Requirements Engineering and Analysis Assignment #1

Community Pharmacy Requirements and Research

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HIGHLIGHT = Fixed Requirements

Requirements Engineering and Analysis Assignment #1

1) Question 1: Identify and define 10 functional requirements for each of the following essential services of a pharmacy software system:
   a) Dispensing
      i) The system shall allow pharmacist technicians to verify medication names before dispensing.
      ii) The system shall allow pharmacist technicians to verify medication dosages before dispensing.
      iii) The system must require patient ID verification before dispensing medications to them.
      iv) The system shall guide the Pharmacist Technicians through the dispensing process by providing sequential instructions for each step which includes:
         (1) Patient verification, Prescription validation, Medication selection, Labeling, Documentation, and Counseling (if required).
      v) The system shall generate accurate labels for dispensing medications including the following information:
         (1) Medication name, Dosage instructions, Warnings, Expiration date, Quantity, Patient name, Prescriber's name, Prescription number, Pharmacy contact information.
      vi) The system shall alert the pharmacist technician for potential drug allergies during the dispensing process.
      vii) The system shall maintain a record of all medications that are dispensed.

viii) The system shall maintain an audit trail for each individual dispensing activity, and contain the following information:

(1) Date and time, Pharmacist Technician responsible for dispensing, Patient name, Medication dispensed, Prescription number, relevant notes or comments associated with the dispensing activity.

(2) Needed due to 21 CFR 1311.205(b)(13) – ecfr.gov

ix) The system shall require pharmacist authorization before finalizing the dispensing process in the form of:

(1) a unique login credential for the pharmacist that is a secure authentication method such as biometric authentication.

x) The system shall track remaining refills for prescriptions then alert pharmacists when they are due.

xi) The system shall integrate with electronic prescriptions, displaying accurate prescription details for pharmacist technicians to verify before dispensing.

b) Prescriptions

i) The system shall allow healthcare providers to electronically submit prescriptions to the pharmacy.

(1) Other Healthcare providers include Physicians, Dentists, etc.

ii) The system shall allow pharmacists to verify the accuracy of prescriptions, including Medication, dosage, patient information.

iii) The system shall guide patients through the prescription renewable process by giving text instructions for each step. (ASK her, she said “Testable?”, how to make it

testable? Seems that its testable because we can check if the text instructions are on there or not.)

iv) The system shall maintain a record of all prescriptions filled at the pharmacy.

v) The system shall provide status updates on the 'prescription process'.

(1) Prescription Process Steps: processed, verified, dispensed, ready for pickup.

vi) The system shall alert pharmacists to errors with prescriptions, such as incomplete patient details.

vii) The system shall require pharmacists' authorization through a secure login before finalizing the prescription of a medication.

viii) The system shall generate transactional documentation, including prescription details and transaction records, for all prescription transactions.

ix) The system shall store transactional documentation in the system's database, for all prescription transactions.

x) The system shall allow for the transfer of prescriptions between pharmacies through secure electronic data interchange (EDI) systems.

(1) This is just in case the patient wants to change pharmacies for whatever reason, such as moving to another state.

c) Medication

i) The system shall maintain a database, accessible to pharmacy staff, of all medications stored, which includes generic brands, named brands, strength, and dosage.

ii) The system shall allow pharmacists and pharmacist technicians to retrieve medication information, which includes usage instructions, side effects, and contraindications (reason to not use a medication).

iii) The system shall perform checks for drug interactions based on patients' prescription profile.

iv) The system shall perform checks for patient allergies to medications based on the patient's allergy profile.

v) The system shall provide patients with pricing information for medications, which includes retail price, co-pay, and discounts.

vi) The system shall track medication expiration dates.

vii) The system shall send an alert to pharmacist technicians when a medication is nearing expiration, providing a notification one week in advance.

viii) The system shall check for any medications that are affected by recalls or safety alerts.

ix) The system shall monitor the availability of certain medications with 5-minute inventory updates when a pharmacist technician is searching for a medication.

(1) Let's the pharmacist technician know that a medication might be on backorder or if it's being saved for specialized use.

x) The system will check for medication usage trends (+/-10%), production rate (+/-5%), and Wholesale prices (+/-5%) to aid in the informed purchasing decisions made by the pharmacy buyer.

d) Health Insurance

i) The system shall verify patient insurance coverage by checking policy details and eligibility.

ii) The system shall handle verifying patient eligibility for health insurance claims.

(1) Removed claim submission, and claim status tracking because insurance does that and makes this requirement atomic.

iii) The system shall calculate the patients' copayments 'accurately' based on their insurance coverage on the medication(s) prescribed to them.

iv) The system shall allow a pharmacist to choose a medication that is preapproved by a patient's insurance company.

v) The system shall generate documentation for insurance coverage, which will include Explanation of Benefits (EOB) statements and Claim Denials.

vi) The system shall store Certificates of Insurance (COI) documentation for insurance coverage.

vii) The system shall provide insurance reimbursement payments, including paid amount and outstanding balances.

viii) The system shall request insurance formularies to determine coverage for the patient.

(1) Formularies are just a list of drugs that are covered by a company's plan.

ix) The system shall align formulary coverage with medication dispensed on a per-prescription per-patient basis.

(1) This is to protect the patient or insurance company from errors when observing what medications are covered in their formularies.

x) The system shall alert pharmacists and pharmacists technicians when a medication is not covered by the patient's insurance or needs authorization.

xi) The system shall provide Pharmacy Benefit Management (PBM) reports for insurance claim data, which includes:

(1) rejection rates, denial reasons, and reimbursement.

e) Medical Inventory

i) The system shall track medication inventory levels, which includes stock quantities, expiration dates, and reorders.

ii) The system shall generate alerts when a medication falls below a 30% threshold.

iii) The system shall replenish a medication when it falls below a 30% threshold.

iv) The system shall save records of medications in the inventory, including:

(1) receipt, storage, dispensing, and disposal.

v) The system shall support yearly inventory audits with batch scanning to align with physical inventory counts with the system's record.

(1) Mandated by the government.

vi) The system shall monitor medication expiration dates and alert the pharmacist technician primary buyer when the medication is expired.

vii) The system shall support the proper disposal of expired and or unused medication that complies with Florida's Regulation Requirements.

viii) The system shall include an automated medication storage system to optimize inventory organization, to reduce prescription fill time to 10 minutes.

ix) The system shall provide inventory analysis reports of inventory data, which includes:

(1) current stock levels, expiration dates, usage trends, stockout incidents.

x) The system shall share real time inventory data between the medical inventory and purchasing system to aid in the purchasing of medication from Wholesalers.

(1) The medical inventory and purchasing system are different in their functions but should be able to share data between them.

xi) The system shall allow pharmacist technicians to dispose of medications that are recalled in the inventory in accordance with Florida's disposing regulations.

2) Question 2: Identify and define 4 nonfunctional requirements for each of the essential services of a pharmacy software system.
    a) Dispensing
        i) The dispensing function should respond to pharmacist technician actions within 2 seconds under normal conditions. (Performance)
        ii) The dispensing function should have a system uptime of at least 99% over a 30-day time frame. (Reliability)
            (1) This will exclude scheduled maintenance times.
        iii) The dispensing UI's usability should let new pharmacist technicians to dispense medication to patients with around 30 minutes of training. (Usability)
        iv) The dispensing function should be scaled to support an increase in prescription volume by at least 50% within a 5-month period. (Scalability)
    b) Prescriptions
        i) Prescription data should be encrypted during 'transmission' using AES-256 encryption with secure key management. (Security)
            (1) Encryption keys should be securely generated, stored, and rotated.
        ii) Prescription data should be encrypted during 'storage' using AES-256 encryption with secure key management. (Security)
        iii) The prescription function should comply with HIPAA regulation of the Security Rule for patient data protection. (Compliance)
        iv) The prescription service should be available 98% of the time during normal operating hours, with the exception of scheduled maintenance windows announced in advance. (Availability)

v) The prescription function should integrate with electronic health record (EHR) systems using HL7 standards. (Interoperability)

c) Medication

i) Medication information retrieval should take no longer than 1 second. (Performance)

ii) The medication database shall include a daily automatic data backup feature to ensure data integrity and prevent any data loss in a case of file corruption or unforeseen events such as natural disasters.

iii) Medication information should be accessible to patients with disabilities, to comply with WCAG 2.0 accessibility. (Accessibility)

iv) The medication function should scale to accommodate an increase in medication database size by at least 100%. (Scalability)

d) Health Insurance

i) Health insurance data access shall be restricted based on user roles, making sure that only authorized users such as a pharmacist can view or modify insurance information. (Security)

ii) All changes to health insurance data should be logged and auditable for the use of pharmacy assistants. (Auditability & Compliance)

iii) Health insurance claims processing, initiated by pharmacist assistant, should be completed within 5 seconds per transaction. (Performance)

iv) The health insurance function should comply with CMS regulations for Medicare claims processing. (Compliance)

e) Medical Inventory

i) Inventory item lookups should execute within 3 seconds per transaction. (Performance)

ii) The inventory function of medication storage should be scaled to allow for an increase in the number of medication items by at least 50%. (Scalability)

iii) Inventory data backups shall be done every 7 days, adhering to a data retention policy of reducing data loss. (Data Integrity)

iv) The inventory management UI shall support group updates for bulk inventory updates. (Usability)

(1) Bulk Inventory Updates: updates that do various operations such as adding, updating, or deleting inventory items.

3) Question 3: Research to discover prevailing regulations or standards (NFR) for pharmacy software systems.

Health Insurance Portability and Accountability Act (HIPAA)

"The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information (PHI) from being disclosed without the patient's consent or knowledge" (CDC, 2022, para. 1). The HIPPA Privacy Rule explains what is covered by HIPPA and extra details about it (CDC, 2022, para. 2). This covers healthcare providers, health plans, healthcare clearing houses, and business associates (CDC, 2022, para. 3). One important note is that "healthcare providers are considered any "providers of service", regardless of size, who electronically transmit health information in connection with certain transactions" (HHS, 2022, para. 10).

An exception to covered groups would be "a group health plan with fewer than 50 participants administered solely by the employer that established and maintains it" (CDC, 2022, para. 3). There are also exceptions to HIPPA where "it is lawful for covered entities to disclose a patient's PHI under the Privacy Rule for the sake of public interest or benefit activities under 12 national priority purposes" (CDC, 2022, para. 4).

For a community pharmacy, the system would need to allow secure transmission of patient data. Authorized healthcare providers (physician/doctor and pharmacist) must be able to transmit this PHI data securely and timely. It must also permit others in the business to use the info for their own range of permissions. There must also be a way to disclose the PHI data in accordance with the exceptions to HIPPA.

National Archives Code of Federal Regulations

These regulations are taken from chapter 21 of the United States Code, sourced from the national archives. They are relevant to access control and data management for the system.

1. § 1306.06 Persons entitled to fill prescriptions.
    a. "A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner". (Nation Archives, 2024a).

This covers all the potential positions a registered pharmacist may take and assigns the power of prescription solely to them.

2. § 1311.200 Pharmacy responsibilities (f).
    a. "When a pharmacist fills a prescription in a manner that would require, under part 1306, the pharmacist to make a notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or in linked files (National Archives, 2024b). When a prescription is received electronically, the prescription and all required annotations must be retained electronically". (Nation Archives, 2024b).

This clarifies that the same responsibilities in a paper prescription still exist for an electronic prescription. The system should be able to handle and store this extra information for each prescription.

Drug Enforcement Administration (DEA)

This allows for a patient to change prescription vendors from one DEA-registered pharmacy to another (DEA, 2023, para. 1). Before a patient had to go through their medical practitioner to cancel the prescription from one pharmacy and reregister it to another (DEA, 2023, para. 2). A prescription can only be transferred once in unaltered electronic form, directly between two licensed pharmacists, between two different pharmacies (DEA, 2023, para. 4).

This provides a limitation on our system that should not be violated. This is important for the community pharmacy system to handle if the patients are coming from another pharmacy or leaving to another pharmacy.

(DEA): electronic prescribing of controlled substances (EPCS) House Bill 831 in FL

This bill requires all prescribers to generate and transmit all prescriptions electronically upon license renewal or by July 1, 2021, whichever is earlier (Florida Board of medicine, 2020, para. 1). The bill also introduced new exceptions to this case (stated in the bill).

This bill makes it mandatory for the community pharmacy to use electronic prescriptions. The exceptions listed must also be accounted for when building the system.

Florida Laws for pharmacies

1. <u>64B16-28.140 Record Maintenance Systems for All Pharmacy Permits</u>
    a. This section defines requirements for records maintained in a data processing system (Florida pharmacy, 2020a). Each section states the specific regulations these standards are bound to. In part 64B16-28.140-1a, it goes over how data in a system should be managed. Part 64B16-28.140-3b states the standard form of

prescription format. Pharmacies are required to keep both hard copy of the original prescription and carry out business strictly with their electronic counterpart (Florida pharmacy, 2020a).

2. 64B16-28.141 Requirements for use of an Automated Pharmacy System by a Community Pharmacy
    a. This section goes over who may use the system, how the system functions in the pharmacy and how the data is handled by the system. Section 64B16-28.141-b states that a pharmacy develops and maintains a policy and procedure manual and proceeds to list mandatory methods a system must provide (Florida pharmacy, 2020b).

General Data Protection Regulation (GDPR)

The European Union's General Data Protection Regulation (GDPR) is the strictest, strongest data protection law in the world (GDPR1). This even surpasses the US equivalent of the California Consumer Privacy Act. All companies, even those outside the EU, are subject to the GDPR if they hold private information of a citizen of the EU (GDPR2).

This is mandatory for larger, national pharmacies, and will become mandatory if a community pharmacy handles patients who are citizens of the EU.

Food and Drug Administration (FDA)

FDA is responsible for approving and regulating the drugs sold in pharmacies. Some pharmacies also compound drugs (FDA 2017). Any pharmacy must be sure that the drugs it has are FDA approved.

4) Question 4: For the pharmacy software system, list some of the safety concerns and hazards (i.e., what this system shall not do) based on the regulations you discovered in question 3 and any other information you might have/find pertinent to the problem.

i. **Unauthorized Access to Patient Data**:

1. The pharmacy's software system should prevent unauthorized access to patient information to maintain compliance with HIPAA regulations.

ii. **Insufficient Data Security Measure**:

1. The system should have cybersecurity measures to protect against data breaches such as viruses or worms. The last thing that we want is for sensitive patient data to be accessed by unauthorized users.

iii. **Incorrect Medication Dispensing**:

1. The system should have a safeguard in place to prevent medication errors. Errors are bound to happen so it's necessary to have a safeguard to deal with these errors. Such as, selecting the wrong medication or dosage. This should be set in place to ensure the patients' safety and be in compliance with FDA regulations.

iv. **Non-Compliance with Electronic Prescribing Standards**:

1. The system should follow the NCPDP standards for electronic prescribing which includes the EPCS requirements. This is so we insure the legality and security of electronic prescriptions for controlled substances.

v. **Poor Prescription Monitoring**:

1. The system should support prescription monitoring features to detect certain drug interaction, allergies, or accidental duplications of medications. This is done so that we can facilitate appropriate medication therapy management.

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