Record Type | A single character which identifies the record layout (all records). |
| Table Name | The name of the table to which the transactions in the update file are to be applied (Header Record). |
| Version Field Count | The number of fields to be validated in the version table (Version Control Record). |
| Version Field n Description | The description of the field that will be displayed in an error message in the event of a version table validation error (Version Control Record). |
| Version Field n Name | The name of a field to be validated in the version table (Version Control Record). |
| Version Field n Value | The value which a field in the version table should have in order for the set of update files to be applied (Version Control Record, Header Record). |
| Version Table Name | The name of the version table (Version Control Record). |

8 Human-Machine Interface

The PECS Graphical User Interface (GUI) enables users to research, update, maintain, and report VA customizations of the Commercial Off The Shelf (COTS) vendor database used in running the Pharmacy enhanced order checks.

8.1 Interface Design Rules

The user interface (UI) design of PECS screens follows other VA web-based interfaces and is described in the PEPS Style Guide. All web pages in the PECS application must be 508 compliant.

The following sections list the guidelines for user interface design.

8.1.1 Visibility of System Status

The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.

8.1.2 Match Between System and the Real World

The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.

8.1.3 User Control and Freedom

Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. Support undo and redo.

8.1.4 Consistency and Standards

Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.

8.1.5 Error Prevention

Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.

8.1.6 Recognition Rather Than Recall

Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.

8.1.7 Flexibility and Efficiency of Use

Accelerators -- unseen by the novice user -- may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.

8.1.8 Aesthetic and Minimalist Design

Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.

8.1.9 Help Users Recognize, Diagnose, and Recover from Errors

Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.

8.1.10 Help and Documentation

Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.

8.2 Inputs

Users interact with the system through a web browser. They enter data from the keyboard and submit it via HTML forms to customize drug interactions and associated information.

Access to the system is strictly controlled by role-based access. Four roles are defined: requestor, approver, release manager and administrator. Security is handled through the use of KAAJEE.

8.3 Outputs

System outputs include table-based result sets and reports in comma-separated format, as described in the following sections.

8.4 Navigation Hierarchy

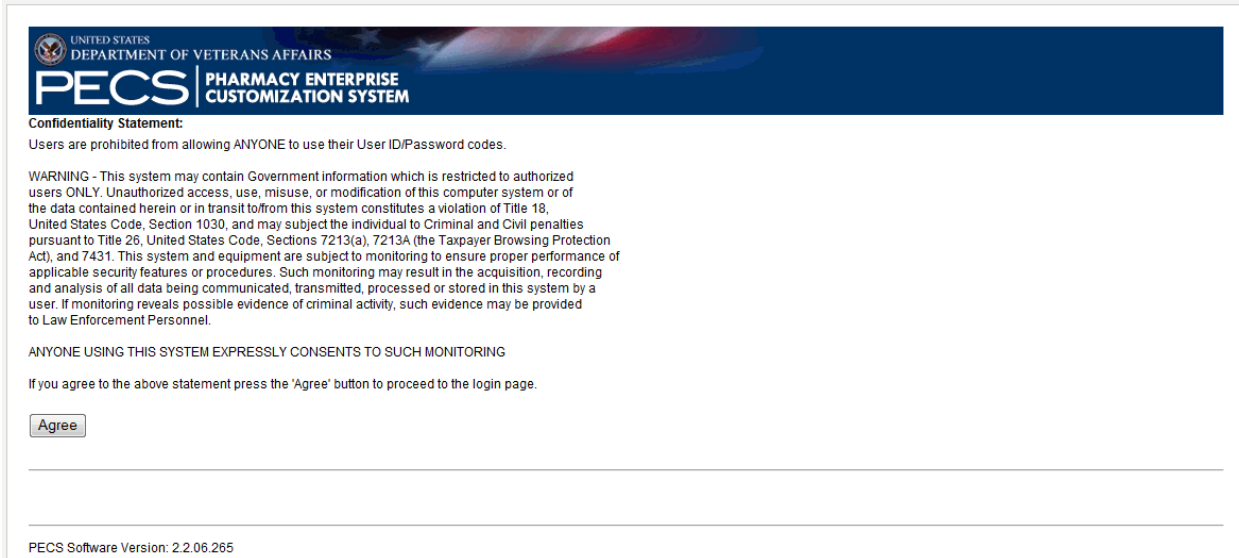
The sections below provide the navigation hierarchy that shows how a user moves through the user interface.

8.4.1 Login Screen

The interaction with this screen begins when the user initiates the action to access the welcome page of the PECS application. The welcome page is entrance page into the application. The user must use an Internet browser that meets the minimum VA version standard. The PECS application does not warrant that it will perform as expected in a non-standard browser version.

Display Confidentiality Statement

The system displays the VA confidentiality statement, restricting the use of computer systems. The user must press the “Agree” button to proceed to the login screen. The agreement of the statement is tracked in the HTTP session. If the user is logged out or the session times out the confidentiality statement must be agreed to again.



The screenshot shows the PECS (Pharmacy Enterprise Customization System) Confidentiality Statement. At the top, there is a header with the United States Department of Veterans Affairs logo and the text "PECS PHARMACY ENTERPRISE CUSTOMIZATION SYSTEM". Below the header, the text "Confidentiality Statement:" is followed by a warning: "Users are prohibited from allowing ANYONE to use their User ID/Password codes." A detailed warning paragraph follows, stating that the system may contain government information restricted to authorized users only, and that unauthorized access, use, misuse, or modification constitutes a violation of Title 18, United States Code, Section 1030, and may subject the individual to Criminal and Civil penalties pursuant to Title 26, United States Code, Sections 7213(a), 7213A (the Taxpayer Browsing Protection Act), and 7431. This system and equipment are subject to monitoring to ensure proper performance of applicable security features or procedures. Such monitoring may result in the acquisition, recording and analysis of all data being communicated, transmitted, processed or stored in this system by a user. If monitoring reveals possible evidence of criminal activity, such evidence may be provided to Law Enforcement Personnel. Below the warning, the text "ANYONE USING THIS SYSTEM EXPRESSLY CONSENTS TO SUCH MONITORING" is displayed. A line of text states: "If you agree to the above statement press the 'Agree' button to proceed to the login page." Below this text is a button labeled "Agree". At the bottom of the screen, the text "PECS Software Version: 2.2.06.265" is displayed.

UNITED STATES
DEPARTMENT OF VETERANS AFFAIRS
PECS PHARMACY ENTERPRISE
CUSTOMIZATION SYSTEM

Confidentiality Statement:
Users are prohibited from allowing ANYONE to use their User ID/Password codes.

WARNING - This system may contain Government information which is restricted to authorized users ONLY. Unauthorized access, use, misuse, or modification of this computer system or of the data contained herein or in transit to/from this system constitutes a violation of Title 18, United States Code, Section 1030, and may subject the individual to Criminal and Civil penalties pursuant to Title 26, United States Code, Sections 7213(a), 7213A (the Taxpayer Browsing Protection Act), and 7431. This system and equipment are subject to monitoring to ensure proper performance of applicable security features or procedures. Such monitoring may result in the acquisition, recording and analysis of all data being communicated, transmitted, processed or stored in this system by a user. If monitoring reveals possible evidence of criminal activity, such evidence may be provided to Law Enforcement Personnel.

ANYONE USING THIS SYSTEM EXPRESSLY CONSENTS TO SUCH MONITORING

If you agree to the above statement press the 'Agree' button to proceed to the login page.

PECS Software Version: 2.2.06.265

Figure 67: Confidentiality Statement

Credentials Screen

The system displays the KAAJEE login screen asking for user login criteria: Access Code and Verify Code.

System Announcements:

U.S. Government Computer System

U. S. government systems are intended to be used by authorized government network users for viewing and retrieving information only, except as otherwise explicitly authorized for official business and limited personal use in accordance with policy. Information from these systems resides on and transmits through computer systems and networks funded by the government. All access or use constitutes understanding and acceptance that there is no reasonable expectation of privacy in the use of Government networks or systems.

The data and documents on this system include Federal records that contain sensitive information protected by various Federal statutes, including the Privacy Act, 5 U.S.C. Section 552a, and veterans' records confidentiality statutes such as 38 U.S.C. Sections 5701 and 7332. Access to the data and records is on a need-to-know basis only.

All access or use of this system constitutes user understanding and acceptance of these terms and constitutes unconditional consent to review and action including (but not limited to) monitoring, recording, copying, auditing, inspecting, investigating, restricting access, blocking, tracking, disclosing to authorized personnel, or any other authorized actions by all authorized

Login: PECS



Access Code:

Verify Code:

☒ Sort by Station Number *

☐ Sort by Station Name *

Institution: *

Login

Figure 68: Credentials Screen

8.4.2 Home Page

The system displays the Home Page with the appropriate links based upon the user's roles and permissions (i.e., user profile). Refer to the PECS RSD security matrix information regarding the functionality available from within the PECS application by role.

UNITED STATES
DEPARTMENT OF VETERANS AFFAIRS
PECS | PHARMACY ENTERPRISE
CUSTOMIZATION SYSTEM

Welcome [Redacted] | [Logout](#)

[Home](#)
[Advanced Query/Customization](#)
[Easy Search](#)
[Drug Pair Lookup](#)
[Reports](#)
[Contact Us](#)
[Help](#)

Welcome [Redacted] [Page Help](#)

Last update to First DataBank DIF database occurred on: 11-23-2012 version: 3.3
Last customization update file creation occurred on: 06-06-2013

My Request History

| Concept | New | Modified | Reviewed | Approved | Rejected | Deleted | All |
|------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|--------------------|
| Drug-Drug Interaction | 6 | 2 | 2 | 4 | 0 | 2 | 16 |
| Professional Monograph | 0 | 0 | 1 | 2 | 0 | 1 | 4 |
| Duplicate Therapy | 1 | 0 | 3 | 4 | 0 | 1 | 9 |
| Dose Range | 6 | 1 | 1 | 3 | 1 | 0 | 12 |

My Assigned Requests for Review

| Concept | Awaiting Review |
|---|-------------------|
| Drug-Drug Interaction | 2 |
| Professional Monograph | 0 |
| Duplicate Therapy | 1 |
| Dose Range | 0 |
| Approved Drug Drug Interactions With Pending Drug Pairs | 0 |

My Assigned Requests for Approval

| Concept | Awaiting Approval |
|---|-------------------|
| Drug-Drug Interaction | 0 |
| Professional Monograph | 1 |
| Duplicate Therapy | 0 |
| Dose Range | 0 |
| Approved Drug Drug Interactions With Pending Drug Pairs | 0 |

My Assigned Requests for Deletion

| Concept | Awaiting Deletion |
|---|-------------------|
| Drug-Drug Interaction | 0 |
| Professional Monograph | 0 |
| Duplicate Therapy | 0 |
| Dose Range | 0 |
| Approved Drug Drug Interactions With Pending Drug Pairs | 0 |

Unassigned Requests

| Concept | Unassigned |
|---|--------------------|
| Drug-Drug Interaction | 84 |
| Professional Monograph | 30 |
| Duplicate Therapy | 46 |
| Dose Range | 69 |
| Approved Drug Drug Interactions With Pending Drug Pairs | 4 |

All Requests

| Concept | New | Modified | Reviewed | Approved | Rejected | Deleted | All |
|------------------------|--------------------|--------------------|--------------------|---------------------|--------------------|---------------------|-----|
| Drug-Drug Interaction | 62 | 29 | 15 | 634 | 84 | 164 | 988 |
| Professional Monograph | 22 | 6 | 11 | 44 | 4 | 15 | 102 |
| Duplicate Therapy | 28 | 15 | 22 | 10 | 1 | 17 | 93 |
| Dose Range | 54 | 10 | 21 | 73 | 4 | 20 | 182 |

[Home](#)
[Advanced Query/Customization](#)
[Easy Search](#)
[Drug Pair Lookup](#)
[Reports](#)
[Contact Us](#)
[Help](#)

Figure 69: PECS Home Page

8.4.3 Advanced Query/Customization Screen

The Customization tab is the main entry screen to access the Order Check modules for both customization and FDB records. The Customization tab provides an “FDB,” “VA,” and “Both” link for each Order Check available to the user’s role. The list of Order Checks available will depend on user role. A partial screen shot is displayed below:

The screenshot shows the PECS (Pharmacy Enterprise Customization System) interface. At the top, there is a header with the United States Department of Veterans Affairs logo and the text "PECS PHARMACY ENTERPRISE CUSTOMIZATION SYSTEM". To the right of the header, there is a "Welcome" message followed by a blacked-out user name and a "Logout" link. Below the header is a navigation bar with links: Home, Advanced Query/Customization (highlighted), Easy Search, Drug Pair Lookup, Reports, Contact Us, and Help. The main content area has a title "Advanced Query/Customization" and a "Page Help" link. Below this is a "Build a Query" section. It contains two dropdown menus: "Select Concept" and "Select VA, FDB, or Both". The "Select Concept" dropdown is open, showing a list of options: Drug-Drug Interaction, Drug Pair, Professional Monograph, Duplicate Therapy, and Dose Range. To the left of the dropdowns, there are three buttons: "Run a Saved" (highlighted), "My Queries", and "My Queries". At the bottom of the screen, there is a footer with the same navigation links as the top bar: Home, Advanced Query/Customization, Easy Search, Drug Pair Lookup, Reports, Contact Us, and Help.

Figure 70: Advanced Query/Customization

8.4.4 Query Builder Screen

The user inputs query criteria specific to the Order Check and database (FDB, VA, or Both VA and FDB records) selected. The user clicks the “Query” button and if results from the database match the query criteria, a result set is displayed in a table.

UNITED STATES DEPARTMENT OF VETERANS AFFAIRS
PECS PHARMACY ENTERPRISE CUSTOMIZATION SYSTEM

Welcome [User] Logout

Home Advanced Query/Customization Easy Search Drug Pair Lookup Reports Contact Us Help

Advanced Query/Customization Page Help

Build a Query

Select Concept Duplicate Therapy Select VA, FDB, or Both Both VA and FDB records

Enter a value to build a query

| | | | |
|---------------|--------------------------|------------|--------|
| Fields | Filter | Value | And/Or |
| Action Status | Contains | approved | AND |
| Fields | Filter | Value | And/Or |
| Action Date | Greater than or Equal to | 2012-01-01 | |

☐ Include Historical Records

Query Name: Approved after JAN-01-2012 Save Query Clear Query

Run a Saved Query

My Queries Other Users' Queries

SAVE DAVE

Load Delete

Home Advanced Query/Customization Easy Search Drug Pair Lookup Reports Contact Us Help

Figure 71: Query Builder

8.4.5 Query Results

This screen presents the results of executing a query.

| VA Tables Results | | | | | |
|------------------------|-------|----------------------|--|---------------|---------------------|
| Export | I | | | | |
| Select | DTCID | Custom Dup Allowance | Description | Action Status | Action Date |
| Active | 1132 | 0 | Thrombin Inhibitors (Non-Heparinoid) | Approved | 2012-06-01 15:33:52 |
| Active | 1338 | 1 | Antidiarrheal Formulations with Gut Flora Microorganisms | Approved | 2012-05-07 10:15:54 |
| Active | 220 | 0 | Lead Poisoning Agents | Approved | 2012-05-03 15:30:01 |
| Active | 376 | 1 | Stimulant Laxatives | Approved | 2012-04-16 23:07:31 |
| Active | 458 | 0 | VA custom: Phenothiazines | Approved | 2012-02-06 09:00:04 |
| Active | 1238 | 0 | Spectinomycin HCl | Approved | 2012-02-02 10:16:19 |

Figure 72: Query Results

Each row in the result set has a hyperlink that enables it to be selected for opening.

8.4.6 Open Record

Records returned by a query can be viewed in detail and acted upon. Which fields are editable and which buttons are displayed depends on both the user role and the record state.

UNITED STATES DEPARTMENT OF VETERANS AFFAIRS
PECS PHARMACY ENTERPRISE CUSTOMIZATION SYSTEM

Welcome [Redacted] [Logout](#)

[Home](#) [Advanced Query/Customization](#) [Easy Search](#) [Drug Pair Lookup](#) [Reports](#) [Contact Us](#) [Help](#)

Duplicate Therapy [Page Help](#)

- To update this record click on the edit button below.

[Edit](#) [History](#) [Print Page](#)

Dtcd 88

Custom Dup Allowance (Required) 1

Description (Required) Bacitracin

Action Status New

Action Date 2013-05-28 12:47:46

Action Performed By [Redacted]

Request Assigned To [Redacted]

Request Submitted By [Redacted]

Reference Text zewq

Action Reason History 2013/05/28 12:47:46 FOUR_APPROVER: cart

Current Action Reason (Required)

Pre-Customization Comment History

[Edit](#) [History](#) [Print Page](#)

[Home](#) [Advanced Query/Customization](#) [Easy Search](#) [Drug Pair Lookup](#) [Reports](#) [Contact Us](#) [Help](#)

Figure 73: Open Record

8.4.7 Easy Search

The easy search window allows users to enter basic drug information and do a quick search on various drugs for both drug-drug interaction and dose range research.

The screenshot displays the 'Easy Search' interface of the Pharmacy Enterprise Customization System (PECS). At the top, the header includes the United States Department of Veterans Affairs logo and the PECS title. A navigation bar contains links for Home, Advanced Query/Customization, Easy Search, Drug Pair Lookup, Reports, Contact Us, and Help. The 'Easy Search' section features a 'Select Search Type' dropdown set to 'Dose Range' and a 'Page Help' link. Below this is the 'Drug Information' section with a text input field containing 'war' and a 'Search' button. The 'Search Results' section lists several drugs, including BenGay Warming Ice Topical Gel, Castiva Warming 0.035% Topical Liquid, Mediplast Corn-Callus-Wart Remover 40 % Adhesive Patch, Theraflu Warming Relief 25 mg-10 mg-650 mg/30 mL Oral Liquid, and various Warfarin Sodium formulations. Below the results are fields for 'Dose Type', 'Dose Route', and 'Demographic Information' (Age, Weight, Height, BSA). A 'Dosing Information' section includes fields for 'Single Dose', 'Dose Unit', 'Dose Rate Unit', and 'Frequency'. A 'Submit' button is located at the bottom of the form. A footer navigation bar repeats the links from the top navigation bar.

Figure 74: Easy Search Window

8.4.8 Reports Screen

This screen presents the user with a list of available reports to run.

The image displays two screenshots of the PECS (Pharmacy Enterprise Customization System) Reports screen. Both screenshots show the same interface, but with different user names in the top right corner: 'FOUR_APPROVER' in the top screenshot and 'FOUR_APPROVER' in the bottom screenshot. The interface includes a header with the PECS logo and navigation links. The main content area is divided into two columns: 'Active Customization Reports' and 'FDB Comparison Reports'. The 'Active Customization Reports' column lists several reports with links to their respective pages. The 'FDB Comparison Reports' column lists reports with links to their respective pages. The bottom screenshot shows a different set of reports in the 'FDB Comparison Reports' column, including 'Drug-Drug Interaction/Drug Pairs' and 'duplicate therapy'.

Top Screenshot (User: FOUR_APPROVER):

- Active Customization Reports:**
 - [FDB Custom Dose Range](#)
 - [FDB Custom Drug-Drug Interaction](#)
 - [FDB Custom Duplicate Therapy](#)
 - [FDB Custom Professional Monograph](#)
 - [Deleted Monograph Customization Report](#)
 - [Null Drug Pairs Customization Report](#)
- FDB Comparison Reports:**
 - duplicate therapy**
 - [2013-12-10](#) [2013-12-09](#) [2013-10-23](#) [2013-10-22](#)
 - [2013-10-22](#) [2013-10-15](#)
 - Dose Range**
 - [2013-12-10](#) [2013-12-09](#)
 - Drug-Drug Interaction/Drug Pairs**
 - [2013-12-10](#) [2013-12-09](#) [2013-10-23](#) [2013-10-22](#)
 - [2013-10-22](#) [2013-10-15](#)

Bottom Screenshot (User: FOUR_APPROVER):

- Active Customization Reports:**
 - [FDB Custom Dose Range](#)
 - [FDB Custom Drug-Drug Interaction](#)
 - [FDB Custom Duplicate Therapy](#)
 - [FDB Custom Professional Monograph](#)
 - [Deleted Monograph Customization Report](#)
 - [Null Drug Pairs Customization Report](#)
- FDB Comparison Reports:**
 - Drug-Drug Interaction/Drug Pairs**
 - [2013-02-07](#) [2013-01-31](#) [2013-01-23](#) [2013-01-16](#)
 - [2013-01-09](#) [2013-01-03](#) [2012-12-25](#) [2012-12-19](#)
 - [2012-12-13](#)
 - duplicate therapy**
 - [2013-02-07](#) [2013-01-31](#) [2013-01-23](#) [2013-01-16](#)
 - [2013-01-09](#) [2013-01-03](#) [2012-12-25](#) [2012-12-19](#)
 - [2012-12-13](#)

Figure 75: Reports Window

8.4.9 Help

PECS Help screen has Help Topics for the application.

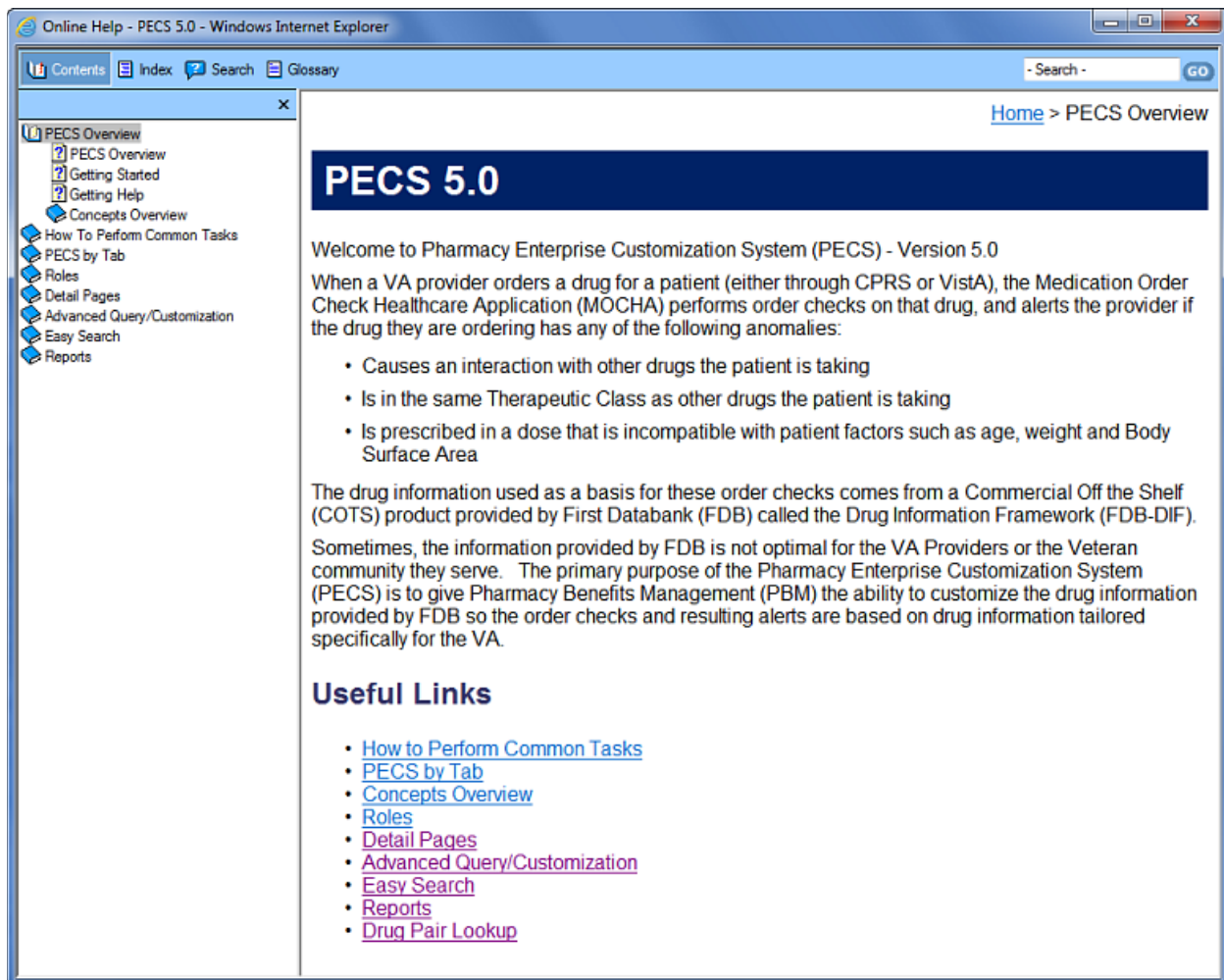


Figure 76: Initial Help Table of Contents

9 Security and Privacy

9.1 Security

PECS 5.0 uses the VA Kernel Authentication and Authorization for J2EE (KAAJEE) security API for authentication and authorization purposes. To log into the application, the development team will use a valid VistA account at a local or national facility, since KAAJEE delegates user authentication to VistA. At the application's login screen, users are prompted for their access and verify codes and will be allowed to select the VistA instance that issued their credentials. Authorization is handled using VistA security keys that are specific to each application.

Early analysis has indicated that authenticating with PIV using the Identity and Access Management (IAM) service does not support the role-based authority necessary for the security strategy used in PECS. Therefore, there is the potential to continue to use KAJEE to manage the roles and PIV to manage the

authentication. Further analysis will need to be performed to design this solution. The HPES Development team will collaborate with the IAM team to understand the features available in IAM and the details of implementing security with the IAM service.

New procedures will have to be put in to place to develop and test with IAM. These procedures will be developed in conjunction with the IAM team and security administrators and must be in place before PECS development of this enhancement can proceed.

KAAJEE authenticates and authorizes users through VistA. IAM authenticates and authorizes users using Microsoft Active Directory. Development and SQA personnel will have to be granted permissions in Active Directory instead of VistA, so the procedures to add, change, update, and remove permissions will have to be modified. Therefore, instead of having canned logins like the test VistA instances have for Development and SQA personnel, the Development and SQA personnel will have to use their own VHA login credentials to test the applications.

Describe specific security mechanisms at the application level, as guided by NIST 800-53 revision 3 (or most current version). Also, summarize the security mechanisms to be provided by the VA GSSs. Reference the Security Risk Assessment.

The following information will be provided to address security controls:

A high-level description of the security controls, grouped according to the 18 control families identified in NIST 800-53 revision 3 (or most current version). A description of all 18 control families must be addressed; if a control family is not applicable, then state that control family does not apply and explain why it does not apply.

A description of the specific security controls that will be provided by existing VA infrastructure or VA GSSs.

Describe the planned use by the application of the infrastructure's centralized security mechanisms and VA GSSs (in particular, the identification and authentication, access control, and audit mechanisms), and infrastructure mechanisms, (e.g., Directory Services) to store user account information. Sufficient detail should be provided to show the feasibility of the integration and/or inter operation of application security mechanisms with infrastructure security mechanisms.

9.2 Privacy

No PHI/PII in PECS.

Identify privacy design considerations. Describe specific privacy mechanisms at the application. Describe how the application's privacy requirements will be met. Reference the System Security Plan (SSP) and Privacy Impact Assessment (PIA).

10 System Integrity Controls

As mentioned previously, for a change to be released to PEPS, it needs to be approved by two different users. This provides a means to verify changes to catch mistakes before they are released.

The system also preserves historical information (no customization record is deleted). That provides an audit trail that can be used to reconstitute all steps a record went through and determine the users who performed those changes.

Attachment A – Approval Signatures

This section is used to document the approval of the System Design Document. The Chair of the governing Integrated Project Team (IPT), Business Sponsor, IT Program Manager, Project Manager, and the members of the Technical and Enterprise Architectural Review Team are required to sign. Please annotate signature blocks accordingly.

REVIEW DATE: December 2014

SCRIBE: 

Signed:



Signed:



Signed:



Signed:



//es// _____ *17/January/2014*

Signed:

Date:

//es// _____ *17/January/2014*

Signed:

Date:

A. Additional Information

A.1 Requirements Traceability Matrix

Please refer to “PECS Requirements Traceability Matrix.xlsx” artifact for Comprehensive Requirements Traceability Matrix. (Here, a high level table is shown below with an RTM for reference purpose only).

Table 37: Requirements Traceability Matrix

| Requirements | Module |
|--|--|
| <p>Home Page</p> <p>The system shall display the application Home web page after the successful login. (3.6.3.10)</p> <p>The system shall provide a panel for all requests based on role. (3.6.2.13) The system shall provide a panel for all requests in different Action Status. The system shall provide a summary count based on record’s Action Status within each panel based on role and panel. (3.6.2.15)</p> <ul style="list-style-type: none">• My Request History• My Assigned Requests for Review• My Assigned Requests for Approval• My Assigned Requests for Deletion• Unassigned Requests• All Requests <p>The system shall provide a hyperlink to query results for each table within each panel based on role. (3.6.2.14)</p> | <p>This requirement has been implemented by PECS Application in Home Page module. Please refer to section 8.4.2 above.</p> |
| <p>Queries</p> <p>The following system functionality will be available for both categories of queries (MyQueries and OtherUsers)</p> <p>The system shall provide tab web pages for MyQueries and OtherUsers query specific to a role. (3.6.6.1)</p> <p>Query Builder</p> <p>The system shall allow user to be able to build and execute queries from the FDB, Custom tables or both. (3.6.6.11)</p> <p>The system shall allow the user to execute one query at a time from the list of available queries. The lists are available queries in either MyQueries or OtherUser queries web pages that are</p> | <p>This requirement has been implemented by PECS Application in Query module. Please refer to section 8.4.4, section 8.4.5 and 8.4.3 above for Queries, Query Builder and Query Result implementation.</p> |

| Requirements | Module |
|--|--------|
| <p>available to process. (3.6.6.14)</p> <p>The system shall provide dropdown list of field names for custom query selections. (3.6.6.20)</p> <p>For queries, the system shall provide a constraint/filter field. (3.6.6.21)</p> <p>For queries, the system shall provide the following pre-defined constraint options to select in the constraint/filter field based on field type. (3.6.6.22)</p> <ul style="list-style-type: none"> • Equal to • Not equal to • Contains • Greater than • Greater than or equal to • Less than • Less than or equal to • Begins with • Ends with <p>For queries, the system shall provide an “and/or” condition set to create complex queries. (3.6.6.24)</p> <p>For the OtherUser queries category, the system shall display available custom queries of the last ten created from other users. (3.6.6.18)</p> <p>For the OtherUser queries category, the system shall provide the user an option to select and process an available custom query. (3.6.6.19)</p> <p>The system shall provide the user the capability to filter (include/exclude) historical records from query results. Note: This option should enable the return of only Active records or the combination of both Active and Historical versions. (CR2479)</p> <p>For Dose Range query the system shall provide a pre-defined search criteria that can be added to a user defined query with default values, following are the pre-defined fields and values (CR3498)</p> <p style="margin-left: 40px;">VA, FDB or VA and FDB search:</p> <p style="margin-left: 40px;">Concept</p> <p style="margin-left: 40px;">Type = 6 and</p> <p style="margin-left: 40px;">AGEHIGHINDAYS Greater than or Equal</p> <p style="margin-left: 40px;">to 6570</p> <p style="margin-left: 40px;">User can add other fields if so desired...</p> | |

| Requirements | Module |
|--|--|
| <p>The system shall provide, for all five concept types, the option to include or exclude Historical records at the point of Querying. This option to include or exclude Historical records will allow the return of ONLY Active records or the combination of BOTH Active and Historical records.</p> <p>Save Query</p> <p>The system shall provide a means, based on user role, to save a custom query after the custom query is submitted. (3.6.6.28)</p> <p>The system shall provide a means to delete a custom query that was created by the user. (3.6.6.27)</p> <p>Query Results</p> <p>The system shall return Query table results which include both Active and Historical records when historical records option is selected.</p> <p>The system shall allow the user to select from the results of a query. (3.6.6.2) The system shall allow the user to open the record by clicking on the hyperlink provided as part of each record.</p> <p>The system shall provide sort (ascending, descending) functionality for each of the resulting columns. (3.6.6.10)</p> <p>For Drug-Drug Interactions and Drug Pairs, the querying and subsequent search results should include both combinations of drugs irrespective of the sequence the drugs were entered into the query ‘Interaction Description’ for Drug-Drug Interactions and ‘Routed Generic #1’ and ‘Routed Generic #2’ for Drug Pairs</p> <p>Export Query Results</p> <p>The system shall provide the capability for the user to export any query results to Microsoft Excel. (3.6.6.8)</p> | |
| <p>Customization Requirements</p> <p>The system shall allow site personnel (Requester and Approver Roles) to enter and submit customization requests based on an existing FDB record, VA customized record or using blank form where permitted. (3.6.4.1)</p> <p>The system shall check that a new VA Customization request is not a duplicate entry. If a duplicate is encountered, a warning message is displayed that a duplicate record exists and user will not be allowed to create a duplicate request. (3.6.4.6)</p> <p>The system support following Action Statuses: (3.6.7.7)</p> <ul style="list-style-type: none"> • Modified • New • Approved | <p>This requirement has been implemented by PECS Application in Customization module. Please refer to section 8.4.3 above.</p> |

| Requirements | Module |
|--|--|
| <ul style="list-style-type: none"> Reviewed Rejected Delete Reviewed Deleted <p>The system shall provide a means to apply updates to non FDB-DIF fields regardless of Action Status. The action status will remain the same and not change. The “action performed by” field will remain the same. The change will not require the Approval Process. (3.6.16.1)</p> | |
| <p>Reports</p> <p>The system should allow the user to export the reports in an MS Excel format</p> <p>The system shall provide a customization report file. The report file shall provide customization records that have been entered regardless of status against the FDB DIF standard reference data. (3.6.11.1)</p> <p>The system shall create a separate report file for each of the five business concept (3.6.11.2)</p> <p>The system shall provide a report where the drug interaction does not have an associated Professional Monograph. The report should display (3.6.16.7)</p> <ul style="list-style-type: none"> Interactionid Interaction description Monograph ID <p>The system shall provide a report when one of the drugs in a pair was removed from the FDB database. The report shall display (3.6.16.6)</p> <ul style="list-style-type: none"> Interactionid Interaction description Rtgenid1_desc Rtgenid2_desc | <p>This requirement has been implemented by PECS Application in Reports module. Please refer to section 8.4.7 above.</p> |

A.2 Packaging and Installation

PECS software deployment deliverables are packaged with a Version Description Document (VDD) that details the software delivered, including version numbers. PECS Installation Guide is also delivered, detailing how the software should be installed.

A.3 Design Metrics

PECS application and deliverables follow the VA defined Quality and SQA process for review, a list of minor and major defects are generated, which are subsequently acted upon to rectify them.

A.4 Glossary of Terms

The following table defines terms used throughout this document.

Table 38: Glossary of Terms

| Term | Definition |
|---------|---|
| ADPAC | Automated Data Processing Application Coordinator |
| AITC | Austin Information Technology Center |
| API | Application Program Interface |
| ATO | Authority to Operate |
| C&A | Certification and Accreditation |
| COTS | Commercial Off-the-Shelf |
| CRUD | Create, Read, Update, Delete functions |
| DAO | Data Access Object |
| DATUP | Application that implements the FDB-DIF update business logic using the FDB Updater APIs to process the update file |
| DBA | Database Administrator |
| DBMS | Database Management System |
| DDL | Data Definition Language. A computer language for describing the records, fields, and "sets" making up a database. |
| EA | Enterprise Architecture |
| EAR | JEE Enterprise Application Archive file. |
| FDB DIF | First Databank Drug Information Framework database |
| FTP | File Transfer Protocol |
| GUI | Graphical User Interface |
| ITC | Information Technology Center |
| JEE | Java 2 Enterprise Edition |
| JMS | Java Messaging Service |
| KAAJEE | Kernel Authentication and Authorization for JEE |
| M | Short name for MUMPS |
| MUMPS | Massachusetts University Medical Programming System |
| MVC | Model-View-Controller |
| NDF | National Drug File |
| OIFO | Office of Information Field Office |
| PBM | Pharmacy Benefits Management |
| PECS | Pharmacy Enterprise Customization System |
| PEPS | Pharmacy Enterprise Product System |
| PRE | Pharmacy Reengineering |
| RDBS | Relational Database System |
| RSD | Requirements Specification Document |
| RTC | Rational Team Concert |
| SDE | System Design & Engineering |
| SQA | Software Quality Assurance |
| SQL | Structured Query Language |
| TRM | Technical Reference Model |

| Term | Definition |
|------|---------------------------------|
| UI | User Interface |
| URL | Uniform Resource Locator |
| VA | Department of Veterans Affairs |
| VAMC | Veterans Affairs Medical Center |

A.5 Required Technical Documents

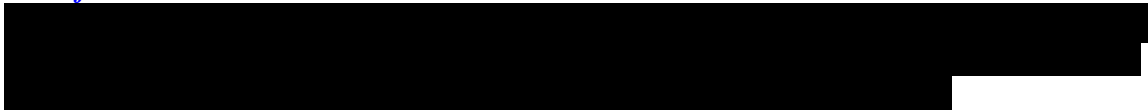
The following documents must be submitted for review to support proper approval:

- Product Architecture Document
- Database Design Document
- Interface Control Document
- System Security Plan

For additional information regarding how to obtain proper approval for this project, refer to the following documents:

Note: Due to policy constraints, active links cannot be included in this document. Please copy and paste the URLs into your browser.

- *IT Infrastructure Standards*



- *Systems Engineering and Design Review (SEDR) process*



- *Enterprise Architecture Web page*



- *One-ONE-VA TRM*



A.6 Attach Documents

Once the SDD is approved, submit the AERB Design Compliance Decision Certificate as an attachment to the completed and approved SDD.

(This page included for two-sided copying.)