Software Requirements Specification

for

Pharmacy Benefit Management Optimization

Version 1.0 approved

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Revision History

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| --- | --- | --- | --- |
| **Name** | **Date** | **Reason For Changes** | **Version** |
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# Introduction

The purpose of this document is to define the requirements for a **Pharmacy Benefit Management (PBM) Optimization Platform**. The system is designed to optimize formulary decisions and drug utilization to reduce pharmacy costs while ensuring appropriate access to medications for patients.

## Purpose

*The purpose of this project is to develop a* ***Pharmacy Benefit Management (PBM) Optimization Platform*** *that helps optimize formulary decisions and drug utilization to control pharmacy costs while ensuring appropriate medication access.*

## Document Conventions

This Software Requirements Specification (SRS) follows standard documentation practices and conventions:

**Bold text** is used for section titles and emphasis.

Italic text is used for references and examples.

**[Requirement IDs]** will be assigned in the format **REQ-<Module>-<Number>** (e.g., REQ-FORM-001 for formulary impact requirements).

External datasets, tools, or references are hyperlinked where applicable.

Priority levels are indicated as:

**High** – Critical functionality required for the platform.

**Medium** – Important but not critical.

**Low** – Optional or future enhancement.

## Project Scope

The platform aims to address the domain challenge of rising prescription drug spending in the US (over $350 billion annually, with 15–20% growth). The solution will enable PBM stakeholders to reduce pharmacy costs by **12%** while maintaining **95%+ member satisfaction** with drug access.

## References

*CMS Part D Prescription Data – CMS Dataset*

*FDA Orange Book – FDA Orange Book*

*DrugBank Open Data – DrugBank Release*

# Overall Description

The **PBM Optimization Platform** is a cloud-based system that helps reduce pharmacy costs while ensuring patient access to appropriate medications. It integrates with PBM systems and leverages public datasets (CMS Part D, FDA Orange Book, DrugBank) to provide real-time formulary analysis, therapeutic alternatives, and cost tracking. Predictive analytics forecast drug utilization trends and spending patterns. The system is HIPAA-compliant, scalable to millions of records, and accessible via secure dashboards.

## Product Perspective

The **PBM Optimization Platform** is a cloud-based solution designed to integrate with existing pharmacy benefit systems, healthcare datasets, and clinical decision-making tools. It will serve as a decision-support and cost-optimization layer for Pharmacy Benefit Managers. The platform leverages public datasets (CMS Part D, FDA Orange Book, DrugBank) and predictive analytics to provide formulary recommendations, cost projections, and drug utilization trends.

## User Classes and Characteristics

***PBM Administrators:*** *Primary users who configure formularies, evaluate drug alternatives, and monitor cost savings.*

***Healthcare Providers:*** *Secondary users who may access recommendations for cost-effective therapeutic equivalents.*

***Patients/Members:*** *Indirect beneficiaries* through optimized access to affordable medications.

## Operating Environment

***Deployment Model:*** *Cloud-hosted SaaS platform.*

***Data Sources:*** *CMS Part D Prescription Data, FDA Orange Book, DrugBank.*

***Integration:*** *API-driven, compatible with PBM systems and electronic health record (EHR) platforms.*

***Accessibility:*** *Web-based dashboards with role-based authentication.*

## Design and Implementation Constraints

*Must comply with* ***HIPAA*** *and healthcare data protection standards.*

*Scalability to process millions of prescription records.*

*Use of structured datasets (CSV, XML, APIs) from public healthcare databases.*

*Must support predictive analytics and real-time dashboard visualization.*

## Assumptions and Dependencies

**Assumptions:**

1. Public datasets (CMS, FDA, DrugBank) will remain accessible and updated regularly.
2. PBM organizations will provide integration access to their internal systems via secure APIs.
3. Users will have stable internet connectivity to access the platform.
4. Cloud infrastructure will provide sufficient computational capacity for predictive analytics.

**Dependencies:**

1. Availability and accuracy of external datasets (CMS Part D, FDA Orange Book, DrugBank).
2. Compliance with **HIPAA** and other healthcare regulations.
3. Third-party hosting/cloud provider for uptime, security, and scalability.
4. PBM organizations’ willingness to integrate the system with existing formulary and claims platforms.

# System Features

The platform provides real-time formulary impact analysis to predict cost savings, therapeutic equivalence optimization to suggest lower-cost alternatives, and drug utilization trend prediction to forecast future spending. It also tracks cost-per-member-per-month, giving PBM administrators clear insights through interactive dashboards.

## Real-time Formulary Impact Analysis

### Description

Analyzes proposed formulary changes and predicts financial and clinical impact instantly.  
**Priority:** High

### Stimulus/Response Sequences

***Stimulus:*** *PBM administrator updates formulary (e.g., adds/removes a drug).*

***Response:*** *System recalculates projected cost savings and patient impact within seconds.*

### Functional Requirements

*REQ-FORM-001: The system shall calculate cost-per-member-per-month (PMPM) impact for formulary changes.*

*REQ-FORM-002: The system shall display comparative analytics between current and proposed formularies.*

*REQ-FORM-003: The system shall generate downloadable impact reports.*

## Therapeutic Equivalence Optimization

### Description

Identifies lower-cost, clinically equivalent drug alternatives to reduce spending.  
**Priority:** High

### Stimulus/Response Sequences

***Stimulus:*** *PBM administrator selects a brand drug for review.*

***Response:*** *System suggests generic or therapeutic equivalents with cost and clinical profiles.*

### Functional Requirements

*REQ-TEQ-001: The system shall query FDA Orange Book to identify equivalent drugs.*

*REQ-TEQ-002: The system shall present alternatives ranked by cost savings and clinical efficacy.*

*REQ-TEQ-003: The system shall allow administrators to approve or reject substitution suggestions.*

## Drug Utilization Trend Prediction

### Description

Uses predictive analytics to forecast drug usage patterns and future cost drivers.  
**Priority:** Medium

### Stimulus/Response Sequences

***Stimulus:*** *System ingests CMS Part D historical data.*

***Response:*** *System generates predictive models of utilization trends and high-cost drugs.*

### Functional Requirements

*REQ-DUT-001: The system shall apply machine learning models on historical claims data.*

*REQ-DUT-002: The system shall generate utilization forecasts up to 12 months ahead.*

*REQ-DUT-003: The system shall alert PBM administrators when projected costs exceed thresholds.*

## Cost-per-Member-per-Month Tracking

### Description

Tracks spending trends and provides metrics at the member level.  
**Priority:** High

### Stimulus/Response Sequences

***Stimulus:*** *PBM administrator views performance dashboard.*

***Response:*** *System displays aggregated PMPM metrics and trend charts.*

### Functional Requirements

*REQ-COST-001: The system shall calculate PMPM costs by drug, category, and plan.*

*REQ-COST-002: The system shall visualize cost data in charts and dashboards.*

*REQ-COST-003: The system shall export PMPM data into standard formats (CSV, Excel, PDF).*

# Data Requirements

The platform relies on multiple healthcare datasets to function effectively. It primarily uses **CMS Part D Prescription Data** for claims and utilization trends, the **FDA Orange Book** for therapeutic equivalence information, and **DrugBank Open Data** for detailed drug profiles. The system ensures data accuracy, integrity, and compliance with HIPAA, while supporting secure acquisition, storage, and reporting. All data is retained according to healthcare regulations and made available through dashboards and exportable reports.

## Logical Data Model

The system processes prescription claims, drug information, and formulary data. Relationships exist between members, prescribed drugs, therapeutic classes, and costs, enabling analysis of utilization and savings opportunities.

## Data Dictionary

Key data elements include:

**Drug\_ID** (unique identifier, string)

**Drug\_Name** (generic/brand, string)

**Therapeutic\_Class** (classification, string)

**Member\_ID** (unique identifier, numeric)

**Claim\_Cost** (currency, float)

**Formulary\_Status** (covered, excluded, or preferred, string)

## Reports

The platform generates reports on formulary impact, drug utilization forecasts, therapeutic equivalence opportunities, and per-member-per-month spending. Reports are available in dashboards and exportable formats (CSV, Excel, PDF).

## Data Acquisition, Integrity, Retention, and Disposal

*Data is acquired from* ***CMS Part D****,* ***FDA Orange Book****, and* ***DrugBank*** *via secure APIs or downloads. Integrity is ensured through validation, de-duplication, and audit trails. Retention follows healthcare regulations, with data stored securely for compliance periods. Disposal includes encrypted deletion of outdated records and backups in line with HIPAA requirements.*

# External Interface Requirements

*The platform offers a secure, web-based dashboard with role-based access for PBM users. It integrates with external datasets and APIs such as CMS Part D, FDA Orange Book, and DrugBank. Being cloud-based, it requires only standard internet-enabled devices. All communication occurs over HTTPS with encryption, using OAuth 2.0 for API security. The system ensures HIPAA-compliant data exchange and protection.*

## User Interfaces

The platform provides a secure, web-based dashboard with role-based access. Interfaces include visual analytics, interactive charts, search/filter options, and export functionality (CSV, Excel, PDF).

## Software Interfaces

The system integrates with external datasets and APIs, including **CMS Part D**, **FDA Orange Book**, and **DrugBank**. It supports RESTful APIs for data exchange with PBM systems and EHR platforms.

## Hardware Interfaces

As a cloud-based SaaS platform, no special hardware is required beyond a standard internet-enabled device (desktop, laptop, or tablet).

## Communications Interfaces

The platform communicates over secure HTTPS protocols with encryption (TLS 1.2+). It supports API authentication via OAuth 2.0 and complies with HIPAA requirements for secure data transfer.

# Quality Attributes

## Usability

The web-based dashboard is designed to be intuitive, with clear navigation, visual analytics, and accessibility features to ensure ease of use for PBM administrators and healthcare providers.

## Performance

The system must process millions of prescription records and generate analytics in near real-time, with dashboards loading within 3–5 seconds.

## Security

The platform complies with HIPAA, uses TLS encryption, secure authentication (OAuth 2.0), and role-based access control to protect sensitive healthcare data.

## Safety

Data validation prevents incorrect or incomplete records from impacting decisions. Automated backups and recovery protocols safeguard against data loss.

# Internationalization and Localization Requirements

The PBM Optimization Platform is primarily designed for the U.S. healthcare market, using U.S. English language, currency (USD), and date formats (MM/DD/YYYY). However, the system architecture supports internationalization, allowing future adaptation for other regions by enabling multiple languages, different currency formats, and regional regulatory compliance. Localization features such as date/time zones, drug naming conventions, and measurement units can be customized if required for global deployment.

# Other Requirements

The platform must comply with **HIPAA** and healthcare data protection regulations. It should include **logging and monitoring** features for all critical operations, with audit trails available to administrators. System installation and updates must be seamless in the cloud environment, requiring minimal downtime. Backup and recovery processes must ensure data resilience, and all integrations must follow healthcare interoperability standards.

Appendix A: Glossary

**PBM (Pharmacy Benefit Manager):** An organization that manages prescription drug benefits on behalf of insurers, employers, and other payers.

**Formulary:** A list of prescription drugs covered by a PBM or health plan.

**PMPM (Per-Member-Per-Month):** A cost metric used to track healthcare spending per enrolled member each month.

**Therapeutic Equivalence:** Drugs that have the same clinical effect and safety profile, making them interchangeable.

**CMS Part D:** U.S. Medicare program providing prescription drug coverage data.

**FDA Orange Book:** Database of approved drugs and their therapeutic equivalence codes.

Appendix B: Analysis Models

**Data Flow Diagram (DFD):** Illustrates how prescription and formulary data move through the platform.

**Entity-Relationship Diagram (ERD):** Defines relationships between members, drugs, claims, and formularies.

**Use Case Diagram:** Captures interactions between PBM administrators, providers, and the system.

**Trend Prediction Model:** Applies machine learning algorithms on claims data to forecast utilization and cost.