

Title: Sidekick

A Raspberry Pi Medication Dispenser

Individual Project Materials through Customer Personas

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CSS 506 B

Problem of Noncompliance in Healthcare (Problem Statement)

According to the National Center for Health Statistics, an average of about 46% of the US population used one or more prescription drugs in the past 30 days. Younger aged patients mostly use medication to treat acute illnesses such as infections and other illnesses such as asthma, depression, and ADHD. However, the highest share drug use is with older adults aged 60 and above, where drug use is at 85%. Most commonly taken drugs are anti-diabetic, antihypertensives and medications to help lower cholesterol to prevent very life-threatening events such as a stroke or heart attack (NCHS 2015-2016). In fact, those aged 65+ take an average of 15-18 prescriptions per year.

What is important to note is that memory impairment and sensory changes can pose as a challenge to adhering to complex medication regimens. Many older adults or those with disabilities move to living situations where they can get help with medications as well as other activities; however, this is not a perfect system. Problems such as high turnover rates and understaffed care teams create a complex ecosystem, where patients do not always receive the quality care they need. Medication administration is not exempt from this. There have been times when patients would receive the wrong medication at the wrong time or medications were not refilled on a timely manner. In the series of events leading up to medication noncompliance, many seem to be from human error. Medication compliance plays an important role in a patient's overall health outcome. Failure to take medications consistently as prescribed can often derail patients away from their goals and sometimes lead to life threatening events.

Another problem set forward to the same demographic of elderly patients is feeling that they are uninformed of the details of their care plan. Many seniors take routine medications without knowing what a medication does and for what diagnosis. Without patients being able to recall the medication's association to diagnoses, they are not able to assess and therefore accurately report progress towards their personal goals. This can prove to be a problem both on a medical standpoint and in regard to the patient's financial health. Patient's need to be able to track progress with current medical regimen and adjust medications as needed, in order to achieve effective treatment.

I decided to name this project "SideKick" because the system serves to promote patient independence and autonomy. The system will approach to solve the problem of noncompliance in a way that is supportive and encouraging, rendering patient as center of the system and full owner and navigator of their device and the data that it encapsulates.

A Medication Dispensing System (Proposed solution)

In order to help aid medication compliance, we need a system that automates the process, tracks activity, provide reminders for timely refills and help patients find the best deals for their medications. The focus of these tasks is not only to promote adherence to their medical regimen but also to promote patient integrity by allowing the user to be an informed and active participant in their own care plan.

Sub-concerns pertaining to the problem of regimen adherence:

Problem	Solution
Misplaced medications	All medications need to be stored, secured, and only accessible by patient and authorized persons
Failing to follow one or more of the “7 rights” of medication administration: right patient, right drug, right dose, right time, right route, right reason and right documentation.	Need a system that dispenses the right medication at the right time with proper documentation
No evidence of patient taking medication	Capture evidence of patient taking medication. This will only be for patients with moderate memory problems, written consent required.
Patient unclear on what medications are for what problem	With each dispense, the system must summarize pertinent information about the medication, including associated diagnosis. This information must also be available at any time.
No self-tracking progress (motivational)	The system will be able to store information such as vital signs. The system can also work with medical records system to import labs, imaging, etc. It can track patient of progress towards goals.
Forgetting when to refill medications	Need a system to remind patient of refill need at least 3-4 weeks in advance.
Unsure of how to get refills	It will also provide actionable options or necessary contact information to obtain refill.
Medications are expensive	Partner with GoodRx to help patient find lowest cost pharmacy for prescriptions.

Entities Affected by this Solution (Stakeholder identification)

Premarket

Government: FDA

- Establish regulatory authority on medical device for basic acceptance criteria (safety, performance, quality, packaging, and labelling) of medical device
- Product registration
- Review of regulations and medical device standards (ISO frameworks risk analysis, risk evaluation, and risk control for medical device design, development, and manufacturing)

Manufacturer: Raspberry Pi foundation

- Consistent quality of product.

Placing on market

Advertising and sales

- Medical device marketing and advertising are regulated to prevent misinterpretation of device and performance.

Post market

Development team

- Regular review of system's HIPAA regulation and compliance
- Post market surveillance and system updates

Purchaser

- Likely to purchase the product. This can be the end user or a contact of the end user.
- May be the one to give software education to the end-user.
- May also be the one to help ensure regular calibration and maintenance.

End-user

- Medical devices are continually assessed when they are used. Users are participants in post-market surveillance and adverse event reporting
- Use system as directed
- Ensure regular calibration and maintenance

Customer's care team

- Patient's primary care physician, nurses, and caregiver's success will help determine the customer's success, which in this case is improved health outcomes.

Types of Customers (Customer Segmentation)

Identification	Description	Characteristics
Patient with caregiver	A patient with a caregiver, whether that is an in-home caregiver or one in a Senior facility, is a customer who needs more assistance with daily activities and requires support available as needed throughout the day.	<ul style="list-style-type: none"> - Usually individuals age 65+ - May have acute or chronic health problem. - Likely has mild-moderate memory and sensory impairment
Patient's Power of Attorney	In medical terms, this is person that the patient chooses to make medical decisions on his or her behalf. In this project, I will be defining this term as someone who the patient authorizes to access his or her account.	<ul style="list-style-type: none"> - Usually spouse, children, and sometimes grandchildren of the patient. - Has a close relationship with the patient. - Usually involved with patient's medical care / plan (Driving to Doctor appointments, picking up refills, etc.)
Patient who lives independently	This patient may live at home independently or with family, but does not usually need help with activities of daily living. However, they may be interested in the system to promote compliance and keep track of progress.	<ul style="list-style-type: none"> - Memory and sensory impairment less of a concern. - Likely making decisions for himself / herself - Not many others involved in his or her medical care.

The Customers I've Decided to Focus on and Why

In this document, I will be focusing on 2 end users, the Power of Attorney and a patient who resides in a senior care facility. They are usefully different from each other because the purchaser will likely not be the primary user of the product; however, his or her wants are very important and likely to affect user's health outcomes. He or she will also be interacting with the software much less and as different type of user with different functionalities. The purchaser will mostly have access to reporting and monitoring features.

Meanwhile, the primary user will be interacting with the system on a more regular basis and holds primary control over the system, unless he or she authorizes a different person. The user will be utilizing most system features including but not limited to medication dispensing and activity logging. All medications and medical data that is inside the system belongs to the patient and the patient only.

User archetypes (Customer personas)

Power of Authority



(image courtesy of [123RF](#))

Name: Susan

Gender: Female

Age: 45

Occupation: Business analyst

Employment status: full-time

Personality: Busy, nurturing, involved

Description: Susan is a full-time business professional with household size of 5. She has 3 children, 2 of which are in grade school. Because of her busy schedule at work and familial obligations, she is not able to care for her father, whom she visits once or twice a month at a senior care facility located 10 miles away.

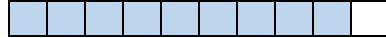
IT and internet proficiency:



Software proficiency:



Mobile device proficiency:

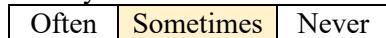


Technology: Susan is very comfortable with using computers. In fact, she uses computers extensively at work. She may need a quick demonstration or tutorial video when first learning a software, but otherwise can navigate the rest of the system on her own. Occasionally contacts IT for trouble shooting purposes.

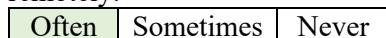
Preferred method of contact: Phone or text

Disability: None

Will be interacting with system directly:



Will be interacting with system remotely:



Likelihood of purchasing the system:



User experience goals: Valuable, reliable, available

System must haves:

- Real time monitoring
- Reporting
- Refill reminders

System must never:

- Share information outside care team
- Ignore non-compliance

Comments, questions, or concerns: Susan is concerned that her father, Greg, is missing medications to treat his chronic illnesses. She is interested in purchasing a product that promotes medication compliance and contacts her whenever he misses a medication.

Patient



(image courtesy of [ClipDealer](#))

Name: Greg

Gender: Male

Age: 79

Occupation: Navy veteran

Employment status: Retired

Personality: Interested, open-minded, nurturing

Description: Greg is a retired veteran who lives in an apartment at a senior care facility. He needs help ambulating longer distances but otherwise can ambulate on his own. His care team helps him with getting in and out of the shower, meal preparation and taking medications. He takes 6-7 medications daily for maintenance of his chronic diseases. He receives medication assistance at an extra monthly cost in his facility.

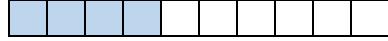
IT and internet proficiency:



Software proficiency:



Mobile device proficiency:



Technology: Greg is not very familiar with many technologies. He has very poor vision and memory, making it difficult to adapt to new technologies. However, Greg loves using Alexa which was installed by his 17-year-old grandson. He uses Alexa to play music and turn on the lights through voice command.

Preferred method of contact: Phone

Disability: Dealing with some memory problems. Wears corrective lenses. Uses wheelchair at baseline.

Will be interacting with system directly:



Will be interacting with system remotely:



Likelihood of purchasing the system:



User experience goals: Valuable, reliable, available

System must haves:

- Easy to read text
- Voice control
- Description of medication

System must nevers:

- Dispense pill without him in the room

Comments, questions, or concerns: Greg would really like to know what medications he is taking and for what problem, so he can track his progress and be able to make informed decisions when at the Doctor's office.

Susan, the busy daughter, no longer has extra time
(Customer Scenario #1)

Susan is a business analyst for large technology company in the city and a mother of 3 children. Susan is also a daughter and Power of Attorney to Greg, a 79-year-old Navy veteran. Before having children, she had more time to spend with her father. She visited him at home multiple times a week. However, her schedule gradually became busier with increased work responsibilities and caring for her children at home. She is no longer able to allocate as much time to care for her father as she used to. She helped her father move into a senior care facility, 15 miles away from her home, where he receives help with daily activities such as showering, meal preparation, housekeeping, laundry, and medication administration. She visits her father twice a month to take him to lunch with family, take him shopping, and pick up medication refills. However, Susan has grown concerned that the care that her father is receiving is inadequate. Her father complains of not receiving medications at timely manner and a few occasions when he feels that he missed a dose. This is very concerning for Susan as she knows that the medications are very important to controlling her father's chronic diseases such as diabetes, hypertension, and high cholesterol.

<<magic happens>>

Susan can relax knowing her father is taking his medications. With an app in her mobile phone, Susan can check which medications her father has taken. However, she never has to worry about checking all the time because the app will alert her when the patient has missed a medication. She will also be notified 4 weeks in advance of any necessary refills to be ordered. She loves the fact that the system logs the patient's medication activity and allows for printable format so that her father can take with him when he presents to the clinic for follow up and wellness visits.

Greg misses his medications

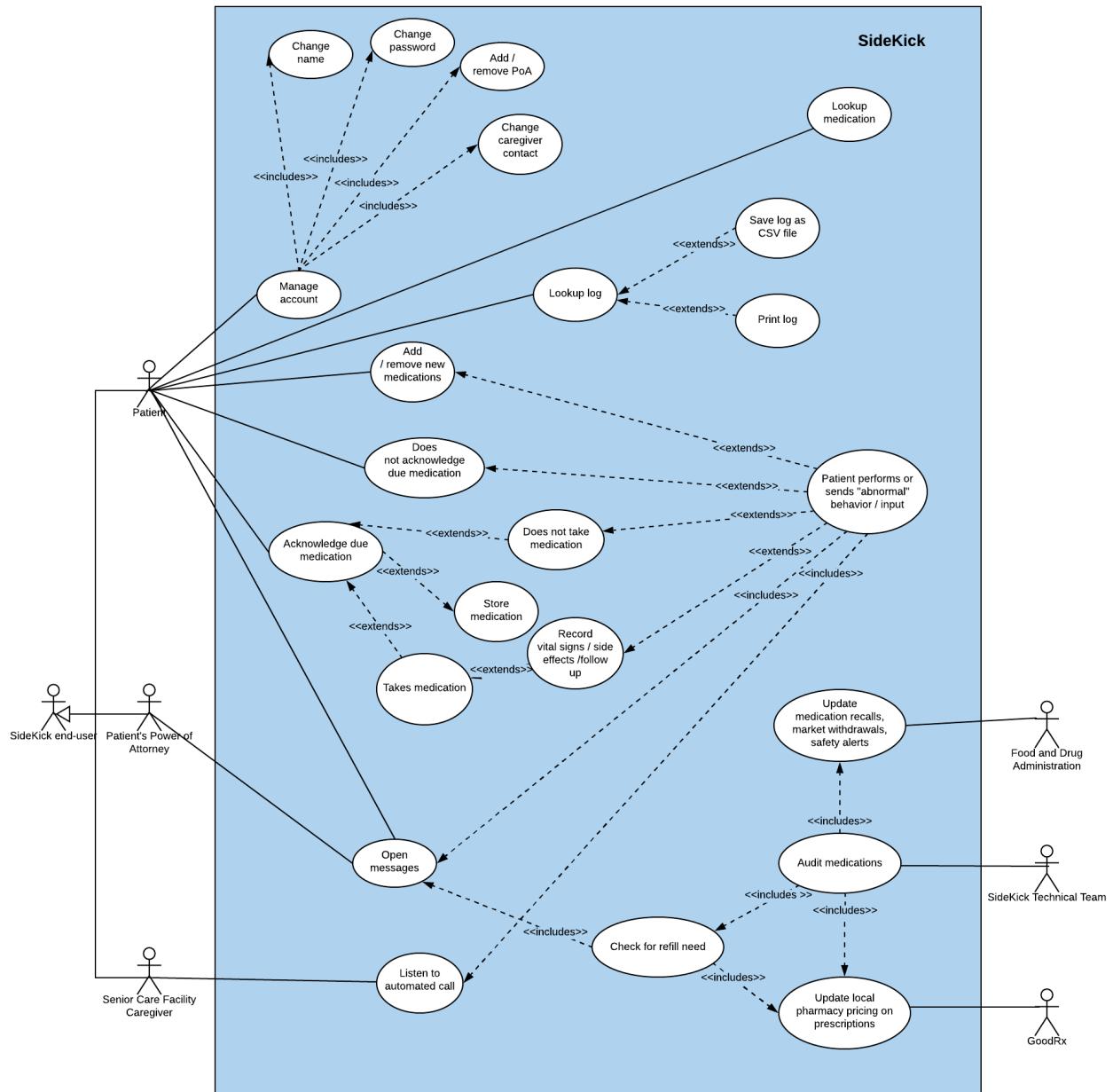
(Customer Scenario #2)

Greg is a 79-year-old retired Navy veteran. He currently lives in a small 1-bedroom apartment at a senior care facility where he receives hygiene care, meal preparation assistance and medication administration. He loves his apartment and is overall very happy with the care he receives. However, with recent understaffing in the facility, he is concerned that he is receiving his medications too late. He believes that there was one or two nights when he missed his medications. Even with proper staffing, Greg wishes there was a way to better understand what medications he is taking and for what problems. Greg feels that he doesn't understand much of his medical regimen and just takes the small cup medications every time it is given to him. He wishes there was a better way to track compliance so he could track his own progress. Greg is also concerned of the cost medications. He was hospitalized last year for a stroke and had to take out a good chunk of his retirement savings to help pay for hospitalization costs. He's been receiving medications at the pharmacy for many years and unsure of where he can receive better pricing for his prescriptions.

<<magic happens>>

Greg now takes every medication on time as prescribed. He feels safe knowing that his medications are secured and only accessible with his voice command and fingerprint. He loves the fact that every time a medication is dispensed, he sees the photo of the medication on the screen to confirm the right medication was dispensed along with pertinent information such as associated diagnosis and progress towards goals. When he goes out with his daughter and grandchildren, he can enter the times he will be gone, and it will dispense medications that he will need to take while he is out. He has also been able to print his activity, with details such as time medication was taken and follow up vital signs. During his last visit with his primary care provider, he was able to note that his blood pressure medication, lisinopril, was not working at its current dose. Greg feels happy and confident to have better understanding and control of his care regimen.

How the Customers Interact with the System (Use case diagram)



What the System Must Do, Organized by Functionality (Functional requirements)

20+ functional

Account management

1. The user must be able to create profile with name, password, and fingerprint.
2. The user must be able to modify password, Power of Authority persons, and caregiver contact at any time.
3. The system must allow user to enter and track his problem list, which includes diagnoses and allergies

Storing & dispensing medications

4. The system must have a way to store medications, allowing for physical separation between different medications.
5. The system must check for any drug interactions or allergic reaction to any new drug being added.
6. The system must be able to dispense 1 medication at a time.
7. The system must dispense the right medication at the right time based on prescription.
8. With each medication dispensed, the system must include an image of the medication and pertinent information such as name, summary, dose, prescription and associated diagnosis.
9. The system could capture evidence of patient taking medication.
10. The system must prompt vitals or follow ups as necessary before or after taking a medication.
11. The system must allow patient to take medications with him/her, he if he or she needs to be away.

Activity logging

12. The system will log activity of added, discontinued, and dispensed medications with timestamp and comments.
13. The system will identify any abnormal side effects, vital signs, and follow ups and generate messages to send to POA and Senior Care Facility Caregiver.
14. The system should allow patient to enter goals for each diagnosis.
15. The system should keep track of progress towards goals.
16. After every medication taken, the system should show a summarized overview of progress towards goals.
17. The system must allow for patient to print all activity or export it as CSV file.

Abnormal event reporting

18. If the patient has not acknowledged scheduled medications, the system must continue to beep. If no acknowledgement within 60 minutes, the system must contact POA and Senior Care Facility Caregiver, notifying them of the missed dose.
19. The system must report any abnormal vital signs or follow ups to POA and caregiver.

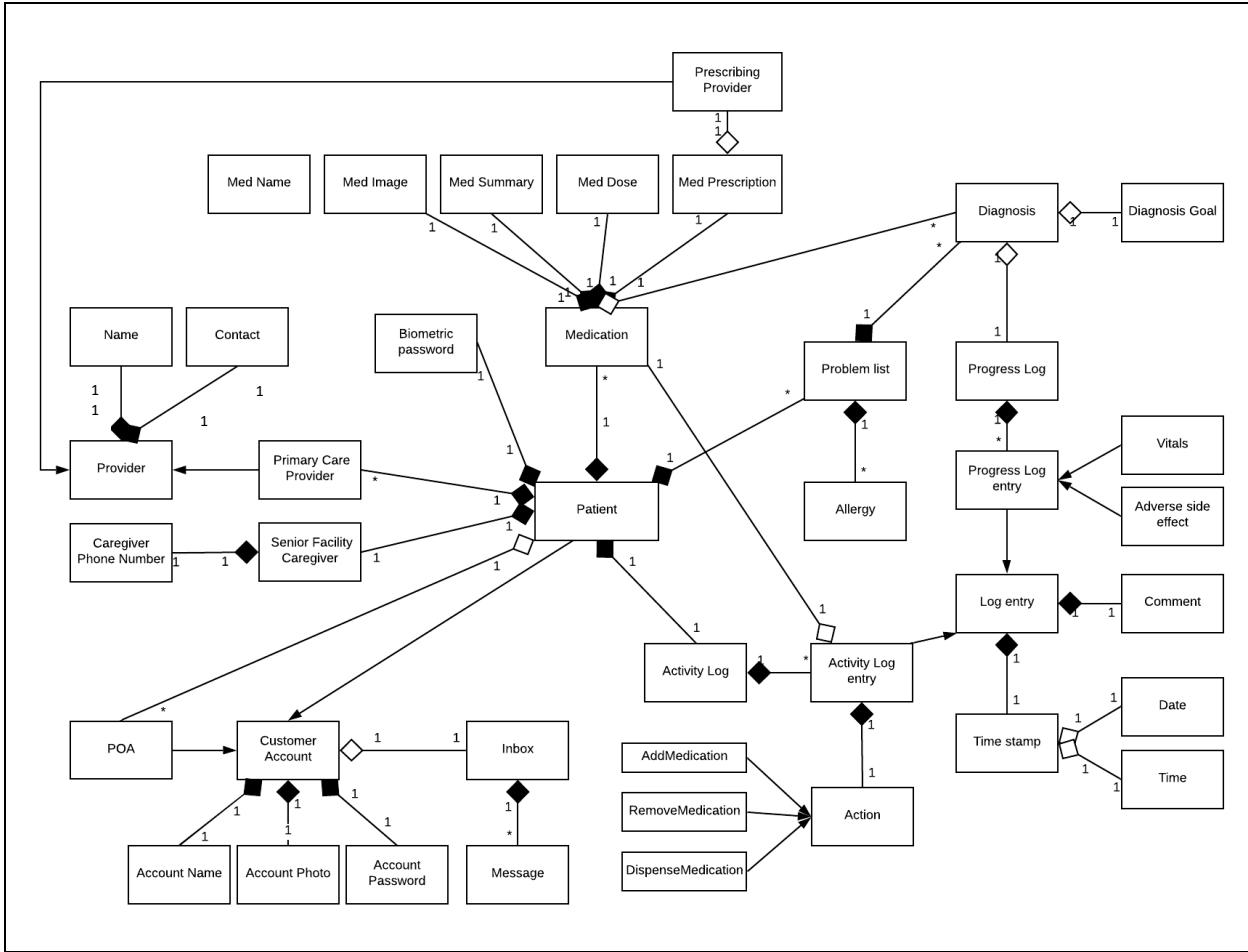
Refill reminders

20. Before sending out refill notifications, the system will check for updates on the medication from the FDA and search for cheapest pricing on the medication between different pharmacies.
21. The system must notify patient and POA of any refill needs, at least 3-4 weeks before last dose.
22. With each refill notification, the system should provide actions or contact information necessary to obtain refill.
23. At every refill, the system will use GoodRx to find pharmacies with cheaper pricing on that medication and return the name, address, and contact of that pharmacy.

10+ non-functional requirements

1. Dependability: The system must be available 99.95 percent of the time. All updates and maintenance must be performed when patient has no scheduled medications. A notice must be provided to the patient at least 2 weeks in advance, with a reminder 1 day and 1 hour prior to system downtime.
2. Dependability: The system must provide 24/7 customer support for all end users of system
3. Dependability: The system must audit all medications daily at 3 AM.
4. Efficiency: The system will not require more than 5 steps when dispensing medications.
5. Usability: The system must have all text easily readable. To better accommodate those with vision impairment, all text must be at a minimum size of 14.
6. Usability: The system must be compatible voice command, for those with difficulty using their hands.
7. Regulatory: They system must dispense medications following the 7 Rights of Medication Administration. The system will allow for patient to decline medication, to abide to patient's right to refuse.
8. Regulatory: The system must keep all medical data private. All personal information must only be available to patient, POAs, and care team.
9. Security: The system must lock and notify all POAs and caregivers after 3 failed authentication attempts.
10. Security: The system must require two factor authentications, which consists of a strong password and biometric authentication.

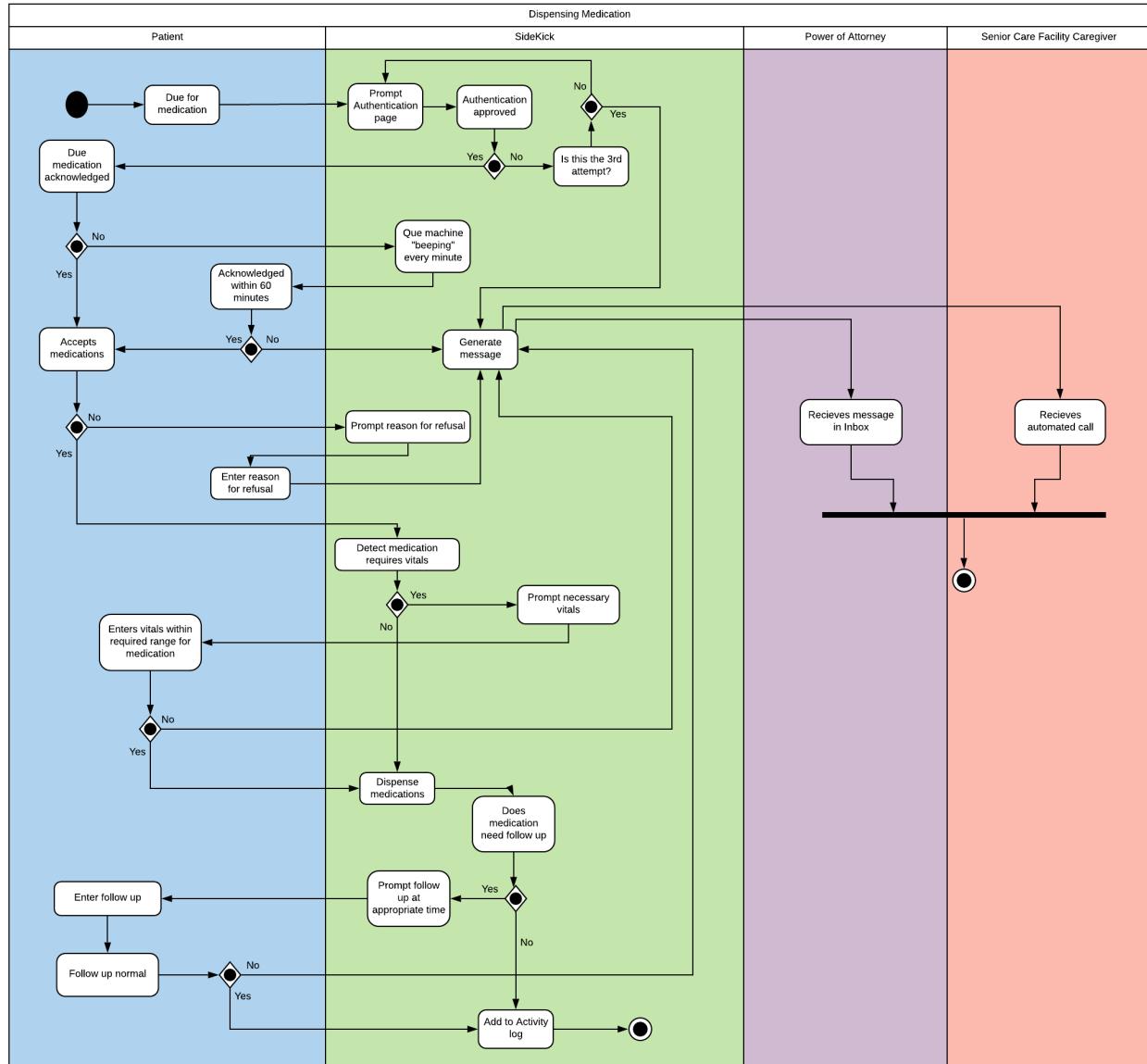
Parts of the System: (Domain diagram)



Design Rationale: This diagram addresses the concerns of definitions. The domain diagram clearly illustrates domains (also can be thought of as classes), what they are, and their relationships. This is particularly useful as it showcases real life objects with generalization, composition, and aggregation. Unlike the activity and deployment diagram, this diagram does a great job in identifying entity classes and functionality. This can be easily understandable by end-users meaning it could help V&V process go by easier. This is also commonly used by developers early the development phase, making the transition from requirements to software components easier.

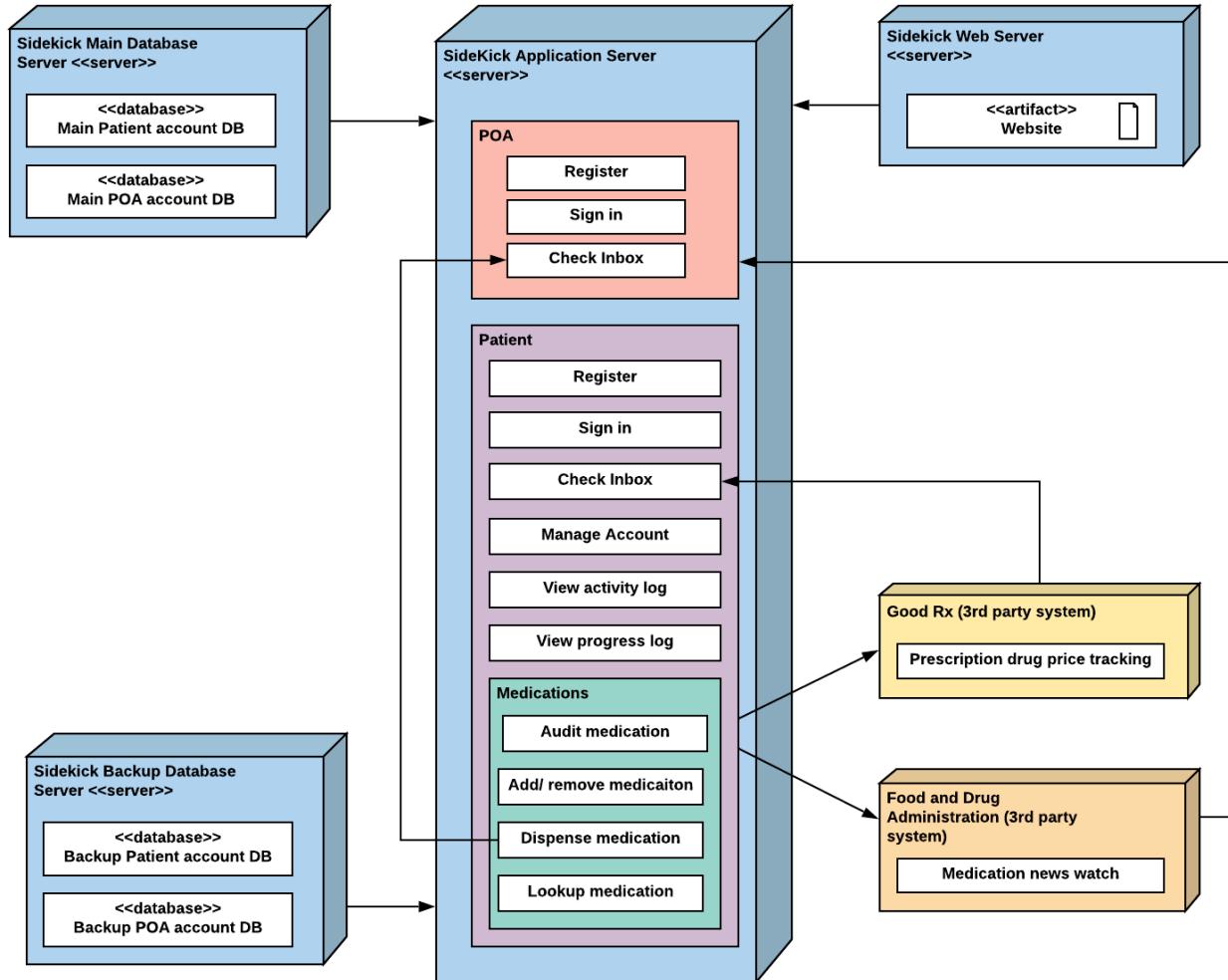
The Process of Taking a Medication (Activity diagram)

Description: My activity diagram tracks the event of a patient acknowledging and taking a medication that is due, based on his or her prescription.



Design rationale: I chose an activity diagram because it clearly shows activities and transitions between them. This can be used early on when first studying how dispensing, monitoring, and reporting work, which makes it very useful for programmers to depict workflows. This is no surprise as activity diagrams are usually very useful when trying to understand a particular use case. The activity diagram is most useful for this use case because not only does it trace an event from start to finish, it also does a great job on showcasing the different paths the system might take given the user chooses one option over the other. Other diagrams such as domain diagram, layered, and deployment don't illustrate conditional statements in such a detailed manner.

How Data is Allocated (Ad hoc physical architecture view)



Design Rationale: This ad hoc view is very helpful for system programmers because it shows the system hardware and how software components are physically distributed. This shows that the data is stored in a database on a DB server that interacts with an application server, which interacts with a webserver. This ad hoc network diagram shows how devices are communicating and exchanging information through the network. Out of all the diagrams, this diagram may be the most useful in laying the type of systems people are using and information exchanged between different parts.

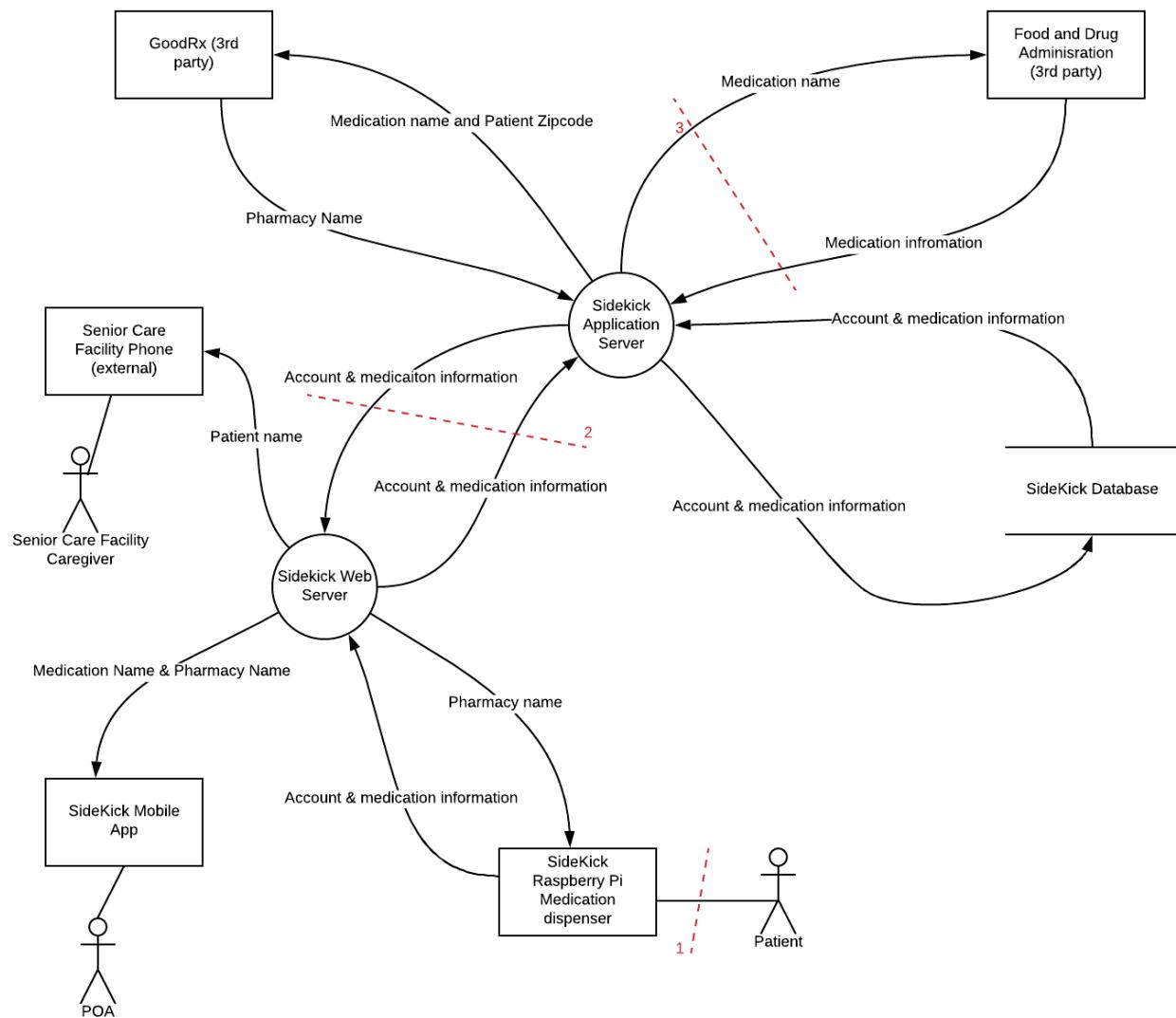
Glossary - an informative definition of each domain object. Make sure you will keep the terminology consistent and coherent across all parts.

Name	Defintion
Account Name	First and last name of account holder
Account Password	Account holder password
Account Photo	Account holder photo
Action	Action that the patient must perform. They can either add, remove, or dispense medications.
Activity log entry	A log entry that contains a medication, action, time stamp and comments.
Adverse side effect	Any undesired harmful effect from a medication.
Biometric password	Biometric input from the user to be used in authentication.
Caregiver Phone	Patient's caregiver's phone number.
Number	
Comment	Any comment a patient wants to add with any type of log entry.
Customer Account	A customer account is any account holder. Currently the system supports only two types of accounts, POA and Patient accounts. Each account contains a name, photo, password, and inbox.
Date	Date of when the activity entry was created.
Diagnosis	An identification of an illness.
Diagnosis Goal	Any goal the patient wants to work towards. This is likely vital signs, for example the patient wants to lower blood pressure to >140/90. But the patient can create more informal goals by free typing.
Inbox	A space for the customer's messages.
Log entry	Generic log entry, which contains a comment and time stamp.
Med Dose	Medication dose as it is written on the prescription
Med Image	Medication image captured when first added and stored into the system
Med Name	Medication name as it is written on the prescription
Med Prescription	How and when to take medication as written on the prescription. It also includes number of pills prescribed.
Med Summary	Quick summary of the medication
Medication	Class containing all necessary information about the medication
Message	System's generated messages, sent to account inbox.

Patient account	Patient's account, which contains most of the Sidekick's functionalities. Patient account can modify authorized POAs. This account can add, remove, dispense medications and modify problem list at any given time. All data and medications in the System belongs to the patient.
Patient Problem list	A Comprehensive list of patient diagnoses and allergies.
POA / Power of Authority	Any person that a patient authorizes to access all his or her medical data.
POA Account	Customer account belonging to POA. This has very limited functionality. Its main feature is that it can receive notifications in inbox.
Prescribing Provider	Name of provider who provided a prescription to the patient.
Primary Care Provider	Name of patient's Primary Care Provider.
Progress Log	A log containing progress log entry to keep track of patient's progress towards diagnosis goals
Progress log entry	A type of log entry that also contains either a vital sign or adverse side effect.
Provider	A health professional that provides treatment and advice based on formal training and experience. Usually, they are health professionals holding one of the following titles: MD, DO, PA, or NP.
Senior Facility	Entity acting as caregiver for the patient. This entity is a health
Caregiver	professionals holding one of the following titles: HCA, CNA, LPN or RN.
Time	Time of when the activity entry was created.
Time stamp	Generated time stamp composed of date and time.
Vitals	A collection of quantitative measurements that assess state of patient's essential body functions.

Data Flow During Medication Dispense and Identified Refill Need (Data flow diagram)

Description: This data flow diagram describes the case when the patient takes the last dose of the medication. When the patient runs out of the medication, it will check for updates on medication recalls and news and then check for the lowest pricing on the medication and return a pharmacy name. It will then generate unique messages to the POA and the caregiver.



Risk with the Patient and the Medication Dispenser

(Threat analysis on boundary #1)

STRIDE THREAT MODELING			
	Threat	Property Violated	Hypothetical events
S	Spoofing	Authentication	Someone could identify as the patient and act as the user. They can dispense prescription drugs that were not meant for them.
T	Tampering	Integrity	Someone could tamper with the account data, writing false information about the patient and his or her medical regimen.
R	Repudiation	Non-repudiation	The end user can claim not seeing notifications on the device.
I	Information disclosure	Confidentiality	Someone could identify as the patient and gain medical records data.
D	Denial of Service	Availability	The dispenser device crashes. This violates availability because the patient does not have access to his or her medications.
E	Elevation of privilege	Authorization	Someone who didn't have consent from the patient can act as the patient.

DREAD RISK ASSESSMENT MODEL		
	Question	Answer
D	How much damage will the attack cause	This boundary can expose very sensitive medical data to an unauthorized user if the attack is successful. Such event is a very clear violation of HIPAA laws.
R	How easy is it to recreate the exploit	It can be fairly easy if the patient is not required to generate a strong password and if we do not use biometric passcode.
E	How easy is the exploit to use / distribute including knowledge and environmental factors	If the attacker gains access into the device, he or she can print or save the .csv file containing sensitive medical data (medications, diagnoses, activity logs). The digital storage presents a greater concern as .CSV file could be easily read and distributed.
A	How many of the system users would be impacted by an attack?	The patient will be the one to be impacted as all information belongs to them.
D	How easy would it be to figure out an exploit	Given that the system requires biometric passcode as well as strong generated passcode, it should be fairly difficult to gain authorization to the device.

Risk in the data flow between the Web Server and Application Server (Threat analysis on boundary #2)

STRIDE THREAT MODELING			
	Threat	Property Violated	Hypothetical events
S	Spoofing	Authentication	Someone could redirect traffic onto a different Application server, pretending they are indeed the SideKick Application server.
T	Tampering	Integrity	Someone could tamper with the network and redirect traffic to a different Application Server.
R	Repudiation	Non-repudiation	The attacker could claim that they never performed such an attack.
I	Information disclosure	Confidentiality	Someone could redirect traffic and gain sensitive medical records data.
D	Denial of Service	Availability	Someone could bring the webserver down by consuming network resources. If the servers are not able to communicate with each other, Sidekick would be denying patients of service as they cannot access their medications.
E	Elevation of privilege	Authorization	An attacker can manipulate data between the application server and webserver and grant themselves as a patient to gain full access data and functionalities reserved for patients only.

DREAD RISK ASSESSMENT MODEL		
	Question	Answer
D	How much damage will the attack cause	This boundary can expose very sensitive medical data to an unauthorized user if the attack is successful. Such event is a very clear violation of HIPAA laws.
R	How easy is it to recreate the exploit	The system will try its best to cover all hypothetical events. It will always log and report any suspicious or abnormal activity in real time to prevent this from happening.
E	How easy is the exploit to use / distribute including knowledge and environmental factors	It should not be too easy for them to exploit the data as it will always go through encryption during transit.
A	How many of the system users would be impacted by an attack?	The patient will be the one to be impacted as all information belongs to them.
D	How easy would it be to figure out an exploit	The system will update itself on known types of web server attacks routinely. It will also log and report any abnormal or suspicious activity. It will counteract such activity with event such as reporting, confirmation, and authorization.

Risks when exchanging information between the FDA (Threat analysis on boundary #3)

STRIDE THREAT MODELING			
	Threat	Property Violated	Hypothetical events
S	Spoofing	Authentication	Someone could impersonate themselves as the FDA.
T	Tampering	Integrity	Someone could tamper with medication information, writing false claims about medication that can influence patient choices once he or she receives updates about the medication.
R	Repudiation	Non-repudiation	The FDA can claim that they never received a request
I	Information disclosure	Confidentiality	N/A
D	Denial of Service	Availability	Failing to get updates from the FDA is depriving the end user of the feature to allow them to keep updated on pertinent information about their medications.
E	Elevation of privilege	Authorization	N/A

DREAD RISK ASSESSMENT MODEL		
	Question	Answer
D	How much damage will the attack cause	This boundary will only exchange medication information, and at the most superficial level. However, if an attacker tampers with the data coming into the system, this can send inaccurate information to the user which can be very harmful as they make decisions based on the information.
R	How easy is it to recreate the exploit	The system will try its best to cover all hypothetical events. It will always log and report any suspicious or abnormal activity in real time to prevent this from happening.
E	How easy is the exploit to use / distribute including knowledge and environmental factors	The information going out will be only the medication name. The information coming in will be about the medication (updates and recalls), which should be freely available to all on the internet.
A	How many of the system users would be impacted by an attack?	The patient is the only one to be affected if such an event was to occur.
D	How easy would it be to figure out an exploit	The system will update itself on known types of web server attacks routinely. It will also log and report any abnormal or suspicious activity. It will counteract such activity with event such as reporting, confirmation, and authorization.

