Software Requirements Specification (SRS)

for

Pharmaceutical System

Version 2.0

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Table of Contents

Revision History

Name	Date	Reason For Changes	Version
Clinton Oho, Evan Barbur, Connor Plonka, Daniel	April 18	Added revisions from Assignment 1	1.1

Lowry, Nicholas Palceski			
Clinton Oho, Evan Barbur, Connor Plonka, Daniel Lowry, Nicholas Palceski	April 20	Added revisions from Assignment 2	1.2
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1. Introduction

<All information in Section 1 must be accurate, relevant to the project, and clearly stated. It should provide useful context, align with the overall goals of the SRS, and add value to the document. Failure to meet these criteria may result in a deduction of up to 20 points (-20 pts).>

This document contains the requirement details for a Pharmaceutical System. Additionally, this document describes the main functionalities and features for the system. The SRS document provides the necessary needs for pharmacies to work efficiently and effectively in real-world scenarios. It defines the functional and non-functional requirements, the corresponding traceability matrix, UML diagrams for each sub-section, and an ER diagram to distinctly identify the outline of the system.

1.1 Purpose

<Identify the product whose software requirements are specified in this document, including the revision or release number. Describe the scope of the product that is covered by this SRS, particularly if this SRS describes only part of the system or a single subsystem.>

The product specified whose software requirements are specified in this document is a pharmacy software system, version 1.0. This system is responsible for aiding pharmacists and pharmacy technicians with the following: the process of dispensing and distributing medication to patients, managing patient prescriptions, maintaining medical device and medication integrity, handling patient insurance plans, and maintaining a healthy inventory. Unless specified, the system shall play a secondary role in these processes, with the qualified pharmacy staff performing the main actions, and the system playing a supporting role. An example of this dynamic is when a pharmacist dispenses medication, the system shall confirm that the amount is appropriate for the patient's circumstances.

1.2 Document Conventions

<Describe any standards or typographical conventions that were followed when writing this SRS, such as fonts or highlighting that have special significance. For example, state whether priorities for higher-level requirements are assumed to be inherited by detailed requirements, or whether every requirement statement is to have its own priority.>

Throughout this document we use Arial font with size 11. Requirements are numbered with some having sub-requirements indented under its corresponding requirement numbered respectively.

For section 3 (functional requirements), higher priority requirements are listed first following lower priority requirements. Priorities are identified with brackets at the end of each requirement, where inside the bracket is a letter representing High priority (H), Medium priority (M), and Low

priority (L). There is also a second set of brackets listing the name of the UML document that the requirement is connected to.

For section 4 (non-functional requirements), the priority system remains the same. With “H” meaning high priority, “M” meaning medium priority, and “L” meaning low priority. However, the second bracket that related the functional requirement to its UML diagram is not present for the non-functional requirements.

1.3 Intended Audience and Reading Suggestions

<Describe the different types of reader that the document is intended for, such as developers, project managers, marketing staff, users, testers, and documentation writers. Describe what the rest of this SRS contains and how it is organized. Suggest a sequence for reading the document, beginning with the overview sections and proceeding through the sections that are most pertinent to each reader type.>

This SRS document is broken down into various sections. With section one being about general document guidelines and clarification. Section two is about the system itself, and the constraints, features, users, etc that come with it. This section is intended to provide an overview of the system, and explain why the requirements in the following sections are included. Section three details the functional requirements for the system. These requirements must be implemented in the system by its development team. Section four details the non-functional requirements, with many of them being separated into sections that describe their purpose (ex. security). Additionally, a requirements traceability matrix is included in this section in order to connect functional requirements with their associated non-functional requirements.

And finally, the last section is the appendix section. With the five appendices included serving different purposes. Appendix A is the glossary, with its purpose being to define any technical terminology/acronyms/abbreviations used in the previous sections. This appendix also provides a description of the UML diagrams used in Appendix B. The next appendix, Appendix B, holds the analysis models (ex. use case diagram) relevant to their specific section of the SRS document. Appendix C includes a detailed explanation of the system, its purpose, and its features. This section is where the requirements are derived from and is thus intended to be an optional resource for viewers to use in order to understand system design and specific design decisions. Appendix D’s purpose is to hold a copy of the NASA Arm report using the requirements listed in sections three and four. The tool is used to evaluate functional and nonfunctional requirements for quality, and was previously used by NASA for their requirement documents. And the last appendix, Appendix E holds the references used throughout the document.

This SRS report is intended for the following groups: developers, project managers, marketing staff, users, and testers. However, the information in each of the sections are not intended for each group equally. For developers, they should look into section two which outlines the context behind the requirements, as well as sections three and four because they detail the functional and non-functional requirements necessary for the system. For the project managers, sections two through the appendices should be prioritized because they will allow them to properly allocate resources and set deadlines. For the marketing staff, sections three and four are the most useful because they showcase what the system will be able to do. For the users, section two is the most useful because it describes what the system is and its purpose(s). For testers, sections three and four should be looked into because they describe the system’s and its capabilities.

1.4 Product Scope

<Provide a short description of the software being specified and its purpose, including relevant benefits, objectives, and goals. Relate the software to corporate goals or business strategies. If a separate vision and scope document is available, refer to it rather than duplicating its contents here.>

The software that is being specified in this document is a pharmaceutical system. The purpose of this system is to help pharmacists more efficiently manage their pharmacy and its patients. Assisting in the dispensing process, handling prescriptions, managing medical devices, applying patient insurance policies, and aiding in the logistical and inventory processes are the broad categories of features that this system contains. This system is not made to replace a pharmacist in any manner nor to hold greater power than a pharmacist. It is simply made to streamline certain processes/tasks to make them easier for the pharmacists. For example, one system feature is to monitor inventory levels and notify pharmacists of any medication low in stock. However, the system does not automatically send a buy order to a supplier. This is because the pharmacist is the one who ultimately decides how to react.

Due to the streamlining of certain pharmacy-related processes, pharmacists will be able to handle more patients. This is due to more time-consuming mundane tasks (ex. applying patient insurance policies when appropriate) being completed faster with the software's assistance. The effect of handling more patients is that the pharmacy can handle more patients at once as well as across a larger period of time. In the long term, the increased traffic shall boost pharmacy profits and allow the pharmacy to extend its services to a greater number of patients.

2. Overall Description

<All information in section 2 must be consistent with the project, it should be informative, < All information in Section 1 must be accurate, relevant to the project, and clearly stated. It should provide useful context, align with the overall goals of the SRS, and add value to the document. Failure to meet these criteria may result in a deduction of up to 20 points (-20 pts).>

This pharmaceutical SRS document outlines the main components that the pharmacy software will rely on. This includes modules such as dispensing, prescriptions, medication and medical devices, health insurance, and medical inventory. The documents provide the necessary details for pharmacies to run efficiently and uphold patient data to high security standards. The requirements follow industry standards, regulations, and policies.

2.1 Product Perspective

<Describe the context and origin of the product being specified in this SRS. For example, state whether this product is a follow-on member of a product family, a replacement for certain existing systems, or a new, self-contained product. If the SRS defines a component of a larger system, relate the requirements of the larger system to the functionality of this software and identify interfaces between the two. A simple diagram that shows the major components of the overall system, subsystem interconnections, and external interfaces can be helpful.>

The context of the product being specified in this SRS is to be a replacement for existing pharmacy software systems. These existing systems are software that is related to record keeping, inventory management, communication with suppliers, medication dispensing, prescription handling, health insurance application, and other pharmacy-related practices. However, if there is an area of the pharmacy that did not previously have software associated with it, then this product is meant to introduce software to that area in order to facilitate a more effective workflow. This system's intention is to replace any software that operates for the previous listed purposes, and combine them into one software that can be operated for a multitude of different purposes.

On a broader scale, this system is also a component of the larger medical industry. As, this software is designed for a pharmacy, not their supplier's, upper management, medical-related federal agencies, etc. The scope of this product encompasses the most-ground level piece of the medical industry, that being the pharmacy that manages and distributes medication to patients. As such, the "higher" level pieces of the medical industry (Ex. Food and Drug Administration) interact with this system in order to communicate to local pharmacists and pharmacy staff about federal regulation changes, global concerns regarding the medical industry, etc.

2.2 Product Functions

<Summarize the major functions the product must perform or must let the user perform. Details will be provided in Section 3, so only a high level summary (such as a bullet list) is needed here. Organize the functions to make them understandable to any reader of the SRS. A picture of the major groups of related requirements and how they relate, such as a

top level data flow diagram or object class diagram, is often effective.>

The major functions of this product that must be performed are or at least allow the pharmacists to perform are divided into five broad categories, seen below. All the functions listed below will be elaborated on in sections three and four.

1. Dispensing

This involves the process of preparing, packaging, and label prescription drugs/devices for patient use. Additionally, this category deals with counseling patients about their medication and other medical-related questions. In regards to the system, its functions shall be:

a. Handle incoming prescriptions from doctors
b. Notify pharmacists of potential dispensing-related issues
c. Valid and store patient information
d. Review labels for accuracy
e. Facilitate refill and return requests

2. Prescriptions

This category is about the process of a doctor writing a prescription for a patient, then the pharmacy handles the preparation and distribution of the prescription to the patient. When it comes to the system, its functions will be to:

a. Verification of prescription details
b. Aiding in the patient counseling process
c. Assist in label generation
d. Confirm patient and doctor identity

3. Medication and Medical Devices

This section refers to proper and safe usage of medication and medical devices. The system's functions as as follows:

a. Provide information about proper medical device use
b. Report defects/general issues with devices
c. Assist in the process of informing patients of potential medication/devices risks
d. Aid pharmacists with device recall requests

4. Health Insurance

This sub-category is about handling the health insurance policies/claims that may vary between each patient. This system's functions in the context of this category are:

a. Store patient's insurance-related information
b. Track all types of claims
c. Identify and track medications requiring pre-authorization
d. Connect with insurance providers' systems

5. Medical Inventory

"Medical Inventory" is about the supply, ordering, and inventory stocking process behind a pharmacy, in other words the logistics of a pharmacy. For this process, the system's functions shall be as seen below.

a. Monitor stock levels
b. Track medical shipments
c. Assist in the delivery ordering process
d. Maintain a connection with suppliers
e. Notify pharmacists of medication that requires disposal

2.3 User Classes and Characteristics

<Identify the various user classes that you anticipate will use this product. User classes may be differentiated based on frequency of use, subset of product functions used, technical expertise, security or privilege levels, educational level, or experience. Describe the pertinent characteristics of each user class. Certain requirements may pertain only to certain user classes. Distinguish the most important user classes for this product from those who are less important to satisfy.>

This system will have a variety of user classes who will use the software for different purposes, with differing levels of access and permissions. The first and highest user class will be the administrator. This user shall have access to the entire system and will be able to perform any action they choose, regardless of permission settings. Of course, this user class will be very limited in terms of who can be in this position. Their role will be to manage user accounts, permissions, roles, and other system settings.

The second highest user class is the pharmacy's manager. This user will have access to every part of the system and will be able to change nearly anything in the system, aside from what the administrator can change of course. The pharmacy manager's role is to manage the pharmacists and pharmacy staff, monitor inventory levels, ensure medication compliance, and monitor prescriptions.

The next highest role is the pharmacist. This user will have access to the parts of the system that specifically pertain to the medication delivery process. This process involves verifying prescriptions, dispensing medication, delivering medication to the patient, and providing patient counseling. The pharmacist will be responsible for adhering to this process.

The fourth highest role will be for the pharmacy technicians. These user's role is to assist pharmacists in the dispensing and prescription processes. Thus, they will have access and permissions in the system that pertain to maintaining patient records, assisting in inventory management, entering medication orders, and other administrative tasks.

The last and lowest user classes are for non-administrative and non-medically trained pharmacy staff. These user classes are not guaranteed to be included in a pharmacy, unlike the other users. Additionally, the purpose of these roles is to support the other user's with various tasks, but not perform anything unique themselves. Because of this fact, each of them will have a very limited access to the system, for example the cashier is only able to handle financial transactions. This limited access is meant to allow them to give them the tools to complete their job

while also limiting security risks. These user classes are the cashier, customer service representative, IT support, and external auditors.

2.4 Operating Environment

<Describe the environment in which the software will operate, including the hardware platform, operating system and versions, and any other software components or applications with which it must peacefully coexist.>

The environment in which this software will operate must be up to modern-day standards in order to perform as efficiently and effectively as possible without demanding a large financial investment. The requirements are as follows:

1. A desktop computer with the latest version of Windows installed (Windows 11 at time of writing)

2. The CPU must operate at 2.5 GHz or greater

3. 8 GB or more of memory

4. At least a 256 GB size Hard Drive, SSD is recommended

5. 24” HD monitor (1080p)

6. 21” Touch Screen (1080p)

7. Printer no older than 5 years

8. 5 or more USB ports

9. A stable Internet connection

10. Thermal Printer no older than 7 years

11. Document Scanner no older than 10 years

12. Barcode Scanner no older than 7 years

13. Receipt Printer no older than 7 years

14. Office phone no older than 8 years

15. Keyboard no older than 10 years

16. Digital stylus/pen no older than 5 years

17. Mouse no older than 7 years

2.5 Design and Implementation Constraints

<Describe any items or issues that will limit the options available to the developers. These might include: corporate or regulatory policies or standards, laws; hardware limitations (timing requirements, memory requirements); interfaces to other applications; specific technologies, tools, and databases to be used; parallel operations; language requirements; communications protocols; security considerations; design conventions or programming standards (for example, if the customer's organization will be responsible for maintaining the delivered software).>

There are a multitude of obstacles that will limit the options available to developers. One of the most prominent obstacles being that the system is intended for a pharmaceutical system. Meaning that the guidelines and regulations set by the following agencies and organizations must be implement where appropriate:

1. U.S. Department of Health and Human Services (HHS)
2. Centers for Disease Control and Prevention (CDC)
3. Food and Drug Administration (FDA)
4. Centers for Medicare and Medicaid Services (CMS)
5. National Institutes of Health (NIH)
6. Health Resources and Services Administration (HRSA)
7. Agency for Healthcare Research and Quality (AHRQ)

Additionally, any guidelines or regulations set by individual states/counties must also be adhered to. And it should be noted that many of the policies and regulations from the listed organizations are not able to be fully implemented in the context of a digital software. Regardless, developers must continue to implement the guidelines set to their best ability, with this context in mind of course. This shall be done in order to assist pharmacists in the most effective and efficient way possible.

Outside of the health-related regulations, the relationship that a pharmacy has with its supplier(s) will also limit the system in some regard. This is due to the fact the software described in this document is solely for a pharmacy, not for pharmacy supplier systems. And while the system shall be able to interact with supplier systems to communicate and perform various tasks, the system will also have to conform to the supplier system's specifications. Some examples of these specifications include, but are not limited to: the supplier's systems only accept order requests in a certain format (ex. Excel spreadsheet), a specific communication method must be used for all pharmacys that use this supplier, or translating commands from one programming language to the supplier's system's language.

For the pharmacy itself, any requirements set by the pharmacy management must be followed. These requirements can range from what database language must be used, to user interface considerations, to which third-party applications must be integrated into the system. Regardless of what the requirement is, the requirements set by upper management must be followed.

Although proper security etiquette should be followed despite the system's context, the context of the system being for a pharmacy increases its importance significantly. As patient records, their insurance information, prescriptions, and more must be protected from malicious third-party actors. The consequences of poor security being that a patient's sensitive information is stolen and able to be exploited as well as the pharmacy facing major legal and financial issues as a result. Because of this, security is a top priority for the system and its design should reflect its priority. This could lead to sacrificing/modifying certain components of the software in order to

prioritize security over system effectiveness (ex. requiring pharmacists to re-login after the system remains idle for five minutes).

And of course, the code of ethics produced by the IEEE Computer Society and the Association for Computing Machinery must be followed at all times. This code is adhered to in order to maintain a healthy relationship with the client, minimize potential legal/financial issues caused by poor software engineering ethics, and foster a better software engineering environment.

2.6 User Documentation

<List the user documentation components (such as user manuals, on-line help, and tutorials) that will be delivered along with the software. Identify any known user documentation delivery formats or standards.>

Alongside the software being delivered, there will be multiple resources available for the various different parties that will interact in some way with this software. For the pharmacy management and technicians, release notes will be released following each update for the purpose of keeping clients updated on changes occurring in the software. Additionally, an installation manual will be included in order to guide pharmacist staff/technicians with installing the software on both existing systems as well as new ones.

For the pharmacists and other pharmacy staff, there will be a user manual available to use. This manual will be an extensive guide on how to effectively use the software to complete their various required tasks (ex. inventory management). Furthermore, video tutorials will be available to provide better clarification on certain aspects/actions of the software. And in the event that the pharmacists, pharmacy technicians, or management require further assistance, a help hotline will be available to help users with issues/questions in real time.

For patients, various written and video tutorials as well as a FAQ section will be included. Within these tutorials there will be step-by-step guides on how to use the software to access their records, view prescriptions, etc.

2.7 Assumptions and Dependencies

<List any assumed factors (as opposed to known facts) that could affect the requirements stated in the SRS. These could include third-party or commercial components that you plan to use, issues around the development or operating environment, or constraints. The project could be affected if these assumptions are incorrect, are not shared, or change. Also identify any dependencies the project has on external factors, such as software components that you intend to reuse from another project, unless they are already documented elsewhere (for example, in the vision and scope document or the project plan).>

In terms of assumptions, this system assumes that the following remain true, or at least mostly true. In the event that one of these assumptions is false, it could affect the requirements stated in this SRS.

1. Federal medical-related regulations do not change dramatically during the software's development process.

2. All users have basic computer literacy skills and have used computer user interfaces before.
3. All users have a stable Internet connection in order to communicate with cloud-based services as well as other related applications.
4. Information received from third-parties (other pharmacies, hospitals, the CDC, etc) is correct and up-to-date.

In terms of dependencies, the system depends on the following for healthy and proper operations:

1. Dependence on an external database that holds drug-related information (ex. First Databank).
2. Access to information held in software that the pharmacy previously used, if applicable.
3. Access to a patient's electronic health record (EHR).
4. Access to up-to-date information regarding drug approvals and recalls from licensed federal authorities (ex. FDA Orange Book)

3. System Features

<This template illustrates organizing the functional requirements for the product by system features, the major services provided by the product. You may prefer to organize this section by use case, mode of operation, user class, object class, functional hierarchy, or combinations of these, whatever makes the most logical sense for your product. Only 10 total FR per system category e.g. Prescriptions, Dispensing, etc.>

3.1 Dispensing

<Don't really say "System Feature 1." State the feature name in just a few words. Or just use e,g Dispensing, or Prescriptions, etc. All functional requirements must be updated and corrected. Review my feedback and correct errors, and add the final version of the FRs in this SRS document (-60 pts). >

3.1.1 Description and Priority

<Provide a short description of the feature and indicate whether it is of High, Medium, or Low priority. You could also include specific priority component ratings, such as benefit, penalty, cost, and risk (each rated on a relative scale from a low of 1 to a high of 9).>

This feature relates to the preparation and distribution of medication to patients by pharmacists. The medication given to patients is usually determined by a doctor and is labeled as a "prescription". The pharmacists take the appropriate steps necessary in order to ensure the integrity of the medication for its intended use. Additionally, they follow the prescriber's instructions for the medication in order to treat patients as the prescriber intended. This section details how the system will help pharmacists in the dispensing process and the tasks surrounding it.

Priority: High
Benefit: 9
Cost: 5
Risk: 6

3.1.2 Functional Requirements

<Itemize the detailed functional requirements associated with this feature. These are the software capabilities that must be present in order for the user to carry out the services provided by the feature, or to execute the use case. Include how the product should respond to anticipated error conditions or invalid inputs. Requirements should be concise, complete, unambiguous, verifiable, and necessary. Put a priority on each requirement, reference the use case diagrams each FR corresponds to>

<Each requirement should be uniquely identified with a sequence number or a meaningful tag of some kind.>

REQ-1: The system shall record all completed dispensing transactions in the patient's record. [H] ["Pharmacy Dispensing System"]

> **REQ-1.1:** The record shall include medication name, dosage, quantity, dispensing date, and pharmacist details.

REQ-2: The system shall automatically check for potential drug interactions with the patient's current medications. [H] ["Pharmacy Dispensing System"]

> **REQ-2.1:** The system shall notify the pharmacist when a potential drug interaction is detected.

REQ-3: The system shall generate a medication label for dispensed prescription. [H] ["Pharmacy Dispensing System"]

> **REQ-3.1:** The label shall display the medication name, dosage instructions, patient name, pharmacy contact information, and warnings required by the Food and Drug Administration.

REQ-4: The system shall maintain a history of all prescriptions dispensed to each patient. [H] ["Pharmacy Dispensing System"]

> **REQ-4.1:** The system shall allow pharmacists, pharmacy technicians, and system administrators to view the records.

REQ-5: The system shall calculate dosage using prescription details and patient data. [H] ["Pharmacy Dispensing System"]

> **REQ-5.1:** The system shall alert the pharmacist when the calculated dosage does not match the prescribed dosage.
>
> **REQ-5.2:** The system shall alert the pharmacist when a mismatch is flagged.

REQ-6: The system shall validate each prescription by checking the patient's age, allergies, and current medication. [H] ["Pharmacy Dispensing System"]

REQ-7: The system shall verify the details before confirming the dispense. [H] [“Pharmacy Dispensing System”]

REQ-7.1: The details include the medication name, dosage, and quantity match the prescription exactly before allowing the dispense.

REQ-8: The system shall verify the availability of prescribed medications in stock. [M] [“Pharmacy Dispensing System”]

REQ-8.1: The system shall suggest alternative medications if the prescribed medication is unavailable.

REQ-8.2: The system shall notify the patient if no alternatives are available.

REQ-9: The system shall allow patients to return unused medication within the pharmacy’s return policy. [L] [“Pharmacy Dispensing System”]

REQ-9.1: The pharmacy’s return policy shall be that the medication has never been opened, the container has not been modified, and that whomever is returning it must present their name, ID, address, Social Security Number, and reason for returning.

REQ-10: The system shall prompt the pharmacist to provide a consultation regarding the medication’s usage, side effects, storage, and precautions before dispensing. [L] [“Pharmacy Dispensing System”]

3.2 Prescriptions

3.2.1 Description and Priority

Prescriptions refers to the set of instructions and medication ordered to be distributed to patients. These instructions and the medication associated with them are given to pharmacists by doctors, physicians, and other licensed medical professionals. These instructions include the preparation, compounding, and administration of the medicine. This prescription is only authorized to dispense a specific medication to a specific patient. The requirements detailed in the next section (3.2.2) are for the purpose of helping pharmacists manage prescriptions easier and distribute them to patients more efficiently.

Priority: High

Benefit: 8
Cost: 6
Risk: 5

3.2.2 Functional Requirements

REQ-11: The system shall allow the pharmacist to validate the prescription information. [H] [“Pharmacy Prescription System”]

> **REQ-11.1:** The prescription information shall include the patient’s name, date of birth, address, drug name, dosage, quantity, prescribing physician’s name, DEA number, and the doctor’s signature.
>
> **REQ-11.2:** The pharmacist shall contact the doctor for clarification before dispensing the medication when discrepancies are found.

REQ-12: The system shall check for potential drug contraindications and patient allergies by cross-referencing the patient’s medical history. [H] [“Pharmacy Prescription System”]

> **REQ-12.1:** The system shall prevent prescription fulfillment when a life-threatening interaction is detected.

REQ-13: The system shall require the pharmacist to verify the patient’s identity using a government-issued photo ID. [H] [“Pharmacy Prescription System”]

> **REQ-13.1:** When the prescription is for a controlled substance, the system shall require the pharmacist to log the patient’s ID in the system for auditing purposes.
>
> **REQ-13.2:** In the case of a minor or incapacitated patient, the system shall require the pharmacist to verify the identity of the legal guardian or caregiver using a government-issued photo ID.
>
> **REQ-13.3:** The pharmacist shall cross-reference the patient’s identity with the prescription details before dispensing medication.

REQ-14: The system shall retrieve and display the prescriber’s name, license number, and issuing authority from the prescription. [M] [“Pharmacy Prescription System”]

> **REQ-14.1:** The system shall display a warning if the prescriber’s credentials are invalid, expired, or unrecognized.

REQ-14.1.1: The system shall prevent prescription processing if prescriber verification fails.

REQ-15: The system shall maintain a digital record of each filled prescription. [M] [“Pharmacy Prescription System”]

REQ-15.1: The system shall allow authorized pharmacists to retrieve prescription records for regulatory compliance.

REQ-15.2: The system shall maintain an electronic log of all controlled substance prescriptions filled.

REQ-15.2.1: The system shall restrict controlled substance dispensing based on refill limitations, prescription expiration, and daily dosage limits.

REQ-15.3: The system shall ensure that deleted or modified prescription records are logged with timestamps for tracking purposes.

REQ-15.4: The system shall retain all prescription records for a minimum of five years.

REQ-16: The system shall generate prescription labels. [L] [“Pharmacy Prescription System”]

REQ-16.1: The label shall include the patient’s name, drug name, dosage, quantity, administration instructions, expiration date, the prescribing doctor’s full name, prescribing doctor’s medical license number, pharmacy address, and pharmacy phone number for patient inquiries.

REQ-16.2: If the medication has specific storage requirements (e.g., refrigeration), this information shall be displayed.

REQ-17: The pharmacist shall provide counseling to the patient. [L] [“Pharmacy Prescription System”]

REQ-17.1: Counseling shall include dosage instructions, possible side effects, contraindications, and storage instructions.

REQ-17.2: The pharmacist shall document on the patient's record whether counseling was accepted or declined by the patient.

REQ-17.3: For high-risk medications, the system shall require a mandatory counseling session before dispensing the medication.

REQ-17.3.1: The system shall reference an internal list of high-risk medications defined by the pharmacy's drug database.

REQ-18: The system shall allow pharmacists to process refill requests. [M] [“Pharmacy Prescription System”]

REQ-18.1: The refill requests shall be processed under the conditions that the prescription explicitly states the number of refills allowed.

REQ-18.2: The system shall verify that the refill request falls within the allowable dispensing time frame specified in the prescription.

REQ-18.3: The system shall provide the patient with an option to send a refill request to the pharmacist when the prescription is expired.

REQ-18.3.1: The system shall detect when a prescription is expired based on the expiration date.

REQ-18.3.2: The system shall notify the patient via SMS or email if their prescription is expired.

REQ-18.4: The system shall notify patients via SMS or email when their prescription is ready for refill.

REQ-19: The system shall receive and store electronic prescriptions from licensed healthcare providers. [M] [“Pharmacy Prescription System”]

REQ-19.1: The system shall ensure compliance with federal and state regulations.

REQ-19.2: The system shall verify the pharmacist’s digital signature on an electronic prescription using a Public Key Infrastructure (PKI)-based certificate validation process.

REQ-19.2.1: The system shall reject electronic prescriptions if the pharmacist's digital certificate is invalid, expired, or revoked.

REQ-19.3: The system shall store the original electronic prescription document for a minimum of 5 years.

REQ-20: The system shall process insurance claims for prescribed medications. [L] ["Pharmacy Prescription System"]

REQ-20.1: The system shall verify insurance coverage for each prescribed medication by querying the patient's insurance provider.

REQ-20.2: The system shall display cost details before completing the transaction.

REQ-20.2.1: Cost details include insurance-covered amount and patient co-pay.

REQ-20.3: The system shall allow patients to proceed with payment if a prescribed medication is not covered by insurance.

3.3 Medication and Medical Devices

3.3.1 Description and Priority

This section refers to the medication itself as well as the medical devices operated by the pharmacy. The general attributes associated with the medication and medical devices will be detailed in the functional requirement section (3.3.2). These attributes are the documentation for proper use, regulations, risks associated, and recall information.

Priority: Medium
Benefit: 7
Cost: 9
Risk: 5

3.3.2 Functional Requirements

REQ-21: The supplier shall provide the documentation for the proper use, maintenance, and adverse effects or risks of its medical device or medication. [H] ["Pharmacy Medication and Medical Devices System"]

REQ-21.1: Documentation for medical devices shall include how to operate the device, what risks there are in operating the device, how to sanitize the device, and how to dispose of the device when it is no longer functioning.

REQ-21.2: Documentation for medication shall include how much of the medication needs to be taken, at what times the medication needs to be taken, what risks the medication has if taken with other drugs, and how to dispose of any excess medication not taken.

REQ-21.3: The system shall print out the documentation for the proper use and maintenance of the medical device or medication.

REQ-21.4: The documentation shall be provided within the packaging alongside the medical device or medication.

REQ-22: The pharmacist shall inform the patient of risks connected to the operation of the medical device provided. [H] [“Pharmacy Medication and Medical Devices System”]

REQ-22.1: Patients shall validate in a written statement that they have been informed of the risks of the medical device by the pharmacist.

REQ-23: The pharmacist shall report adverse side effects, defects, and/or risks that were not previously disclosed in the documentation of the medication or medical device to the supplier. [H] [“Pharmacy Medication and Medical Devices System”]

REQ-23.1: Adverse side effects, defects, and risks will be identified through patients reporting any adverse side effects, defects, or risks that they have experienced to the pharmacist.

REQ-23.2: Patients shall submit reports of adverse side effects, defects, or risks through a form submission into the system.

REQ-24: The pharmacist shall not provide a patient any medical product that has been recalled. [H] [“Pharmacy Medication and Medical Devices System”]

REQ-25: The supplier shall adhere to Title 21, Subchapter D of the Code of Federal Regulation when producing and distributing medications. [H] [“Pharmacy Medication and Medical Devices System”]

REQ-26: The supplier shall adhere to Title 21, Subchapter H of the Code of Federal Regulation when producing and distributing medical devices. [H] [“Pharmacy Medication and Medical Devices System”]

REQ-27: The pharmacist shall inform the patient of adverse side effects of the medication prescribed. [H] [“Pharmacy Medication and Medical Devices System”]

REQ-27.1: Patients shall validate in a written statement that they have been informed of the adverse side effects of the medication by the pharmacist.

REQ-28: The pharmacist shall read the documentation pertaining to the use and risks of a medical product. [H] [“Pharmacy Medication and Medical Devices System”]

REQ-28.1: The documentation pertaining to the medical product shall be read in its entirety by the pharmacist before the pharmacist provides the medical product to patients.

REQ-28.2: The pharmacist shall not recommend a medical product without having read the necessary documentation pertaining to the product.

REQ-28.3: The system will request the pharmacist to confirm that they have read the documentation before allowing them to provide a medical product.

REQ-29: The pharmacist shall inform any patient if a medical product they have been previously provided has been recalled within 24 hours of being notified of the recall by the supplier. [M] [“Pharmacy Medication and Medical Devices System”]

REQ-30: The pharmacist shall submit a form providing a reason why a medical device or medication was returned by a patient into the system. [H] [“Pharmacy Medication and Medical Devices System”]

3.4. Health Insurance

3.4.1 Description and Priority

This section relates to the health insurance associated with each pharmacy patient. Typically, insurance plans and policies differ from patient to patient for a multitude of

reasons. As such, the requirements listed below address how the system and pharmacies will handle patient insurance plans and everything associated with them. The goal is to make this middleman process less tedious and faster for pharmacists, since it does not directly relate to the medication's preparation and delivery.

Priority: Medium
Benefit: 6
Cost: 4
Risk: 2

3.4.2 Functional Requirements

REQ-31: The pharmacist shall store patient insurance information in the patient's record. [H] ["Pharmacy Health Insurance System"]

> **REQ-31.1:** Patient insurance information includes insurance provider, insurance date issued, insurance expiration date along with primary, secondary, and tertiary policies specified by the healthcare provider.

REQ-32: The system shall connect to insurance provider databases to verify insurance coverage in real-time. [H] ["Pharmacy Health Insurance System"]

REQ-33: The pharmacist shall store logs of reimbursements on the patient's record. [H] ["Pharmacy Health Insurance System"]

> **REQ-33.1:** Reimbursement logs shall include the amount, date, payer details, reason, and any comments.
>
> **REQ-33.2:** The payer is the person or company handling the reimbursement of a patient (e.g., insurance provider, supplier).
>
> **REQ-33.3:** Payer details include name, pay type (e.g., medicaid, medicare, private insurance), payment method (e.g., check, online, direct deposit), insurance company code, customer service phone number, mailing address, and payer transaction reference ID.

REQ-34: The pharmacist shall track the status of submitted claims on the patient's record. [H] ["Pharmacy Health Insurance System"]

> **REQ-34.1:** The system shall notify the pharmacists of any updates or changes to submitted claims within 24 hours.

REQ-35: The system shall identify medications requiring pre-authorization. [H]

["Pharmacy Health Insurance System"]

REQ-35.1: The system shall generate a Pre-authorization Request Form (PAF).

REQ-35.2: The system shall assist in submitting the PAF.

REQ-35.3: The PAF document shall contain patient details, prescriber information, and medication details often given by the insurance provider.

REQ-35.4: The NCPDP shall provide the needed details if the insurance provider fails to produce them.

REQ-35.5: Patient details shall include name, phone number, email, date of birth, gender, social security number, and address.

REQ-35.6: Prescriber information shall include prescriber name, phone number, email, office/clinic address, National Provider Identifier number, medical license number, and specialty of work (e.g., psychiatrist, oncologist, general practitioner).

REQ-36: The system shall notify pharmacists of insurance coverage limits, pre-authorizations, and copays within 10 minutes. [H] ["Pharmacy Health Insurance System"]

REQ-37: The pharmacists shall track the status of pre-authorization requests. [M] ["Pharmacy Health Insurance System"]

REQ-37.1: The system shall notify pharmacists of updates to pre-authorization requests within 24 hours.

REQ-38: The system shall calculate insurance coverages and out-of-pocket expenses to patients based on their insurance plan within 5 minutes. [M] ["Pharmacy Health Insurance System"]

REQ-39: The pharmacist shall submit insurance claims electronically within 48 hours. [M] ["Pharmacy Health Insurance System"]

REQ-39.1: Submitted insurance claims shall follow the National Council of Prescription Drug Programs' standards.

REQ-40: The system shall provide resources for the pharmacist to appeal denied claims. [L] [“Pharmacy Health Insurance System”]

3.5. Medical Inventory

3.5.1 Description and Priority

“Medical Inventory” refers to the logistics behind a pharmacy. The process of ordering new supplies, disposing of old supplies, connecting with suppliers, etc. Additionally, the inventory stock levels of the pharmacy are also included in this section. The requirements present here are for the maintenance of a healthy supply chain as well as facilitating a more streamlined experience for the pharmacy when interacting with suppliers and distributors.

Priority: Medium
Benefit: 8
Cost: 6
Risk: 5

3.5.2 Functional Requirements

REQ-41: The system shall monitor the stock levels of the medication inventory to ensure that a medication does not drop below 50% of its max capacity. [H] [“Pharmacy Medical Inventory System”]

> **REQ-41.1:** The system shall notify the pharmacist if a medication’s supply drops below 50% capacity.

REQ-42: The system shall notify pharmacy staff of medication that must be disposed of because it is mislabeled. [H] [“Pharmacy Medical Inventory System”]

> **REQ-42.1:** Mislabeled medication refers to medication whose national drug code, brand name, generic name, form, dosage strength, total amount, lot number, expiration date, medication instructions, manufacturer date, distribution source, or barcode is incorrect when compared to its entry in DailyMed.

REQ-43: The system shall notify pharmacy staff of medication which is set to expire within the next two months. [H] [“Pharmacy Medical Inventory System”]

REQ-44: The system shall track a medication's location, from the supplier's warehouse to sale in the pharmacy. [H] ["Pharmacy Medical Inventory System"]

REQ-45: The system shall allow the creation of user roles for different staff members, with different permissions associated. [H] ["Pharmacy Medical Inventory System"]

REQ-46: The system shall notify suppliers of any failed delivery, after its inspection. [H] ["Pharmacy Medical Inventory System"]

> **REQ-46.1:** Failed deliveries occur when a delivery does not include the entire shipment of ordered medication, has been tampered, or does not include accurate medication instructions and information.
>
> **REQ-46.2:** The system shall allow pharmacy staff to submit return requests to their suppliers following a failed delivery.

REQ-47: The system shall update the stock levels following a successful delivery after pharmacy staff confirmation. [M] ["Pharmacy Medical Inventory System"]

> **REQ-47.1:** The confirmation of the update shall be approved by pharmacy staff within 24 hours of the delivery.

REQ-48: The system shall allow pharmacy staff to generate a list of medications to be ordered, based on low medication stock levels. [M] ["Pharmacy Medical Inventory System"]

> **REQ-48.1:** The system shall verify the contents of the list by cross referencing the list's contents with current stock levels.

REQ-49: The system shall allow pharmacy staff to submit a medication order list to their suppliers. [M] ["Pharmacy Medical Inventory System"]

> **REQ-49.1:** This list shall include the medication's name, manufacture date, national drug code, brand name, generic name, form, dosage strength, total amount, lot number, expiration date, medication instructions, manufacturer date, distribution source, barcode, supplier name, and quantity.

REQ-50: The system shall accept confirmation reports from suppliers that verify a shipment's successful order. [L] ["Pharmacy Medical Inventory System"]

REQ-50.1: These confirmation reports will contain the shipment's ID, date of delivery, date of warehouse departure, driver(s) name and ID, medication name, medication ID, and the current date.

REQ-50.2: The system shall notify the pharmacy staff once a report is received within 24 hours.

4. Other Nonfunctional Requirements

<all non-functional requirements must be updated and corrected. Review my feedback and correct errors, and add the final version of the NFRs in this SRS document (-40 pts). Only 4 total NFR per system category e.g. Prescriptions, Dispensing, etc >

text

4.1 Performance Requirements

<If there are performance requirements for the product under various circumstances, state them here and explain their rationale, to help the developers understand the intent and make suitable design choices. Specify the timing relationships for real time systems. Make such requirements as specific as possible. You may need to state performance requirements for individual functional requirements or features. Add a priority on each NFR >

Dispensing:

NFR-1: The dispensing system shall process prescriptions within 2 seconds. [L]

NFR-2: The dispensing system shall provide a clear and structured interface for pharmacy technicians and pharmacists. [L]

NFR-2.1: The dispensing system shall display labels and instructions for entering prescriptions, verifying medications, and printing labels. [L]

Prescriptions:

NFR-3: The prescription system shall generate prescription labels within 5 seconds. [L]

NFR-3.1: When a system delay occurs, a notification shall be displayed to the pharmacist with an estimated processing time. [L]

NFR-4: The prescription system shall generate compliance reports monthly. [M]

NFR-4.1: Compliance reports shall track prescription errors, controlled substance logs, and pharmacist interventions. [M]

NFR-4.2: The reports shall be accessible to authorized pharmacists in a downloadable format (PDF, CSV). [L]

NFR-4.3: The system shall allow filtering reports based on date range, prescriber, drug category, and patient demographic data. [L]

Medication and Medical Devices:

NFR-5: Documentation for medical products provided by the supplier shall be written to be understood by persons with no previous medical background. [L]

NFR-6: The pharmacist shall be available Monday through Friday from 6 AM to 10 PM to answer questions from a patient about the risks or adverse effects of a medical product by telephone and electronic mail. [L]

Health Insurance:

Medical Inventory:

NFR-7: The inventory system shall require a name, ID, timestamp, and reason for edit to be included whenever a pharmacist edits the inventory logs. [M]

4.2 Safety Requirements

<Specify those requirements that are concerned with possible loss, damage, or harm that could result from the use of the product. Define any safeguards or actions that must be taken, as well as actions that must be prevented. Refer to any external policies or regulations that state safety issues that affect the product's design or use. Define any safety certifications that must be satisfied. Add a priority on each NFR >

Dispensing:

NFR-8: The dispensing system shall ensure 99.9% uptime during the dispensing process. [H]

Prescriptions:

NFR-9: The prescription system shall maintain an uptime of 99.5%. [H]

NFR-9.1: The system shall have a data recovery plan. [H]

NFR-9.2: Scheduled maintenance shall not exceed 30 minutes of downtime per week. [M]

NFR-9.3: Scheduled maintenance shall be performed from 12:00 AM - 12:30 AM. [M]

Medication and Medical Devices:

NFR-10: Reports providing information for a recall of a medical product, including name of the affected product, reason for the recall, and how many units are impacted shall be delivered from the supplier to the pharmacist within 24 hours. [M]

NFR-11: Patients will be informed if a medical product provided to them was recalled within 24 hours. [H]

Health Insurance:

NFR-12: The insurance system shall maintain a 99% uptime to ensure verification and claims processing happen uninterrupted. [H]

NFR-12.1: The system shall be back up and running within 1 hour on the off chance of it going down. [M]

NFR-13: The insurance system shall maintain a connection with insurance databases 99% of the time during pharmacy hours. [H]

Medical Inventory:

NFR-14: The inventory management system shall maintain a 99% system uptime. [H]

NFR-15: The inventory system shall maintain a connection between the pharmacy and its suppliers 99.9% of the time. [H]

NFR-15.1: This connection shall be used to send reports and receive reports between the pharmacy and their suppliers. [M]

4.3 Security Requirements

<Specify any requirements regarding security or privacy issues surrounding use of the product or protection of the data used or created by the product. Define any user identity authentication requirements. Refer to any external policies or regulations containing security issues that affect the product. Define any security or privacy certifications that must be satisfied. Add a priority on each NFR >

Dispensing:

NFR-16: The system shall ensure that patient data, prescription details, and medication history are encrypted. [H]

NFR-16.1: Access to sensitive information shall be restricted to authorized users (pharmacists, technicians). [H]

Prescriptions:

NFR-17: The system shall comply with the Health Insurance Portability and Accountability Act's regulations. [H]

NFR-17.1: The system shall use multi-factor authentication for pharmacists accessing prescription data. [H]

NFR-17.1.1: The system shall validate multi-factor authentication using the pharmacist's system password and a verification code sent to their registered work email address. [H]

Medication and Medical Devices:

Health Insurance:

NFR-18: The system shall comply with the Health Insurance Portability and Accountability Act "Privacy Rule" to protect patient insurance data. [H]

NFR-19: The system shall adapt to changes in the Product Liability Insurance Policy within 24 hours. [H]

Medical Inventory:

NFR-20: The system shall have a multi-factor authentication system that requires the pharmacist's username, password, ID, and phone number to verify their identity. [H]

4.4 Requirements Traceability Matrix

<Create a comprehensive detailed traceability matrix. Identify which functional requirements (FR) are impacted by each non-functional requirement (NFR). State their relationship, dependency or quality attribute each one provides, as well as additional components that will add value, see my lecture slides on requirements traceability matrix. Ensure that each dependency is explicitly stated. Only Show the FR that corresponds to an NFR and maintain the same number system you used in the previous questions within this document. Provide a detailed introduction and explanation about your traceability matrix and its purpose, because programmers, testers and other stakeholders will need this vital information.>

Functional Requirement	Corresponding Non-functional Requirement	Dependency
FR-1: The system shall record all completed dispensing	**NFR-3**: The system shall ensure that patient data,	Security requirement — protects sensitive data from

transactions in the patient's record.	prescription details, and medication history are encrypted.	unauthorized access.
FR-2: Validate each prescription by checking patient's age, allergies, and current medications.	**NFR-1:** The system shall process prescriptions within 2 seconds.	Performance requirement — ensures validations (age, allergies, meds) happen instantly to avoid delay.
FR-3: The system shall notify the pharmacist when a potential drug interaction is detected.	**NFR-1:** The system shall process prescriptions within 2 seconds.	Performance requirement — enables fast interaction checks during prescription review.
FR-4: The system shall suggest alternative medications if the prescribed medication is unavailable.	**NFR-4:** The system shall provide a clear and structured interface for pharmacy technicians and pharmacists.	Usability requirement — makes alternative medication suggestions easy to view and act on.
FR-5: The system shall alert the pharmacist when the calculated dosage does not match the prescribed dosage.	**NFR-1:** The system shall process prescriptions within 2 seconds.	Performance requirement — enables fast alerts for dosage mismatches to prevent errors.
FR-6: The label shall display medication name, dosage instructions, patient name, pharmacy contact info, and FDA warnings.	**NFR-4:** The system shall display labels and instructions for entering prescriptions, verifying medications, and printing labels without delays that could	Usability requirement — helps create clear, compliant, and readable labels efficiently.
FR-7: The system shall verify medication name, dosage, and quantity before allowing dispense.	**NFR-4**: The system shall display labels and instructions for entering prescriptions, verifying medications, and printing labels.	Usability requirement — enhances visual clarity during medication verification.
FR-8: The system shall prompt the pharmacist to provide a consultation before dispensing.	**NFR-1**: The system shall process prescriptions within 2 seconds.	Performance requirement — enables fast alerts for dosage mismatches to prevent errors.
FR-9: The system shall allow pharmacists, pharmacy technicians, and admins to view records.	**NFR-3.1**: Access to sensitive information shall be restricted to authorized users.	Security requirement — only authorized roles (pharmacist, tech, admin) can access sensitive records.
FR-10: The system shall allow patients to return unused medication within the pharmacy's return policy.	**NFR-2:** The system shall ensure 99.9% uptime, minimizing any interruptions to the dispensing process.	Availability requirement — ensures the return policy workflow is always available during pharmacy hours.

FR-11: The system shall allow the pharmacist to validate the prescription information.	**NFR-5.1:**The system shall use multi-factor authentication for pharmacists accessing prescription data.	Security requirement to ensure all data to be verified is secure and appropriately accessed.
FR-12: The system shall check for potential drug contraindications and patient allergies by cross-referencing the patient's medical history.	**NFR-6:** The pharmacy prescription system shall maintain an uptime of 99.5%.	Performance requirement to ensure the system can verify and cross-reference data between databases at all times.
FR-13: The system shall require the pharmacist to verify the patient's identity using a government-issued photo ID.	**NFR:5:** The system shall comply with the Health Insurance Portability and Accountability Act's regulations.	Security requirement ensures that all parties accessing the patients data are authorized to do so.
FR-14: The system shall retrieve and display the prescriber's name, license number, and issuing authority from the prescription.	**NFR-8.1:** The system shall generate compliance reports monthly.	Security requirement to ensure that the patient's data is logged and keeping the logged data safe and secure.
FR-15: The system shall maintain a digital record of each filled prescription.	**NFR-6.1:** The system shall have a data recovery plan.	Performance requirement to ensure that all data is recoverable from a back-up if lost.
FR-16: The system shall generate prescription labels.	**NFR-7:** The system shall generate prescription labels within 5 seconds.	Performance requirement to ensure the system can generate the labels accurately and efficiently.
FR-17: The pharmacist shall provide counseling to the patient.	**NFR-8.1:** Compliance reports shall track prescription errors, controlled substance logs, and pharmacist interventions.	Safety requirement to ensure the system has the ability to document counselling sessions between pharmacist and patient.
FR-18: The system shall allow pharmacists to process refill requests.	**NFR-5.1:** The system shall use multi-factor authentication for pharmacists accessing prescription data.	Security requirement to ensure only authorized pharmacists with valid credentials can access prescription data.

FR-19: The system shall receive and store electronic prescriptions from licensed healthcare providers.	**NFR-6.1:** The system shall have a data recovery plan.	Performance requirement to ensure all healthcare prescription data is recoverable in case of system data loss.
FR-20: The system shall process insurance claims for prescribed medications.	**NFR-5:** The system shall comply with the Health Insurance Portability and Accountability Act's regulations.	Security requirement to ensure that patient's insurance rights and data are protected.

FR-21: The supplier shall provide the documentation for the proper use, maintenance, and adverse effects or risks of its medical device or medication.	**NFR-9:** Documentation for medical products provided by the supplier shall be written to be easily understood by persons with no previous medical background.	Usability of the documentation for medical devices relies on it being easily understandable to the general populace.
FR-21: The supplier shall provide the documentation for the proper use, maintenance, and adverse effects or risks of its medical device or medication.	**NFR-9:** Documentation for medical products provided by the supplier shall be written to be easily understood by persons with no previous medical background.	Usability of the documentation for medications relies on it being easily understandable to the general populace.
FR-24: The pharmacist shall inform the patient of adverse side effects of the medication prescribed.	**NFR-10:** The pharmacist shall be available Monday through Friday from 6 AM to 10 PM to answer questions from a patient about the risks or adverse effects of a medical product by telephone and electronic mail.	Having the pharmacist available for questions by these means allows for availability to patients who need more information on a medication.
FR-25: The pharmacist shall inform the patient of risks connected to the operation of the medical device provided.	**NFR-10:** The pharmacist shall be available Monday through Friday from 6 AM to 10 PM to answer questions from a patient about the risks or adverse effects of a medical product by telephone and electronic mail.	Having the pharmacist available for questions by these means allows for availability to patients who need more information on a medical device.
FR-27: The pharmacist shall report adverse side effects, defects, and/or risks that were not previously disclosed in the	**NFR-11:** Reports providing information for a recall of a medical product, including name of the affected product,	Performance requirements should be set to ensure speedy informing of adverse side effects for medication to

documentation of the medication or medical device to the supplier.	reason for the recall, and how many units are impacted shall be delivered from the supplier to the pharmacist within 24 hours.	the supplier.
FR-27: The pharmacist shall report adverse side effects, defects, and/or risks that were not previously disclosed in the documentation of the medication or medical device to the supplier.	**NFR-11:** Reports providing information for a recall of a medical product, including name of the affected product, reason for the recall, and how many units are impacted shall be delivered from the supplier to the pharmacist within 24 hours.	Performance requirements should be set to ensure speedy informing of defects of medical devices to the supplier.
FR-30: The pharmacist shall inform any patient if a medical product they have been previously provided has been recalled within 24 hours of being notified of the recall by the supplier.	**NFR-12:** Patients will be informed if a medical product provided to them was recalled within 24 hours.	Performance requirements should be set to ensure speedy informing of any recalls to patients and thus ensure safety.

FR-31: The pharmacist shall store patient insurance information in the patient's record.	**NFR-15:** The system shall maintain a connection with insurance databases 99% of the time during pharmacy hours.	Storing patient insurance data relies on the information coming from insurance databases.
FR-32: The system shall connect to insurance provider databases to verify insurance coverage in real-time.	**NFR-15:** The system shall maintain a connection with insurance databases 99% of the time during pharmacy hours.	To keep track of insurance coverages in real-time, the system needs to be reliable and consistent when connecting with providers databases.
FR-33: The system shall notify pharmacists of insurance coverage limits, pre-authorizations, and copays within 10 minutes.	**NFR-14:** The system shall comply with the Health Insurance Portability and Accountability	Dealing with patient insurance information needs to be handled with care to protect patient data and privacy.

	Act “Privacy Rule” to protect patient insurance data.	
FR-34: The pharmacist shall submit insurance claims electronically within 48 hours.	**NFR-15:** The system shall maintain a connection with insurance databases 99% of the time during pharmacy hours.	Submitting insurance claims requires connection to insurance databases.
FR-35: The pharmacist shall track the status of submitted claims on the patient's record.	**NFR-13:** The insurance system shall maintain a 99% uptime to ensure verification and claims processing happen uninterrupted.	Updates and changes to claims need to be tracked all the time so the system needs consistent up-time.
FR-37: The pharmacists shall track the status of pre-authorization requests.	**NFR-13:** The insurance system shall maintain a 99% uptime to ensure verification and claims processing happen uninterrupted.	Maintaining the system's uptime will help with tracking status’ for patients.
FR-38: The system shall provide resources for the pharmacist to appeal denied claims.	**NFR-13:** The insurance system shall maintain a 99% uptime to ensure verification and claims processing happen uninterrupted.	The system needs to be up and running to fetch resources for the pharmacist to assist patients.
FR-39: The pharmacist shall store logs of reimbursements on the patient's record.	**NFR-14:** The system shall comply with the Health Insurance Portability and Accountability	The details of patients need to be stored safely and correctly, respecting patient privacy information.

	Act “Privacy Rule” to protect patient insurance data.	
FR-40: The system shall calculate insurance coverages and out-of-pocket expenses to patients based on their insurance plan within 5 minutes.	**NFR-13:** The insurance system shall maintain a 99% uptime to ensure verification and claims processing happen uninterrupted.	To compute the patients breakdowns, the system needs to keep a reliable connection with provider databases to get that important information.

FR-41: The system shall monitor the stock levels of the medication inventory to ensure that a medication does not drop below 50% of its max capacity.	**NFR-17:** The inventory management system shall maintain a 99% system uptime.	Relies on system uptime in order to function in real time.
FR-44: The system shall track a medication’s location, from the supplier’s warehouse to sale in the pharmacy.	**NFR-19:** The system shall maintain a connection between the pharmacy and its suppliers 99.9% of the time.	Only able to track a medication’s location during the delivery process if the pharmacy and supplier have a digital connection to each other.
FR-45: The system shall notify suppliers of any failed delivery, after its inspection.	**NFR-19:** The system shall maintain a connection between the pharmacy and its suppliers 99.9% of the time.	The pharmacy is only able to notify the supplier if they have a connection with them.
FR-46: The system shall update the stock levels following a successful delivery after pharmacy staff confirmation.	**FR-20:** The system shall require a name, ID, timestamp, and reason for edit to be included whenever a pharmacist edits the inventory logs.	Pharmacy staff must verify themselves before editing the logs on the inventory, including when gaining supplies.
FR-47: The system shall allow pharmacy staff to generate a list of medications to be	**FR-18:** The system shall have a multi-factor authentication system that requires the pharmacist’s username,	The multi-factor authentication system prevents non-pharmacy staff from ordering medication.

ordered, based on low medication stock levels.	password, ID, and phone number to verify their identity.	
FR-48: The system shall allow pharmacy staff to submit a medication order list to their suppliers.	**FR-18:** The system shall have a multi-factor authentication system that requires the pharmacist's username, password, ID, and phone number to verify their identity.	There must be a connection present between the two parties in order for the pharmacy to send the list and for the supplier to accept the list.
FR-49: The system shall accept confirmation reports from suppliers that verify a shipment's successful order.	**FR-19:** The system shall maintain a connection between the pharmacy and its suppliers 99.9% of the time.	There must be a connection present between the two parties in order for the system to accept reports of any kind from their supplier.

Appendix A: Glossary

<Define all the terms necessary to properly interpret the SRS, including acronyms and abbreviations. You may wish to build a separate glossary that spans multiple projects or the entire organization, and just include terms specific to a single project in each SRS. Provide detailed description for each UML diagram you include.>

1. Food and Drug Administration (FDA) - the United States federal agency whose responsibility is to protect and promote public health via the control and supervision of food safety, tobacco products, caffeine products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products. Their primary goal is to enforce the laws and regulations that fall under the Federal Food, Drug, and Cosmetic Act (FD&C).

2. Dose - a quantity of a medicine or drug taken or recommended to be taken at a particular time.

3. Dosage - the size or frequency of a dose of a medicine or drug.

4. Prescription - an instruction written by a medical practitioner that authorizes a patient to be provided a medicine or treatment.

5. Drug Enforcement Administration (DEA) - a United States federal law enforcement agency under the U.S. Department of Justice tasked with the purpose to combat illicit drug trafficking and distribution within the U.S.

6. Short Message Service (SMS) - a text messaging service that allows the exchange of short text messages between mobile devices.

7. National Council for Prescription Drug Programs (NCPDP) - an American nonprofit standards development organization that represents most of the sectors that fall under the U.S. pharmacy services industry.

8. Pre-authorization Request Form (PAF) - a document used to obtain prior approval from a health insurance plan before receiving certain medical services or medications.

9. Health Insurance Portability and Accountability Act of 1996 (HIPAA) - establishes federal standards protecting sensitive health information from disclosure without patient's consent.

10. Contraindication - a condition that serves as a reason not to take one or multiple certain medications due to the harm that it could cause the patient or will cause the patient.

11. Public Key Infrastructure (PKI) - a system that uses digital certificates to verify the identity of users and devices, and to secure communication channels.

12. Primary Insurance - insurance policy that pays first for a claim. It's the first line of defense for covering costs, and it pays up to the limits of its coverage.

13. Secondary Insurance - insurance plan that pays for medical expenses after the primary insurance plan has paid. It can also be called supplemental or voluntary insurance.

14. Tertiary Insurance - This is a third-party coverage that comes into play after both the primary and secondary insurances have paid their parts. It is not often used but is an exception when complex situations where multiple coverages are necessary.

15. Standard Operating Procedures (SOPs) - A written set of instructions that describe how to perform a task or process safely and effectively.

16. Claim - Formal request for reimbursement from an insurance company for covered losses.

17. Coverage - The amount of risk or liability that an insurance policy protects.

18. Deductibles - A specified amount of money that the insured must pay before an insurance company will pay a claim.

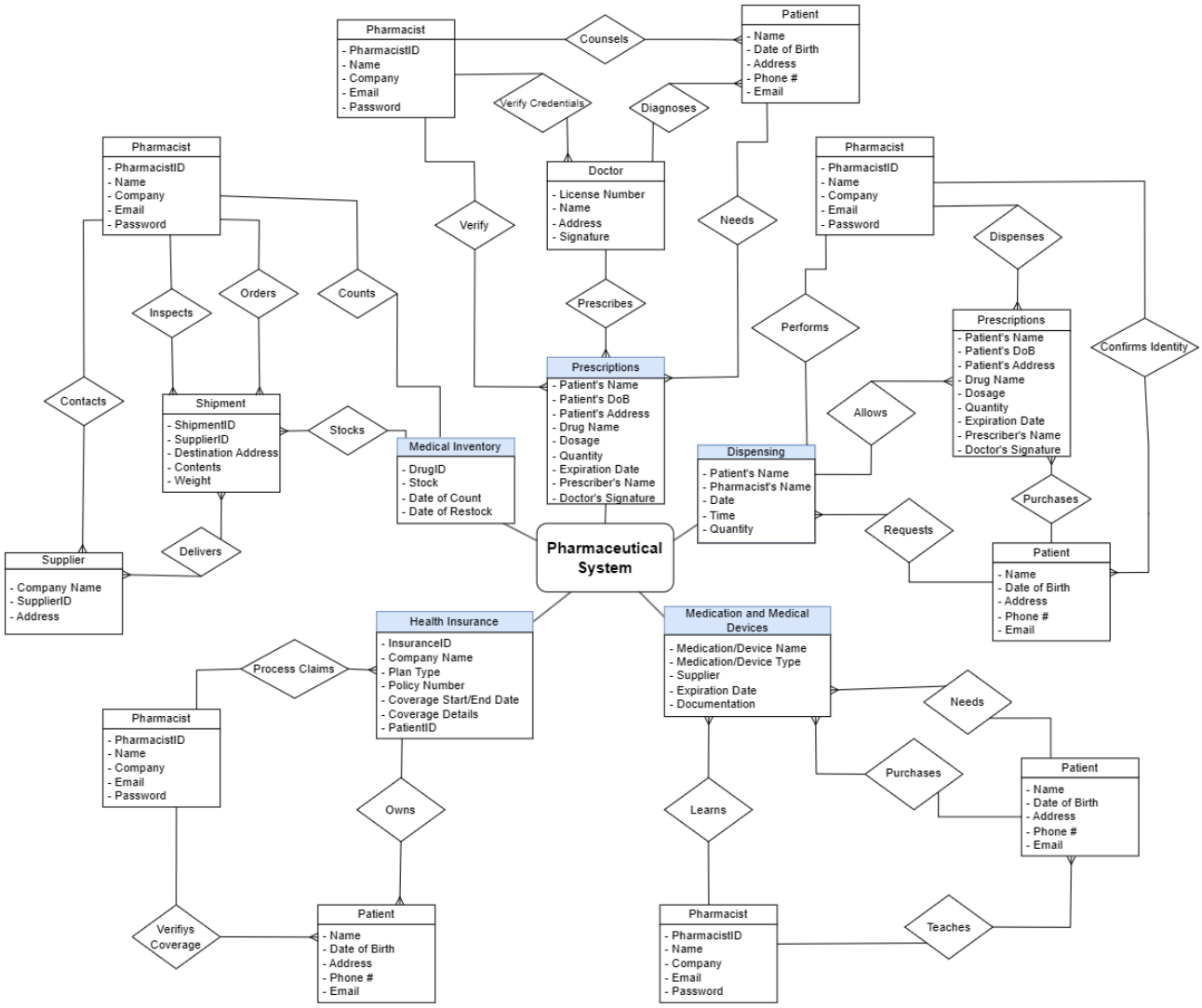
19. Co-pay - A set amount of money a patient pays for a covered health care service.

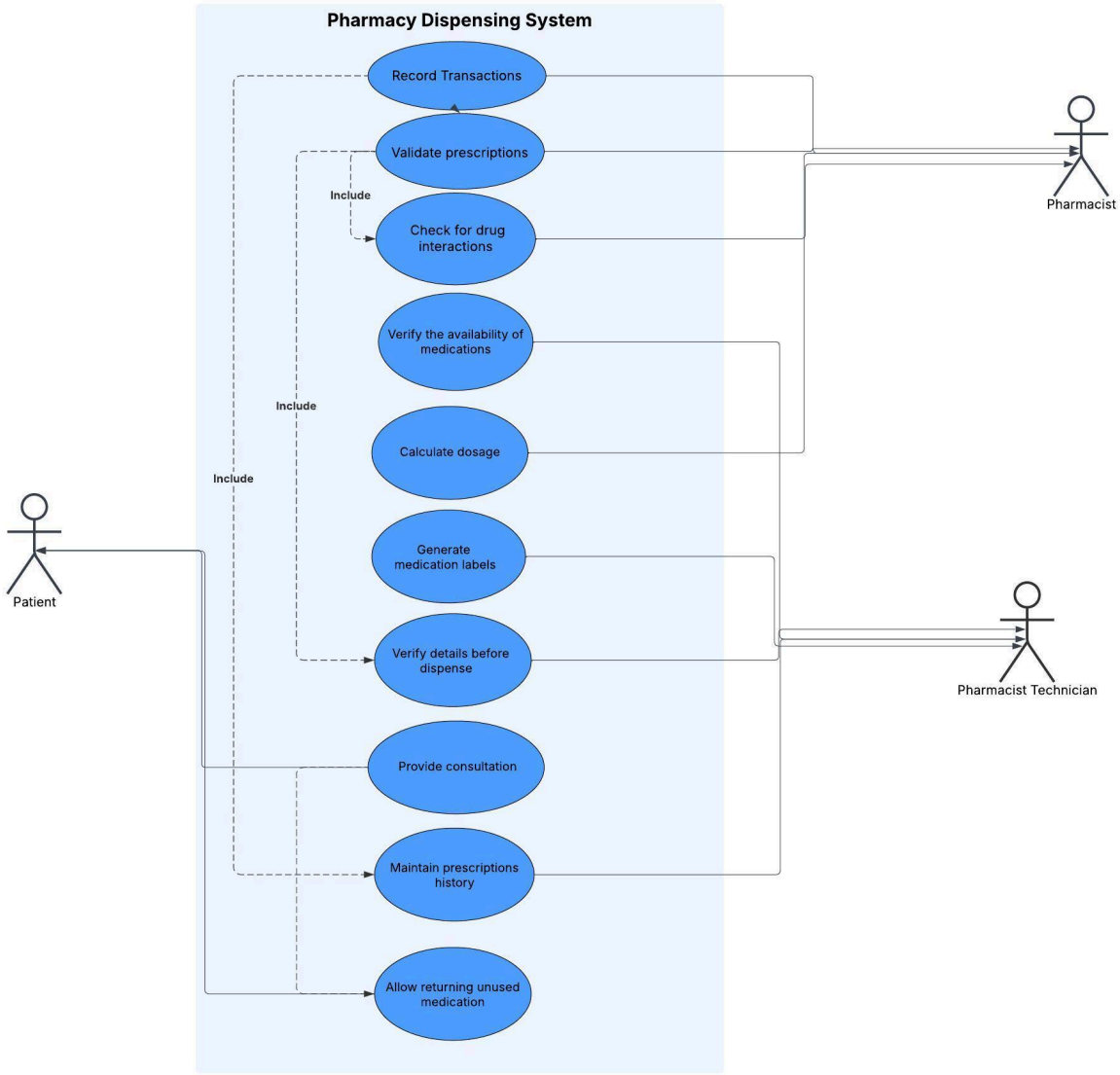
20. Formulary - A list of prescription drugs that are covered by a health plan.

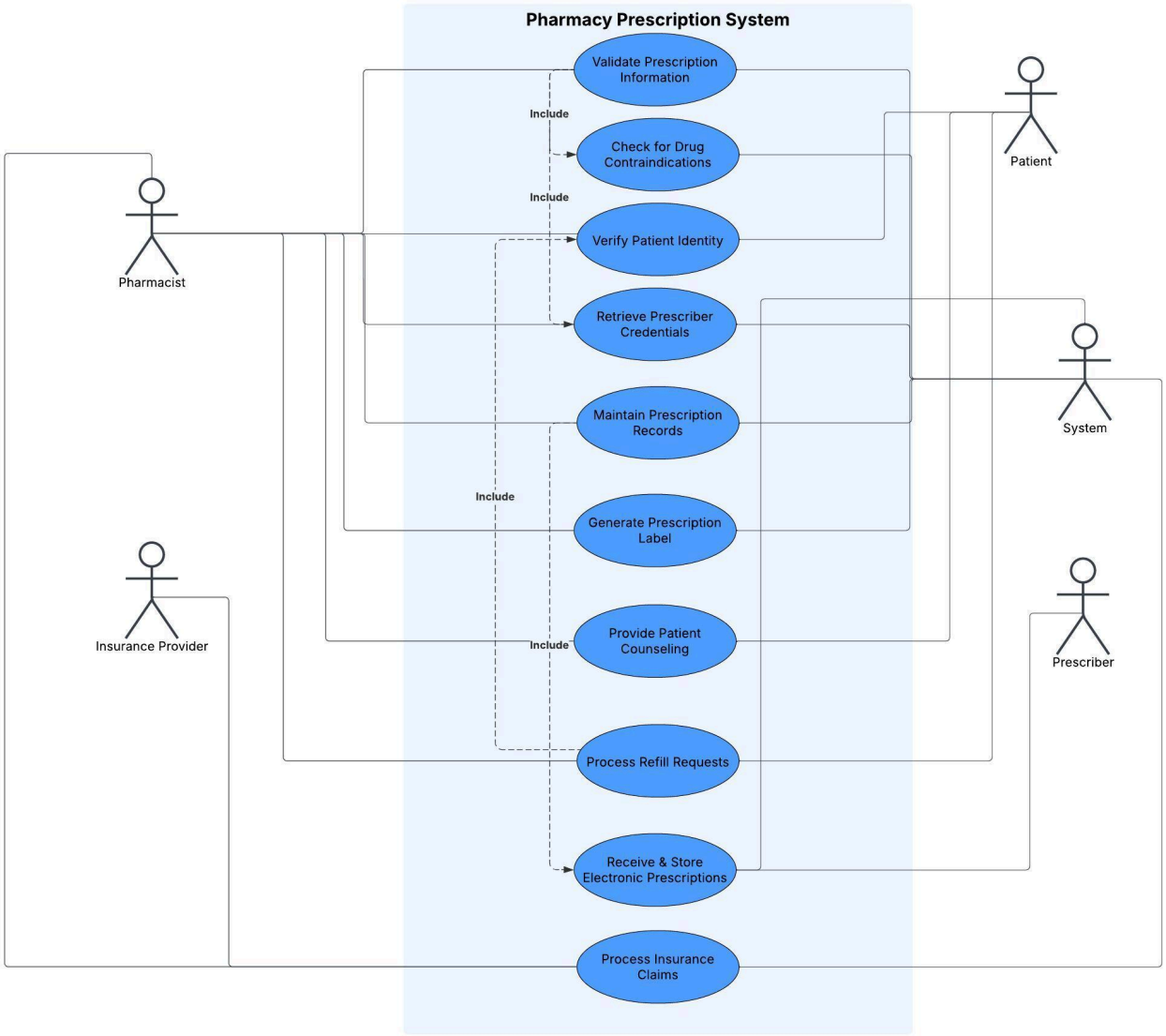
Appendix B: Analysis Models (UML)

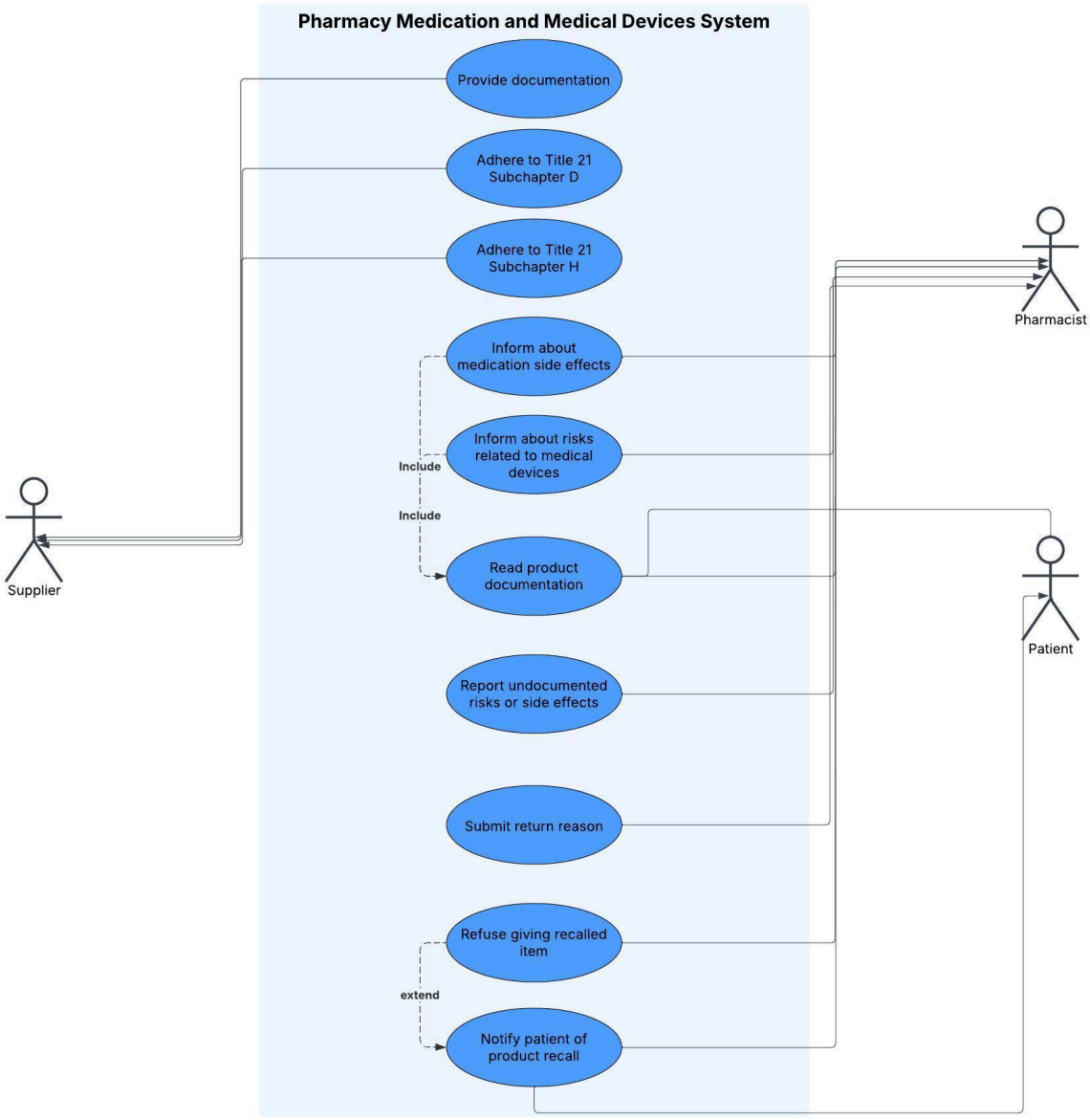
<Required in this report, include any pertinent analysis models, such as Use Case Diagrams, Entity Relationship Diagram, Review my feedback and correct all diagrams, and add the final version of each Use Case diagram and ERD in this section of the document (-30 pts).>

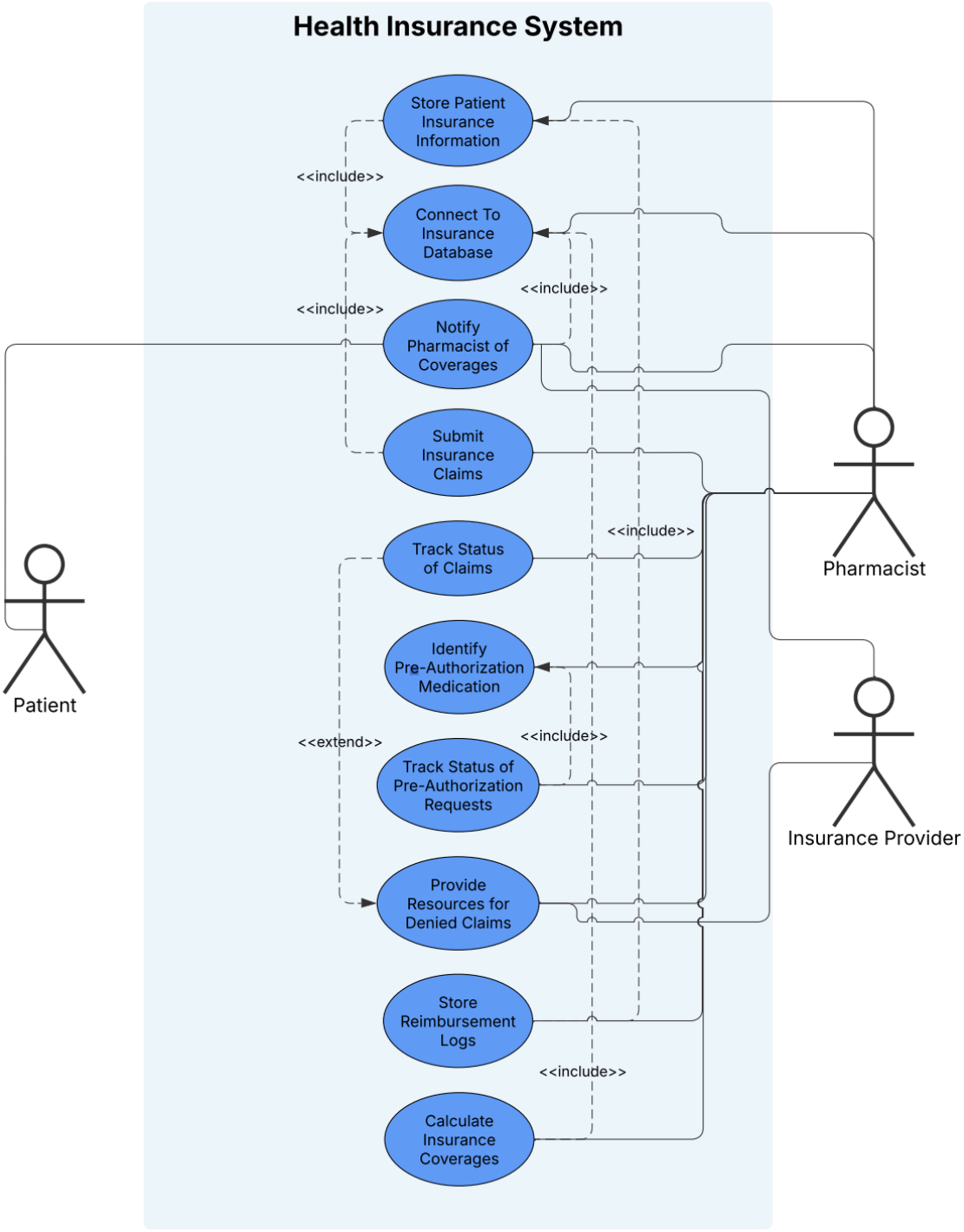
Entity Relationship Diagram:




Pharmacy Dispensing System
Record Transactions
Validate prescriptions
Include
Check for drug interactions
Verify the availability of medications
Include
Calculate dosage
Include
Generate medication labels
Verify details before dispense
Provide consultation
Maintain prescriptions history
Allow returning unused medication
Pharmacist
Patient
Pharmacist Technician


Pharmacy Prescription System
Validate Prescription Information
Include
Check for Drug Contraindications
Include
Verify Patient Identity
Retrieve Prescriber Credentials
Maintain Prescription Records
Include
Generate Prescription Label
Include
Provide Patient Counseling
Process Refill Requests
Receive & Store Electronic Prescriptions
Process Insurance Claims
Pharmacist
Insurance Provider
Patient
System
Prescriber


Pharmacy Medication and Medical Devices System
Provide documentation
Adhere to Title 21 Subchapter D
Adhere to Title 21 Subchapter H
Inform about medication side effects
Inform about risks related to medical devices
Include
Include
Read product documentation
Report undocumented risks or side effects
Submit return reason
Refuse giving recalled item
extend
Notify patient of product recall
Supplier
Pharmacist
Patient


Health Insurance System
Store Patient Insurance Information
<<include>>
Connect To Insurance Database
<<include>>
<<include>>
Notify Pharmacist of Coverages
Submit Insurance Claims
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Track Status of Claims
Identify Pre-Authorization Medication
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<<include>>
Track Status of Pre-Authorization Requests
Provide Resources for Denied Claims
Store Reimbursement Logs
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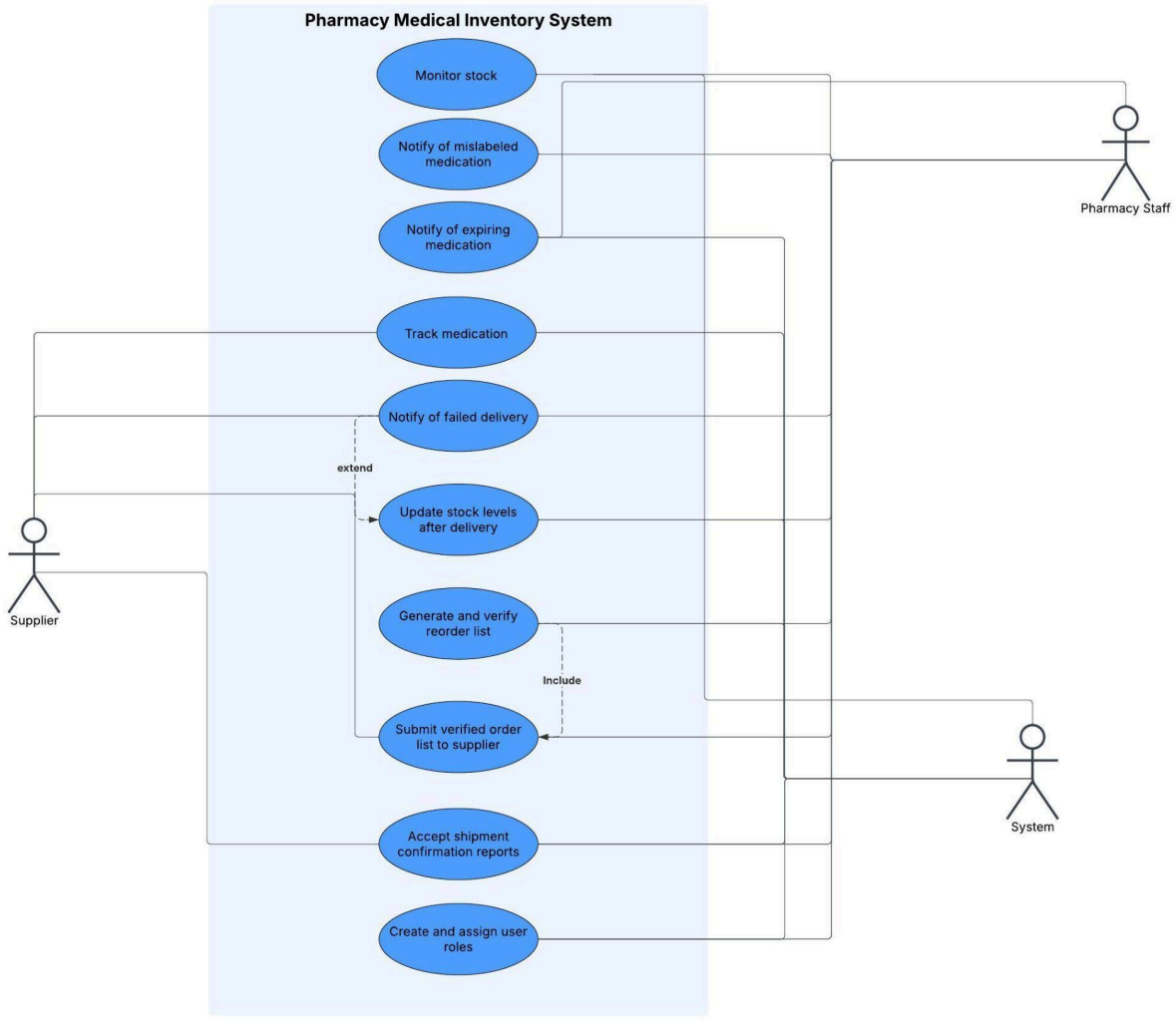
Calculate Insurance Coverages
Patient
Pharmacist
Insurance Provider


Pharmacy Medical Inventory System
Monitor stock
Notify of mislabeled medication
Notify of expiring medication
Track medication
Notify of failed delivery
extend
Update stock levels after delivery
Generate and verify reorder list
Include
Submit verified order list to supplier
Accept shipment confirmation reports
Create and assign user roles
Pharmacy Staff
Supplier
System

Appendix C: Domain Analysis Report

<This is the documentation and data you gathered in Assignment#1. Review my feedback and correct it, and add the final version in this section of the document (-30 pts). Ensure that you add references from this report to references in Appendix E. There should be only one reference list with unique numbers for each reference.>

Dispensing

Actions

The dispensing process begins when a patient presents a valid prescription from a licensed healthcare provider. Along with the prescription, the patient may provide personal details, such as contact information and medical history, to ensure that the prescribed medication is suitable and safe for their specific health needs. If the patient has any questions about the medication or requires clarification, they can ask the pharmacist or pharmacy technician. Once the medication is prepared and dispensed, the patient is responsible for verifying its accuracy, ensuring that they have received the correct medication with the proper dosage [2].

Pharmacists are crucial in reviewing the prescription for its legality, accuracy, and safety. This includes checking for any potential drug interactions or contraindications with other medications the patient may be taking. After ensuring the medication's suitability, the pharmacist provides counseling on how to properly use the medication. This includes advising the patient on the correct dosage, potential side effects, and safety precautions to take while using the medication [3]. In doing so, pharmacists play a key role in patient education, empowering patients to use their medication safely and effectively.

Pharmacy technicians assist in the medication dispensing process by entering prescription details into the pharmacy management system. They retrieve the medication from storage, measure or count the prescribed dosage, and label it with appropriate instructions. Technicians also play an important role in supporting the pharmacist by assisting in the final verification of the medication before it is handed to the patient. This step ensures that the medication dispensed is accurate and safe for the patient's use [1].

Functions

The actions performed by the patient, pharmacist, and pharmacy technician are driven by specific objectives. The patient's main role is to ensure they receive the correct medication and fully understand how to take it safely. Pharmacists are tasked with verifying that the medication is accurate, legal, and suitable for the patient, in addition to providing essential education on how to use the medication and any safety precautions. Pharmacy technicians support the dispensing process by ensuring the medication is prepared accurately, properly labeled, and documented correctly in the pharmacy system [4].

Procedures

The procedures followed in the dispensing process begin when the patient presents the prescription and provides any necessary personal details. The patient then waits for the medication to be prepared. Once the medication is ready, the patient confirms its accuracy with the pharmacist. The pharmacist reviews the prescription, checks for potential drug interactions, and provides guidance on proper usage. Simultaneously, the pharmacy technician enters the prescription information into the system, retrieves and prepares the medication, labels it, and helps the pharmacist with the final verification of the medication before it is given to the patient [5].

Prescriptions

The Florida Department of Health defines a prescription as any order for drugs or medicinal supplies written or transmitted by a licensed practitioner, including orders from out-of-state practitioners if deemed valid by a pharmacist. It can be in written or electronic form, and pharmacists may also order products from a designated formulary [6 p.3]. When it comes to the topic of prescriptions for a pharmacy, there are a few stakeholders we need to consider; Stakeholders such as the patient, the pharmacist, and the doctor of the patient. These stakeholders all share an important part of the prescription process. I will go through each stakeholder and talk about their role when it comes to prescriptions, including the actions, functions, and procedures they may have with prescriptions.

Most importantly, we have the patient stakeholder. Without the patient, there would be no prescription. The actions a patient will take include presenting the prescription to the pharmacist (paper form, electronically, or verbally), confirming their personal information, picking up the prescribed medication, asking questions for clarification, and reporting side effects. It is very important that the patient clearly and precisely gives their personal information to their doctor or pharmacist, including details such as medical history, allergies, and any current medications they are taking. It is also important that the patient identify and let it be known any side effects they are having from their prescription medications. It has been shown that many drug-related problems (DRPs) have been discovered through interviews between a pharmacist and patient [7]. In one study of over 100 DRP's, it was found that 84% of these DRP's were discovered through talking with the patient [8].

The functions of the patients, which can be looked at as what the patient's actions aim to achieve, are ensuring their prescription is the correct medication, complying with their prescribed treatment, and seeking information involving their prescription. These functions serve an important role because the patient needs to not only want to take the medication but understand why they are taking the medication and what results it may lead to. Many patients can become "nonadherence" patients, or patients who don't adhere to the prescription recommendations from their pharmacist or doctor. This can occur due to many reasons such as a misunderstanding the need for the medication, a fear of side-effects, or even a worry of dependency of the medication [9]. This is why it is so important that the patient asks questions and ensures their understanding of their prescription.

The procedures of the patient, or the step-by-step process for the patient, include submitting the prescription, confirming the details of the prescription, receiving and then checking the medication, engaging in counseling with the pharmacist or doctor, and following up with them on any concerns or results[10]. The procedures of the patients should go as follows:

1. **Obtain their prescription from their doctor:** This is the first step in the prescription process from the patient's point of view, and without it, the rest of the process cannot begin.
2. **Go to the pharmacy:** The patient takes the prescription to the pharmacy where it will be filled by a pharmacist.

3. **Submit their prescription(s) to their pharmacist:** The patient submits the prescription to the pharmacist, either in paper or electronic form.
4. **Confirm their details with the pharmacist:** The patient shall include their name (with valid ID), insurance the patient may have, and any allergies they have, to ensure that the prescription is filled accurately.
5. **Receive and verify their medication:** The patient receives the medication and checks it for accuracy, ensuring it matches the prescribed drug and proper dosage.
6. **Ask the pharmacist any questions regarding their medication:** The patient should take the opportunity to ask the pharmacist about dosage instructions, side effects, and any other concerns they may have.
7. **Adhere to the recommended dosage and follow-up:** Finally, the patient should follow the prescribed dosage schedule and report any issues or side effects to the doctor or pharmacist.

While the patient plays a critical role in ensuring that the prescription is correct and adhered to, the pharmacist is perhaps even more responsible for ensuring the accuracy of the prescription from the information they are given. The actions of the pharmacist include receiving and then reviewing the prescription, verifying the medication, consulting with the patient, and following up with the patient. When verifying the prescription, the pharmacist needs to ensure the prescription includes the date of issue, the patient's name, address, and date of birth, the doctor or clinicians name, address, and DEA number, the name of the drug, the drug strength, the dosage, the quantity prescribed, directions for use, number of refills, and the signature of the prescriber[11]. It is very important that the pharmacist thoroughly checks all the information for accuracy to ensure that the prescription is accurate.

These actions are crucial for the pharmacist so the pharmacist's functions can be met. These functions would include ensuring patient safety, providing counselling for the patient, ensuring legal and ethical compliance, and promoting prescription adherence. The relationship between the pharmacist and the patient is ideal for these functions to be carried out. As mentioned before, the patient should talk with the pharmacist about any questions they may have. But the patient's lack of knowledge when it comes to prescriptions can lead to the patient not knowing what concerns they should even have. This is why it is important that the pharmacist takes the lead when it comes to counselling with the patient before the prescription is given and a follow-up after the patient has gone through a dosage cycle. The pharmacist wants to make sure, when communicating with the patient, that their communication is clear and that the patient understands the information they have been given[12 p.10].

The procedures a pharmacist takes when it comes to prescriptions include receiving and verifying the prescription, checking for interactions and contradictions, dispensing the medication, providing patient counselling, documentation and record-keeping, managing refills, and patient monitoring and follow-up. The pharmacist's procedures when filling a prescription are as follows[13]:

1. **Obtain the prescription order:** The pharmacist will obtain the prescription order from the patient either electronically or physically on paper.

2. **Review the prescription for legality and correctness:** This includes verifying the name on the prescription by asking the patient, verifying that the prescription was presented within 1 year of being written, and verifying the address of the patient.
3. **Review the original medication order with the doctor:** The pharmacist will make sure the correct dosage form is included on the prescription, also that the correct strength is included on the prescription.
4. **Determine if a generic substitution is allowed:** The pharmacist will determine if a substitution is allowed based on the information on the prescription.
5. **Obtain the correct medication:** The pharmacist will obtain the medication that is listed on the prescription.
6. **Check the medication for the expiration date.**
7. **Calculate the amount:** The pharmacist will verify the number of tablets or capsules that they are going to need to dispense based on the prescription they've been given and count out the correct amount. The pharmacist shall also recount the amount to verify accuracy.
8. **Fill the prescription:** The pharmacist will fill the correct container with the proper amount that was previously counted and verified and issue the correct label on the container.
9. **Transaction with patient:** The pharmacist will go through the payment process with the patient verifying any insurance, as well as counselling the patient about the patient's prescription.

The pharmacist is the middleman when it comes to the prescription process. All the information that is verified by the pharmacist comes from the patient and the patient's doctor. The doctor's role in the prescription process is highly important due to the accuracy needed of the prescription, as well as the one who initially prescribed the medication. The actions of the doctor in the prescription process are assessing the patient, diagnosing the condition, writing and authorizing the prescription, choosing the medication, and providing instructions for the medication. It is crucial that the doctor does not cut any corners when filling out the prescription for the patient. It has been found that most prescriptions written by doctors do not contain all the information desired for a prescription[14].

The functions of a doctor for the prescription process should include diagnosis of the patient's condition, ensuring safe and effective treatment, promoting medication adherence, and monitoring the treatment process. As I mentioned before, the prescription is useless if the patient doesn't adhere to the doctor's instructions. It is very important that the doctor provides clear instructions for the patient and educates them on the purpose and proper use of the medication. The patient went to the doctor for good reason and is looking for a solution to their health-related problem. Though doctor's need to be wary of any pressure put on them by the patient. A study found that patients who were expecting to receive a prescription during their doctor visit were 3 times more likely than patients with no expectation[15]. But even more so, the doctor's who expected that the patient was expecting medications were over 10 times as likely to receive a prescription[15]. This shows that the doctor's opinions about the patient's expectations was the strongest determinate when it came to prescribing. This is why it is very important that the doctor consult with the patient thoroughly and set aside any expectations that they or the patient may have.

When prescribing a patient, the doctor generally follows these procedures:

1. **Assess the patient:** The doctor shall assess the patient for any ailments or complications the patient is having.
2. **Diagnose the condition:** The doctor will determine what the problem is and determine if a prescription medication is needed by the patient.
3. **Select the medication:** The doctor will choose the medication by their previous diagnosis of the patient.
4. **Write the prescription:** The doctor will write a prescription for the patient. It is important that the doctor fills out all the required information as accurately as possible. The required information includes name, address and category of professional licensure of the prescribing practitioner, prescribing practitioner's federal DEA registration number for controlled substances.
5. **Provide instructions and guidance:** The doctor will talk with the patient and explain to them what the purpose of the medication is for, as well as the best practice in taking the medication to ensure the best results.
6. **Follow-Up and Monitoring:** The doctor should follow-up with the patient, perhaps by scheduling a future visit, and by doing so is then able to monitor the patient's condition and results from the prescription.

The prescription process is a collaborative effort involving key stakeholders: the patient, pharmacist, and doctor. Each stakeholder plays a critical role in ensuring the prescribed medication is both appropriate and effectively managed. The patient initiates the process by obtaining the prescription and adheres to its instructions, while the pharmacist ensues the accuracy, safety, and clarity of the prescription. Meanwhile, the doctor diagnoses and prescribes the mediation, offering essential guidance for its proper use. Through clear communication, verification, and ongoing monitoring, these stakeholders work together to safeguard patient health, promoting optimal outcomes and minimizing risks associated with import use of medications. Understanding each of their roles is fundamental to improving patient care and the overall success of the prescription process.

Medication and Medical Devices

Actions

A pharmacy provides a myriad of medicinal products and medical devices to its patients. Suppliers in the United States are to follow all required guidelines made by the FDA to ensure that all products are safe for patients to use. For medical devices, this would include but are not limited to adhering to quality system regulations, labeling guidelines, and reporting guidelines [16]. Suppliers that provide dietary supplements such as vitamins also have to follow certain regulations to ensure their products are not adulterated or improperly labeled [17]. All other types of drugs and medicines also will need to be produced in a way that adheres to good manufacturing practice regulations [18].

Pharmacists, regardless if they work in the United States or not, act to ensure that the medicine and medical products they receive are of good quality and not expired, as well as making sure that any medical device is suitable for intended use and service [19]. Other medicines should also be used in such a way, with vitamins being checked so that they are safe and that they do not have adverse effects when interacting with other supplements or medications [20]. Pharmacists can also help guide patients and discuss the best medicine or medical devices that will treat their ailment with the least risk and least amount of adverse effects.

Functions

The functions of the supplier and the pharmacist is ensuring the best quality and proper use of the medicine and medical devices they produce and provide to treat different patients. Suppliers follow the regulations and provide needed instruction and documentation to pharmacists so that their products are properly prescribed; the pharmacist learns about their patients and discusses important details to ensure that they are given the correct product, and that the product is not deficient in any way that would harm the patient. They best ensure patient care and safety by functioning as regulators of themselves.

Procedures

Many procedures exist for different scenarios surrounding medicinal and medical products. For example, certain manufacturers follow the procedures laid out in 21 CFR 7 [21] when having to recall products. They also have their own specific procedures for recall, as do pharmacies, necessary enough that guidelines have been created to lay out what specific parts are needed for effective procedures, such as for choosing who's responsible, determining action needed, and escalating any recalls as necessary [22]. Procedures for recommending medicine or devices would include, for the pharmacist, first learning about the ailment the patient is suffering from; then looking at the patient's medical records and history; discussing with the patient any and all alternatives to find what best suits them; and then giving them the requested product that is of proper quality, as in not expired and in good working condition if it is a device, or unadulterated if it is a drug or vitamin supplement.

Health Insurance

Actions

- Verify Insurance Coverage:

  Pharmacists confirm patient's insurance information before prescribing medications and services to determine the coverages offered by insurance. [23]

- Process Insurance Claims:

  Pharmacists submit claims to patients insurance providers to handle any repayment for given medications and/or services provided. [24]

  Claims shall include patients' full name, date of birth, address, Insurance ID number, and group number (if applicable).

- Inform Patients on Insurance Specifications:

  The pharmacists educate patients about their benefits, deductibles, and co-pays from the insurance providers to help them make educated decisions. [24]

- Manage Pre-Authorizations:

  Some healthcare providers and insurance companies require prior authorization to get medications so it is important for the pharmacists to coordinate with them. [25]

- Handle Reimbursement Situations:

  The pharmacists try to build a working relationship with insurance companies to support patients' compensation or denied claims. [26]

Functions

- Manage Insurance Info:

  Securely maintaining patients records of insurance including policy numbers, coverage, and any changes to their insurance. [27]

- Manage Claims System:

  Tracking the status of insurance claims and payments received are done using the pharmacy system. [28]

- Manage Formulary:

  Managing formulary is accessing and understanding insurance formularies so the medications that are covered differently based on insurance plans can be properly shared to both prescribers and patients. [29]

- Financial Counseling:

  Letting patients know of more cost-effective options for medication like alternatives and also programs that exist to help financially. [27]

- Standard Operating Procedures (SOPs):

  Creating efficient and reliable procedures for insurance verification, claims submission, and appeals can make the processes consistent and more risk-free. [30]

Procedures

- Insurance Verification Process:
  - Patients' insurance information is to be collected during their first visit or when there is a change in insurance status. [27]
  - Use the system to verify coverage details or contact insurance providers directly.
  - Record patients verified information in the system.
  - This information includes the patients full name, date of birth, phone number, address, gender.
  - This information includes insurance providers name, insurance plan, name/type (e.g., PPO, HMO, Medicare).
  - Additionally, this information includes eligibility confirmation status (verified/not verified), date of verification, insurance contact or reference ID (if called), policy number / member ID, plan effective dates (start and end, if known), relationship to policyholder (e.g., self, spouse, child).

- Claims Submission Process:
  - Enter prescriptions along with insurance details into the management system. [31]
  - Submit claims electronically to the correct insurance provider.
  - Monitor claim status and follow up on any rejections or issues.

- Pre-Authorization Handling:
  - Identify medications that require prior authorization based on insurance formularies. [31]

- Collaborate with the prescriber to get clinical information.
- Clinical information includes diagnosis codes (ICD-10) (e.g., E11.9 for Type 2 diabetes without complications), documented medical condition(s) (including severity and duration), allergies and contraindications, name and dosage of requested medication, Intended duration of therapy, previous treatments tried and failed, reason why formulary/preferred alternatives are not suitable, prescriber's full name, specialty, National Provider Identifier (NPI), contact information (phone, fax, email).
- Prior authorization requests shall be submitted to the insurance company and be able to track their status.

- Patient Education and Counseling:
  - Inform the patients about their coverage and any limits or requirements from the insurance provider. [32]
  - Discuss possible out-of-pocket costs and give alternative options if needed.
  - Help patients in understanding the appeals process for claims that have been denied.

- Reimbursement Solutions:
  - Review denied or underpaid claims to determine the cause.
  - Communicate with insurance companies to resolve inconsistencies.
  - Keep patients informed throughout the process and provide support if necessary. [33]

- Standard Operating Procedures (SOPs):
  - Create SOPs for dealing with prior authorizations, denied claims, and insurance verifications processes. [34]
  - Train staff on updated insurance policies, SOPs, and any compliance requirements.

Medical Inventory

The backbone of any community pharmacy is their ability to manage their medical inventory system. This system allows pharmacists/pharmacy technicians/medical professionals to execute a various number of actions as well as allowing for greater efficiency. It manages the local inventory, the ordering and delivery of medication, cost control, supply chain optimization, etc. Proper inventory management is crucial in order to maintain a steady and healthy supply of medical supplies as well as the prescriptions/drugs for patients. With the functions of this system being separated into five broad categories: inventory management and tracking, order placement, receiving shipments, stocking, and expired/returning medication.

Inventory management refers to the system managing the stock of medication/other resources in the pharmacy. Proper inventory management ensures that all medication/other necessary resources are fully stocked for their patient's needs [22]. Additionally, the system must maintain up-to-date information on all medication for purposes of audits, financial reports, safety regulations, and to help pharmacists make better informed decisions when ordering more products [20, 6]. In order to complete these tasks, the system monitors and records the item description, quantities, physical location, expiration dates, and supplier information of all medications/resources in the pharmacy. [18]. This process is done via regular inventory audits and updates. These audits allow for increased accuracy and help to identify: any potential errors present between the recorded quantities of items and the actual stock of them, any medication whose supply is low, or any medication which is expired/nearing expiration [17]. Furthermore, a tracking system is implemented to track a medication's movement both within the pharmacy and prior to its arrival [17, 21, 22]. Regardless of the action done in reference to the medical inventory, all actions (ex. Disposal of expired medication, sale of medication, etc) must be documented and input into the system to ensure inventory accuracy alongside the regular audits.

The procedures executed in order to fulfill these tasks are as follows:

1. Regularly review the inventory levels of all medication, typically using an inventory management software
2. Identify medication whose supply is running low via audits [39, 40]
3. Generate a list of medication that needs to be restocked [39, 40, 41]
4. Verify this list with the actual stock levels to avoid over stocking [39, 40]
5. Actively update the inventory numbers of each medication after each sale, disposal of expired/damaged medication, and new deliveries [42]
6. Verify recorded inventory with actual inventory in order to avoid differences between the two [40]
7. Deal with any discrepancies with actual and record supply when necessary [39, 40]
8. Document and record any changes to inventory levels [40, 42]

Submitting drug orders is a frequent occurrence at pharmacies due to the constant need for medication, especially during different times of the year. This process works hand-in-hand with the inventory management system since it begins when a prescription's supply runs low.
Using historical data as well as demand forecasting, pharmacists determine an appropriate quantity of a medication to order then reach out to their suppliers [39, 41]. "Demand forecasting"

refers to pharmacists predicting the amount of medication that will be sold in the foreseeable future based on the medication's specific purpose, time of year, pharmacy location, budget, history, etc [39]. Once the order is placed, after confirming all details of course, it is then verified by the inventory management system in order to avoid overstocking, then tracked during the delivery process to ensure a safe and timely delivery. And for more commonly used medications (ex. ibuprofen), there is the option of an automatic ordering system to order prescriptions automatically once the supply falls enough [41]. With the option to set minimum and maximum stock levels based on the pharmacy's needs.

In order to complete the above process the followed must be executed:

1. Review historical data and implement demand forecasting in order to make better judgements on medication quantity orders, if applicable [40]
2. Verify that the list of medication needed to be ordered is accurate with current inventory [39, 40, 44]
3. Place orders for medication after confirming that all the information related to medication is correct (names, quantity, etc) [42, 44]
4. Submit orders for delivery and track delivery process [40]

Following the successful delivery of the previously ordered medication, the pharmacy must accept and verify the integrity of the incoming medication. They must ensure that all of the received orders are the correct quantity, include the correct information (expiration dates, names, etc), and have not been damaged/tampered with [42]. Additionally, the pharmacy must confirm that all the orders reach the pharmacy in a timely manner [39, 44]. In the event of a delay, the pharmacy must act accordingly in order to avoid a medication's supply running out.

To complete the accepting shipment process the pharmacy must:

1. Verify that the information related to the shipment delivered is the same as the information in the order receipt [42, 44]. Any incorrect information present must be documented and the medication must be quarantined off in order to assess the severity/impact. Then, the pharmacy will decide how to handle the medication, either by returning it, disposing it, etc. The supplier/distributor must also be notified of this issue
2. Confirm all products were not damaged/tampered with [42]. Any product damaged/tampered with must be returned/disposed of immediately and reported back to the supplier/distributor and pharmacy inventory management system
3. Document shipment's arrival and record order information [40, 43]

Once the shipment arrives successfully, the medication must then be stored inside the pharmacy for later use. The main goal of the stocking process is to organize the pharmacy's inventory neatly and effectively in order to optimize physical space, minimize the time it takes to locate a drug, and maintain all safety regulations. This is done by storing all medication/other resources in their appropriate locations using a system of categorization. This categorization system typically uses medication names, type, and/or use guidelines in order to sort [39, 40, 43, 44]. However, medications that require specific storage methods (ex. temperature sensitive or controlled substances) would be stored separately in their own areas under a similar but smaller

categorization method. It is crucial for pharmacies to adhere to the safety measures required for certain medications in order to ensure their safe state when handed to a patient [42].

The procedures done to properly store medication are as follows:

1. Store medication/other resources in their appropriate areas based on organization system (labels, expiration dates, names, etc) [40, 42, 44]
2. Guarantee all safety measures and guidelines are upheld when storing medication (ex. certain medication requiring to be stored in cold environments) [42]

Although it does not have a specific point in time in which it is executed like the previous sections, medication will inevitably expire or have to be returned. And regardless of when this is to happen, it is necessary to understand the proper handling of medication when it needs to be disposed of/removed. As, the main purpose of handling these issues in a proper manner is to prevent the distribution of these expired/compromised medications to patients [42, 44]. These medications could put the life of the patient at risk as well as lead to large legal and financial issues in the future. To prevent these medications from reaching the patient the pharmacy must record the expiration dates of all the medications present and actively verify that none of the medications has expired [42, 44]. And using inventory management software to verify this is useful, it does not hurt to manually verify each and every one. When the medicine does expire, it must be disposed of as soon as possible for safety. However, one must also adhere to medication disposal regulations because simply throwing it in the trash can may not be the safest option for all medication [42]. When it comes to incorrect or damaged medication/items, one must return them to their supplier/distributor and adjust product ordering practices accordingly. And after each disposal/return, the pharmacy must record each instance as well as adjust inventory stock records.

To fulfill these requirements successfully the pharmacy must:

1. Actively verify that the medication stocked as not expired, typically via a software system [41, 42, 44]
2. Dispose of any expired medications according to safety guidelines [42]
3. Return incorrect/damaged/tampered with medication to supplier/distributor
4. Record any changes in inventory levels due to expiration or other factors [40, 42, 44]

Inventory Management & Tracking

The general standard in regards to an inventory management system is to just have one in the pharmacy, thus classifying it as a functional requirement for a pharmacy to operate properly. That method of which to implement it is up to the pharmacists, classifying it as a nonfunctional requirement. This also applies to the medication tracking system, with its inclusion being an industry standard but its specific implementation changing from pharmacy to pharmacy. However, there is a general formula to both; That being that medication is typically sorted by name, type, and safety regulations. And the tracking system uses extensive documentation and barcodes to track medication.

Order Placing

In regards to order placement, the standard for all pharmacies is to verify that the medication being ordered is correct at multiple times throughout the process. Additionally, a pharmacy must not order too much supply on one medication in order to avoid wasting a portion of them. And while it is not required for the process to function, many pharmacies implement demand forecasting in order to better predict what medication to order. Other methods of being able to better predict a medication's future are also recommended but not required. After the order is placed however, the order and all of its details must be documented.

Receiving Shipments

Similar to the order placement process, when a pharmacy receives shipments of medication it is required to verify the integrity of all products for damage, correct information, and for the correct quantity. In the event of any incorrect information and/or damaged products, they must be either disposed of in accordance with the disposal guidelines for that specific medication or returned to the supplier/distributor. And once the shipment is received and verified, its arrival and contents must be documented.

Stocking

Although the method of which to physically store the products is up to the pharmacy, and thus nonfunctional, any medication that has specific safety measures attributed to it must be stored in the stated environment. For example, some medications must be held in hotter or colder environments in order to ensure integrity. Similarly to the inventory management system, a general method of storing the medication must be implemented but the specific implementation is subjective.

Expired Medication & Returning

Both the standards and guidelines attributed to expired medication are to actively verify that the medication present in the pharmacy has not expired. This process must be done but can be done manually, via inventory management software, or both. It is required to dispose of any medication that has expired in accordance with the medical disposal guidelines for that specific medication. As, some medication must be disposed of differently than other medication. After disposal/return, the change in inventory must be documented either physically or digitally.

Safety Concerns and Hazards

Dispensing:

Key safety concerns include medication errors, which could result from incorrect prescriptions or labeling. Data breaches are another hazard, compromising patient privacy. System downtime can disrupt operations, while non-compliance with regulations can lead to legal consequences. Lastly, inadequate clinical decision support can lead to overlooked drug interactions, endangering patient safety [4].

Prescriptions:

There are many safety concerns and possible hazards when it comes to prescriptions. The system needs to be able to validate all aspects of the prescription and patient information, including patient information, dosage, and pricing. A medication error due to the software dispensing the wrong medication due to the pharmacist inputting the wrong data is a hazard that must be avoided. The pricing needs to be validated too. A mistake in the insurance information, or the pricing of the billing can lead to either the patient or the pharmacy being hurt financially. The software also needs top-tier security features. A data breach could expose sensitive patient information and potentially harm the pharmacy's reputation. Also, any sort of denial of service (DoS) attack could cause the system to go down for any amount of time. Extended downtime in the software could prevent pharmacists from processing prescriptions, which could delay patient care.

Medication and Medical Devices:

The main safety concern would be ensuring that medications and medical devices that are expired, adulterated, not functioning properly or defected are not given to patients to be used; and if any such medication or device is found, that it be recalled in an effective manner so that no person is harmed by the faulty medications or devices.
Another safety concern is that the patient may not require a certain medication or device and that it will do more harm to them due to other factors such as past medical history or other medications and devices being used by the patient. Pharmacists will have to make sure that they do not harm their patient and look through all necessary information to make the best informed decision and recommendation, with the system helping the pharmacist by providing all necessary information during the process of recommending a medication or device.

Health Insurance:

- Pharmacies deal with personal patient information that is sensitive which makes them a high-value target for attacks. Complying with regulations such as HIPAA is needed to maintain trust and prevent legal consequences. [13]
- Claim denials can happen when errors in insurance verification occur. If the system is not up-to-date on policy changes, automated processing of claims can produce errors. [14]

- Patients can receive the wrong dosages or medications if the system fails to process prescription data correctly. Severe health risks can present themselves if alerts are not happening properly. [15]
- If the system does not have proper authorization and monitoring functionality, fraud can occur. Fraud claims can be made unexpectedly by both pharmacists and patients if the system has loopholes. [13]
- Workflow and patient care can be slowed down if the software appears to crash or have slow response times, especially when handling higher workloads. The system's uptime and stability is important as insurance verification and claim processes are dependent on it. [16]

Medical Inventory:

In regards to the medical inventory process and its subprocesses, the main safety concern is the integrity of the medication in the pharmacy. Meaning that the medication located at the pharmacy is thoroughly examined at each step of the process. When ordering the products the pharmacists must ensure that the product being ordered is exactly what they need in the pharmacy. Once delivered the product must have the correct information present and not show signs of damage/sabotage. When storing the products they must be stored in their proper environments if applicable. An example being that controlled substances need to be stored in locked containers to prevent their distribution without strict pharmacist consent. The medication must be regularly verified that they are not expired and if so must be disposed of in accordance with medical disposal guidelines.

Appendix D: NASA ARM Report

<Add the full copy of the NASA Arm report after you have finalized all requirements(-10 pts).>

FinalNasa Arm Report (link to Microsoft 365 copy, will also submit copy of it with this report on Canvas).

Appendix E: References

<List any other documents or Web addresses to which this SRS refers. These may include user interface style guides, contracts, standards, system requirements specifications, use case documents, or a vision and scope document. Provide enough information so that the reader could access a copy of each reference, including title, author, version number, date, and source or location Follow IEEE reference and incline citation Standard (-20 pts).>

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*Please note that **15 points will be deducted** from the final grade of the SRS report for any inconsistencies in requirements descriptions, style, diagrams, UML notation, terminology, formatting, and similar issues. I have provided feedback on these inconsistencies throughout each group assignment, and this issue should not carry over into the final SRS report. It is crucial that students ensure the SRS is written in a cohesive, uniform, and well-organized manner.*