Pharmaceutical Solutions Inc.

Project ID: MSBA-203

Project Name: Pharmaceutical Solutions Inc.

Project Manager Name: Professor Joseph Taylor

Document Author Name: Endalk Aychiluhim
Girma Tiruneh
Saaj Sidhu

Revision Number: 001

Document Date: May 12, 2022

Approved By: Professor Joseph Taylor

Project Sponsor: California State University, Sacramento

Reviewed By:

Professor Joseph Taylor, **Project Manager**	Pharmaceutical Company, Infrastructure
Customer	Doctor approved patients
Development	Final Stage
QA	Defense During Proposal Presentation
Security	Available

Table of Contents

1. Purpose

In the United States, prescription drug prices are significantly higher than other countries around the world. Prices of these drugs have been increasing without any reason since 1960, and a large number of patients can not afford them. As a consequence, not only patients or customers are affected, instead, pharmaceutical or drug companies and commercial business licensed companies are losing large amounts of revenue by disposing of expired prescription drugs. As a solution, our project proposed that commercial business licensed companies to facilitate international online dispensing systems at a much lower price in order to make more revenue by selling at a reasonable price and sell a large number of prescription and nonprescription drugs without losing a quality with a high acceptance rate by customers. The main purpose of this business proposal is to compare drug prices between The U.S and other countries based on manufacturing costs and to import as well as opportunities to improve affordability, and increase revenue.

Our customer, Pharmaceutical Solutions Inc., is a prospective public for Profit company. The mission of the Pharmaceutical Solutions (under formation) is to challenge/disrupt the current US pharmaceutical market to bring the price of prescription and nonprescription medicine to the ‘real’ worldwide market price.

2. Business Metric Requirements

Profit (as a result of lower cost) is our measure. Preliminary study shows that the price of the US prescription drugs are two and half times the price in other countries. Prescription drug prices in the United States are significantly higher than in other nations, with prices in the United States averaging 2.56 times those seen in 32 other nations, according to a RAND Corporation report.

We plan the project will identify a strategy to reduce the price of prescription and nonprescription drugs by half.

The preliminary study shows it is realistic and attainable. The project will be completed 160 days

Topic	***Response***
What will the BI solution developed in this project do?	Find the root cause of ever increasing prices for prescription and nonprescription drugs. Compare and analyze production costs of the US and neighboring other countries? formulate a comparative advantages import vs. produce. Stipulate the effect of import on R & D in the US if import is found to be more cost effective. Disrupt the current US pharmaceutical market facilitating online dispensing from other countries.
Who is going to use the output of this solution?	Pharmaceutical Solutions Inc. (the customer) is the primary beneficiary from the project in the form of future profit. The public at large will benefit from reduced price and increased quality because of international competition. The US government will benefit from the saving (Medicare cost)

2.1 Business Gains

There are many benefits that can be gained with this proposal that goes beyond money. Prescription drug companies have been able to significantly increase prices to a nearly unaffordable rate. Our proposal solves the problem of limited competition in the pharmaceutical market. This allows lower prescription drug prices seen in other countries, to make more of a presence in the American market. There is little price regulation when it comes to prescription drugs. Drug manufacturers have no consequences or incentive to stop increasing the price.Many customers have had to pay the price for this. Many people who are not able to afford these prices, have ended up not getting their medication and dying as a result. By providing cheaper alternatives from global competitors, American drug companies will be pressured to lower their prices.This can contribute to a dramatic positive impact towards Pharmaceutical Solutions Inc.'s reputation. More people will view the company in a positive light, now that they are challenging the U.S pharmaceutical market. It will also give the Pharmaceutical Solutions.Inc more good will in the eyes of the customer. This is due to customers being able to afford their medications, and take care of health issues. Pharmaceutical Solutions will be considered an innovative commercial company that helped pave the foundation for providing affordable prescription drugs in America. The company will own an advanced system for storing prescription information that no other company has.

2.2 Key Business Questions/Drivers

KBQ ID #	Key Business Questions or Drivers	Submitted by
KBQ1001	How much does prescription and nonprescription drugs cost in the U.S?	Endalk Aychiluhim
KBQ1002	Which age groups are needed the most?	Girma Tiruneh
KBQ1003	What is the total number of prescriptions filled annually in the U.S from 2013 to 2025?	Saaj Sidhu
KBQ1004	What is the total U.S population that took five or more prescription drugs within 30 days?	Endalk Aychiluhim
KBQ1005	What are the methods to reduce drug prices and make more accessible for large revenue?	Girma Tiruneh

3. Business Design

3.1.1 Existing Business Process Details

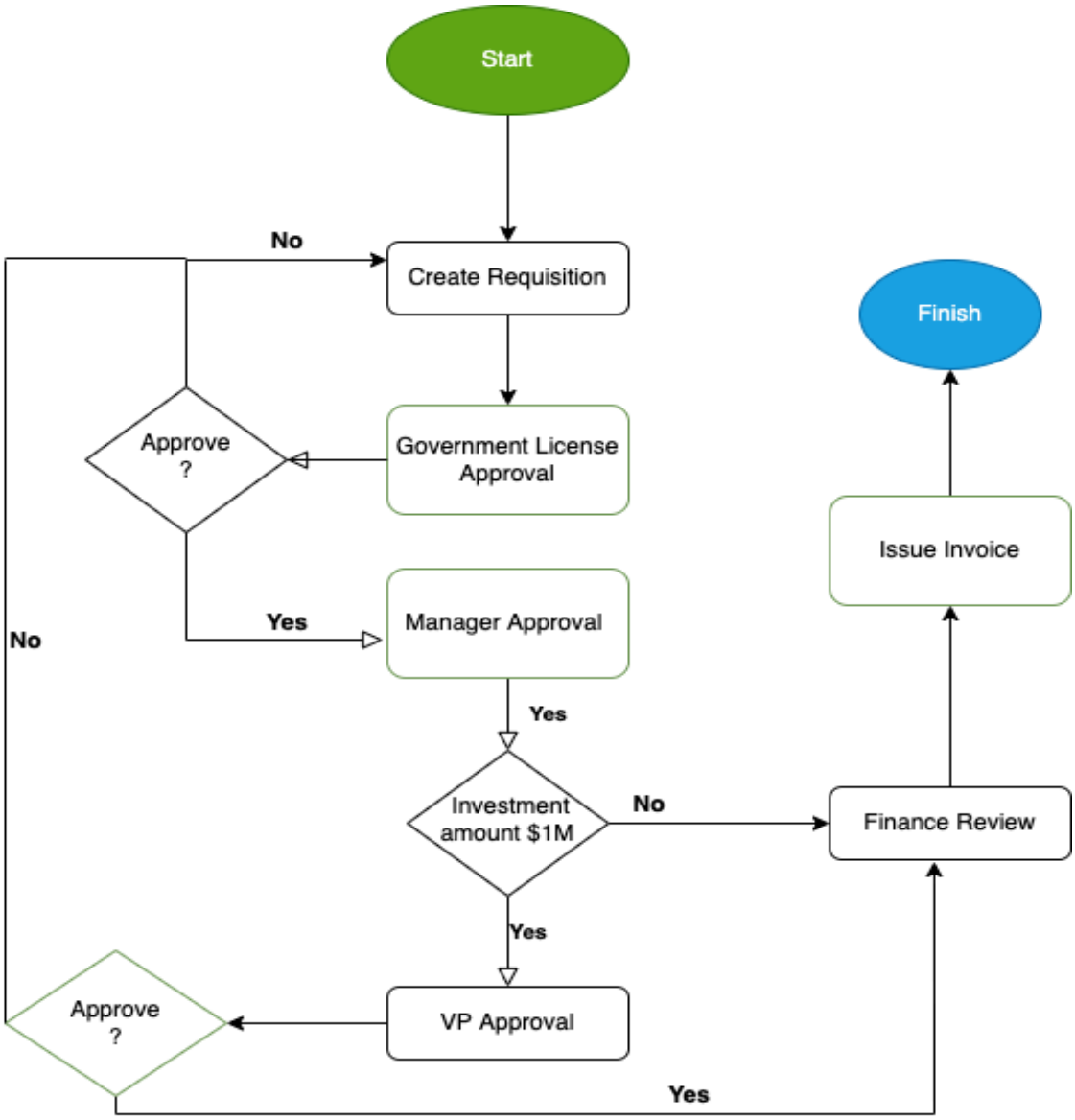
- Outside Providers must approved by FDA (Food and Drugs Administration)

  to be competitive in the market

- Customers can sort drugs based on prices and name of brand manufactures.
- Follow HIPAA(Health Insurance Portability and Accountability Act) protocol.

3.2 Proposed Business Process Diagram

The next flow diagram describes the process of prescription drugs starting from a Pharmaceutical Solutions Inc to approve a government license and import to the U.S with a total capital of one million dollar.



3.2.1 Proposed Business Process Details

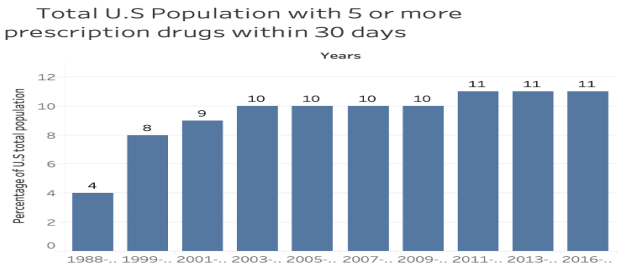
The business proposed is similar to Amazon. Two additional parties that will be added in the platform besides the buyer and the seller are provider and approver.

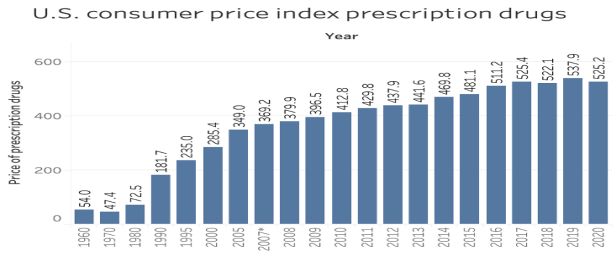
Provider is the patient's doctor or hospital system who places the prescription in the system. The system checks FDA approval for the prescription and lists out pharmaceutical companies or pharmacies approved to provide prescription medication in the United States.

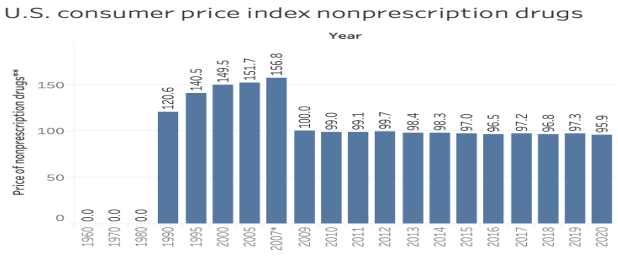
Then the patient logs-in and retrieves medication outstanding for him/her. The system will provide him/her the option such as generic vs brand, pharmacy, country, delivery method etc…

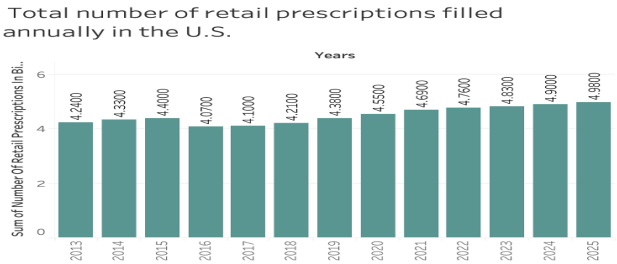
3.2.2 Dashboard and Graphs

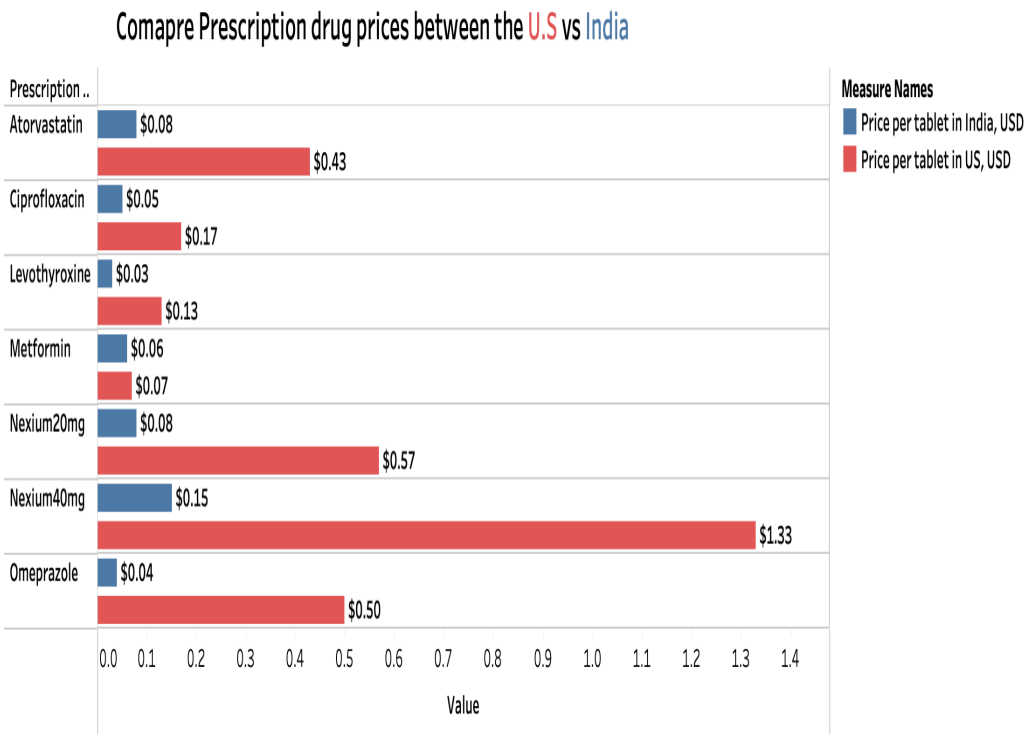
The next dashboard and graphs are indicating how price prescription drugs are expensive and increase over a period of time. In addition, it shows compare price of prescription drugs of other countries are much cheaper than the U.S.



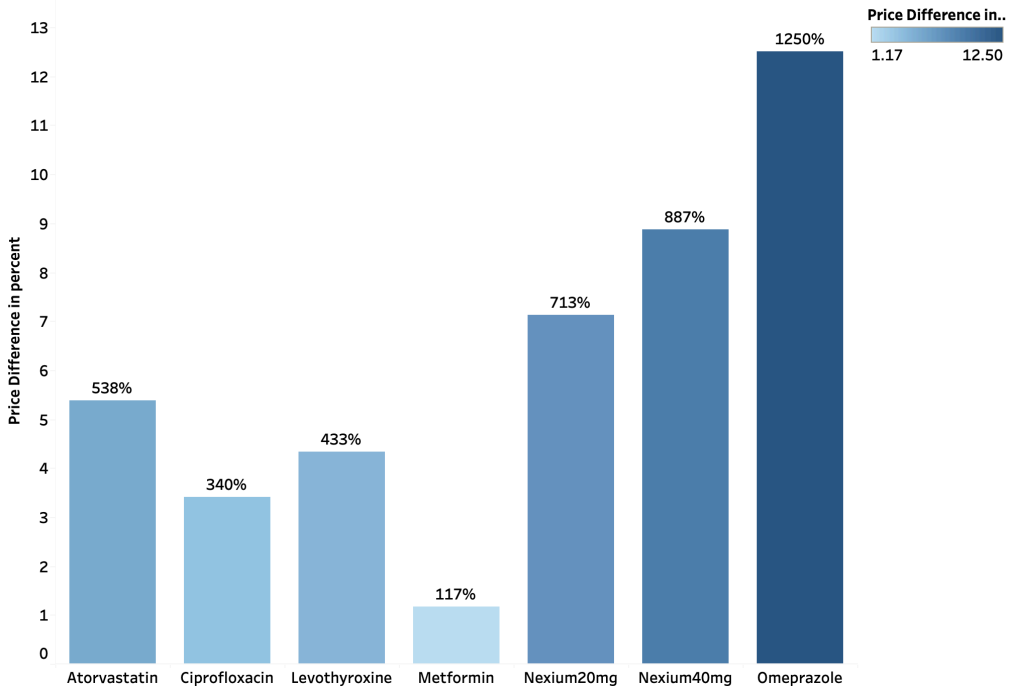




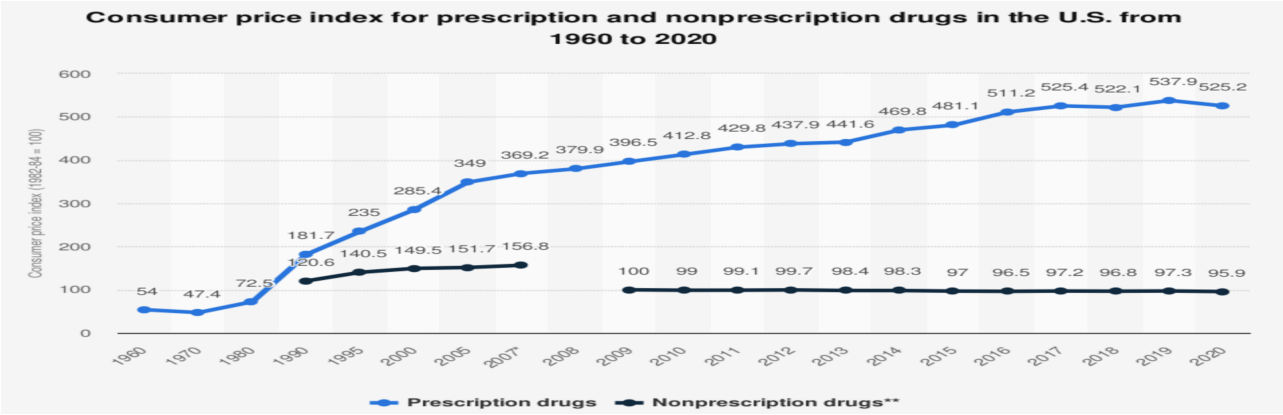




1. Atorvastatin: 1x a day
2. Ciprofloxacin: 2x a day/3-14days
3. Levothyroxine: 1x a day
4. Metformin: 2x a day
5. Nexium: 1x a day/ 4-8 weeks
6. Omeprazole: 1x, 2x or 3x a day 4-8 weeks.

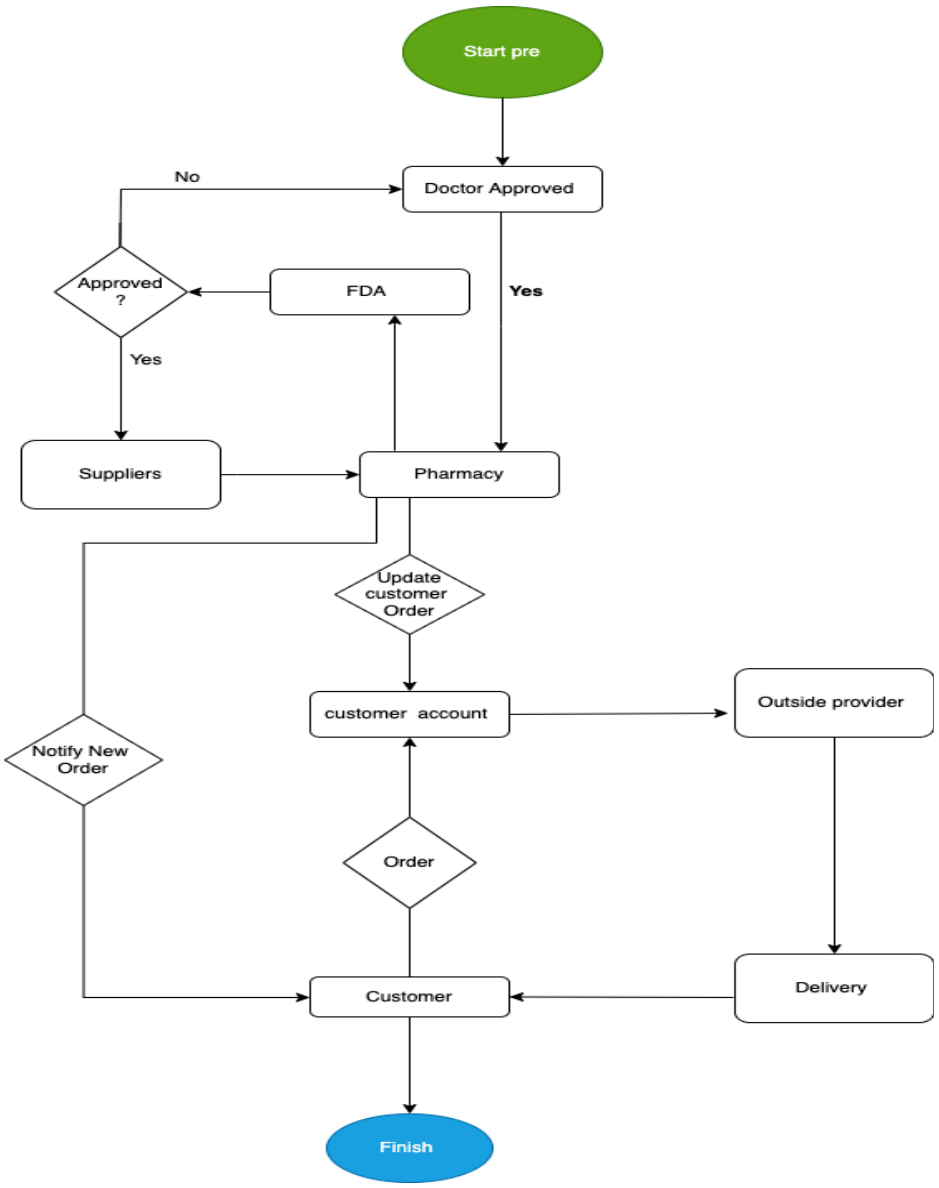


- Our proposal excludes non-prescription drugsSince price of these drugs are affordable.
- Prices of prescription drugs are rising over time.
- Rises 973% since 1960



3.2.3 Information Flow Diagram

The next flow diagram shows how prescription drugs are ordered from a doctor to a specific patient/customer.



3.3 Use Cases

Request	Valid Equivalence Partitions	Invalid Equivalence Partitions

Customer create requisition	1) Doctors approve prescription drugs and send it to pharmacy	2) If patients is needs non prescription medication, doctor do not request a prescription drugs
Pharmacy accept request from a doctor	3) Pharmacy request for approval from FDA	4) Drugs don't have a generic/scientific need to be checked back to the doctor.
FDA check the drug approval	5) FDA approved drugs notify to suppliers	6) Non approved drugs are notified to a primary doctor by the FDA .
Suppliers notify to pharmacy	7) Suppliers notify to pharmacy to with a legal QR code to the next level	8) If suppliers do not get the request, the request takes long time to process
Pharmacy notification and update	9) The pharmacy notified the customer and updated the customer account at the same time.	10) Pharmacy process takes longer time to process if suppliers can not send the access code
Customer access and order	11) Customer order approved drugs using customer account	12) If the pharmacy can not update customer requests inside a customer account it takes a longer time to process.
Customer account authenticatio n and authorization	13) Customer account works for a right customer by using authorization and authentication and sending order requests to outside providers.	14) The request is denied if customer authentication and authorization can not match with the actual profile
Outside Provider accept orders	15) Outside providers accept prescription drugs	16) If an outside provider can not have an order in store, it takes longer to deliver.

	and deliver to a customer address	

3.4 User Stories (for Agile Path)

A. As a research assistant, I want to find data on global drug prices and manufacturing costs, so that I can locate the markets with the cheapest prices
B. As a software engineer, I want to develop a system for storing prescription information, so that customers can understand their options for retrieving their medications.
C. As a provider, I want to place the prescription in the system, so that the system can check for FDA approval.

3.5 User Experience Test Script

The first task that we will go over involves customer users creating their account. The customer will go to the home page and click create account. If they do this,they will be redirected to a page that allows them to create an 8 character password and will be assigned a patient ID. Once they create their password and have an ID assigned to them, they will click next. Once this is done they will be taken to a page where they will fill out their personal information such as ssn and medical history, and email for double verification.. The next task will go over customer users finding the pharmacy page. On the home page, there should be a toolbar with various options. One of the options will be Pharmacy. If you click the pharmacy button it should direct you to the pharmacy page. This is where you can locate the pharmacy that you want to have your prescription sent from. The next task will go over employee users locating patients. Once the NPI is logged in (Explained below) the user would see an option that stats “Healthcare Physician”. The user will click on this option and it will take them to a page where they can enter a social security number. Once they enter the social security number and click enter, they should be granted limited authorization to a customer’s account, in order to fill in prescription information.

3.5.1 User Data Validation Test Scripts

Test ID	001
Purpose of Test	Ensure data entered are compatible with other users i.e. FDA, pharmacies, healthcare providers and other regulatory bodies for seamless transfer of information. Ensure that the data present in final target systems are valid, accurate, as per business requirements and good for use in the live production system. Avoid wrong filling of prescriptions by putting a redundant control system. Information access control by physician and pharmacy.

Test Environment	NCPDP_ID:- This is the unique, national identification number assigned by the National Council for Prescription Drug Programs (NCPDP) to every licensed pharmacy in the United States and its territories NDC:- Drugs are identified and reported using a unique, 10-digit three-segment number called the National Drug Code (NDC) which serves as the FDA's identifier for drugs. FDA publishes the listed NDC numbers in the NDC Directory which is updated daily. Drug establishments are required to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded or processed for sale in the U.S. at their facilities. The first set of numbers in the NDC identifies the labeler (manufacturer, repackager or distributor). The second set of numbers is the product code which identifies dosage or strength. The third set identifies package code (package sizes and types). Social Security number (SSN): Unique identifier of customers Client account number (CAN): Unique identifier of customers. As we will not be using SSN frequently, we

	will have CAN as an alternate unique identifier of customers. User Identification (UserID):- customers and providers will log in to the system using a unique user ID. National Provider Identifier Standard (NPI):- NPI is a 10-position, intelligence-free numeric identifier (10-digit number). This means that the numbers do not carry other information about healthcare providers, such as the state in which they live or their medical specialty. Providers and physicians will have two step login processes. Pharmacies enter NCPDP_ID. Then a dropdown menu appears for each user/pharmacist. Choose the pharmacist and enter a password. Providers/Physicians enter National Provider Identifier (NPI). Then choose a physician user and enter a password.

Test Steps	National Council for Prescription Drug Programs (NCPDP) NCPDP_ID:- ● 5-digit numeric value only. If not the error message “invalid NCPDP” . ● Check 5-digit numeric value in the library of licensed pharmacies, if not found error message “Pharmacy not found”. ● When the correct pharmacy is found, request for additional confirmation displaying the name of the pharmacy “Is this your pharmacy?” National Drug Code (NDC) :- ● 10-digit three-segment number called the, If the code do not constitute the digit and segment criteria, error message “Invalid NDC” ● If the correct NDC is not found in the library, error message “Prescription not found” ● If the right prescription found confirmation request displays “Please verify your prescription” Social Security Number (SSN): ● Healthcare providers use SSN to enter prescription and customer uses to retrieve accounts.

	• If non numeric or wrong digit of numbers interred, display error message “Invalid SSN” • If the right SSN used check with the library and request for confirmation “Please verify if this is the right patient” Client Account Number (CAN):- • Pharmacies use CAN to enter, fill and ship prescriptions. Customers use it to retrieve accounts. • If non numeric or wrong digit of numbers interred, display error message “Invalid CAN” • If the right CAN used check with the library and request for confirmation “Please verify if this is the right patient” National Provider Identifier (NPI):- • Non numeric character or wrong digit entered, display an error message “Wrong NPI” • If NPI does not match to a physician/provider in the library, display error message “NPI not found”

	● If NPI found in the library request for confirmation, display a request for confirmation message "Please verify physician/provider information" Providers and physicians will have two step login processes. ● Pharmacies enter NCPDP_ID. Then a dropdown menu appears for each user/pharmacist. Choose the pharmacist and enter a password. ● Providers/Physicians enter National Provider Identifier (NPI). Then choose a physician user and enter a password.

Expected Result	National Council for Prescription Drug Programs (NCPDP):- ● Retrieve correct pharmacy ● Show/match correct inventories available to fill patients' prescriptions with National Drug Code (NDC). National Drug Code (NDC) :- ● Retrieve correct drug with a correct dosage as prescribed by the healthcare provider. ● Match with the pharmacies with available inventories. ● Match with the correct customer for whom the prescription is for. Social Security Number (SSN): ● Uniquely identify customers. ● Retrieve prescriptions history of customers. ● Retrieve physician information of customers. Pharmacists will have access only to a single NCPDP_ID

	Physicians will have access only to a single National Provider Identifier (NPI):

3.6 Analytic Needs

a. Analyze the effect of increasing prescription drugs on the national economy and specifically MediCare.
b. Analyze data from domestic and international drug prices, administrative costs, and shipping costs.
c. Determine the potential customers (number, age and insurer.
d. Estimate the profitability and scalability of the business.
e. Analyze the drug administration requirements and develop a process for approval, monitoring and administering foriegn suppliers.

#	*Analytic Process*	Key Business Questions				
		KBQ10001	KBQ10002	KBQ10003	KBQ10004…	KBQ1XXX
AR1001	Measure the burden of ever increasing prescription drug costs on the National economy.	X				
AR1002	Measure the effect of increasing cost of prescription drug on MediCare		X			
AR1003	Measure the potential revenue and cost saving by identifying potential customers		X	X	x	
AR1004	Measure potential profitability of Pharmaceutical Solutions Inc.		x		X	

3.7 Operational Needs

A. Increase accessibility by adding more locations
B. Make the system user friendly and operate the business 24/7
C. Review any delays and solve the problem
D. Make prescription drugs more affordable and reliable for customers
E. Increase customer satisfaction

#	*Operational Processes*	Key Business Drivers				
		KBQ10001	KBQ10002	KBQ10003	KBQ10004 …	KBQ1XXX
OR1001	Increase accessibility and open-up more pharmacy locations			x		
OR1002	Make the system user friendly and 24/7 online support system		x			
OR1003	Review any delays and solve the problem				X	
OR1004	Make drugs more affordable and reliable for customers	x				
OR1005	Increase customer satisfaction	x				

4. Requirements

4.1 BI Requirements List

- Customer/Patient
  - Name
    - First name
    - Middle name (optional)
    - Last name
  - Address
    - Street number
    - Street name
    - City
    - State
    - Zip code
    - Country
    - Phone number
  - Prescription Drugs
    - Generic name
    - Scientific name
    - Dose
    - Amount
    - Price
    - Direction and side effects if any
    - Duration
- Doctor
  - Name
    - First name
    - Last Name
    - Title

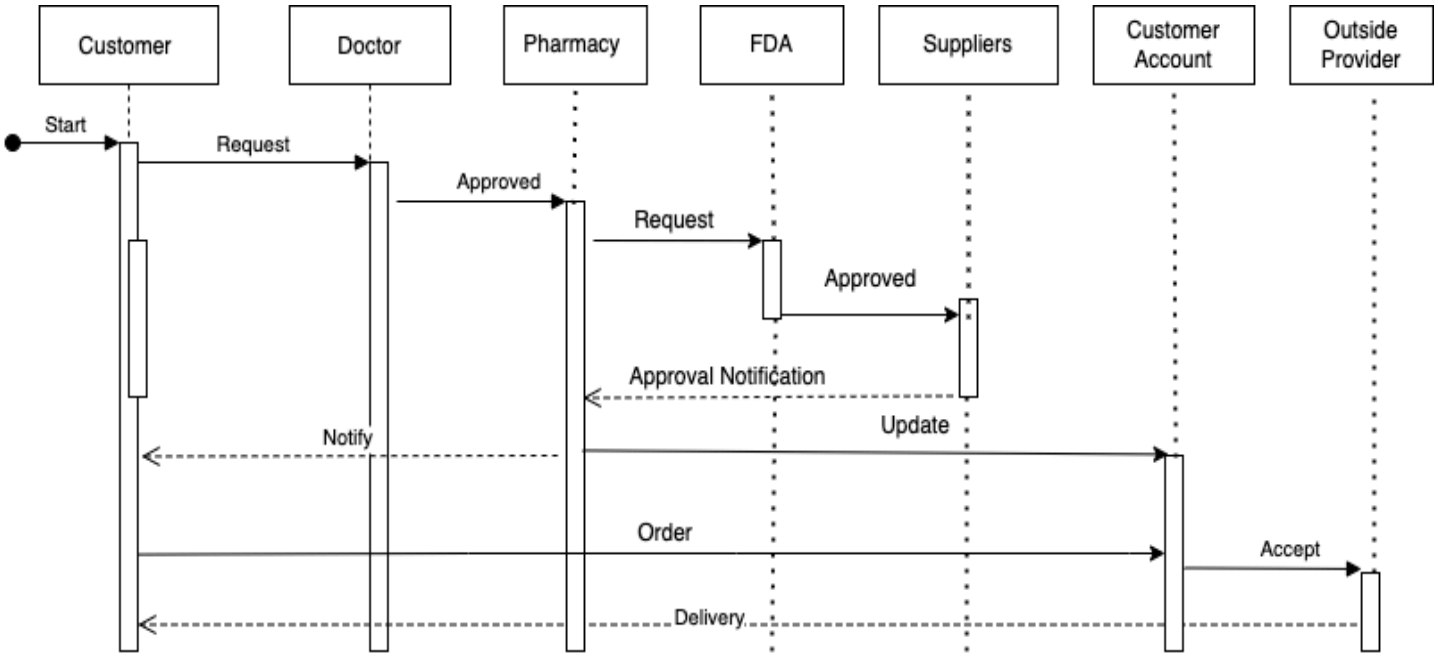
        - Address
            - Street number
            - Street name
            - City
            - State
            - Zip code
            - Country
            - Phone number
- Pharmacy
    - Name
    - Address
        - Street number
        - Street name
        - City
        - State
        - Zip code
        - Country
        - Phone number
- FDA
    - Authority License number
    - Address
        - Street number
        - Street name
        - City
        - State
        - Zip code
        - Country
        - Phone number
- Suppliers
    - Name
    - License number
    - Address
        - Street number
        - Street name
        - City
        - State
        - Zip code
        - Country
        - Phone number
- Customer Account
    - Customer Profile
        - Name
            - First name
            - Middle name (optional)
            - Last name

        - Address
            - Street number
            - Street name
            - City
            - State
            - Zip code
            - Country
            - Phone number
        - Customer Medical History
            - Diagnostic with
            - Duration
        - Customer Doctor visit
            - Date
            - Duration
        - Prescription Drugs
            - Generic name
            - Scientific name
            - Dose
            - Amount
            - Price
            - Direction and side effects if any
            - Duration
        - Credit Card number
            - Billing address
                - Street number
                - Street name
                - City
                - State
                - Zip code
                - Country
        - Physician name
            - Name
                - First name
                - Middle name (optional)
                - Last name
            - Address
                - Street number
                - Street name
                - City
                - State
                - Zip code
                - Country
                - Phone number
- Outside Provider
    - Name
    - License number
    - Address

            - Street number
            - Street name
            - City
            - State
            - Zip code
            - Country
            - Phone number
- Delivery Agent
    - Customer account
    - Customer Address
        - Street number
        - Street name
        - City
        - State
        - Zip code
        - Country
        - Phone number
    - Credit Card number
        - Billing address
            - Street number
            - Street name
            - City
            - State
            - Zip code
            - Country
            - Phone number

4.2 Screen Layouts or Prototypes

Next diagram shows how UML explains the prescription drugs business goes from the beginning to the end customer. There are seven entities or classes mentioned. These entities have their own role during customer requests.



4.3 Report Layouts

4.3.1 **Non-Functional Requirements**

* Status is as follows: **Proposed**-requirement has been suggested; **Reviewed**-has gone through a peer review; **Approved**-requirement was allocated to a baseline; **Verified**-has gone through verification & passed. Additional follow on statuses for design & QA documents should include Tested-has been developed & through a testing cycle to ensure proper action; Deferred-will be implemented in a future release; Canceled-a decision was made not to implement the requirements at all; Rejected-the idea was never approved.

#	Non-Functional Requirements	Question	Status*	Additional Info	Response
01	Reliability	Is the system reliable in any circumstance?	Proposed	The system need a reliable connection, fast and user friendly functionality	The system needs to be reliable in any circumstance, Since it is a healthcare provider system, it needs to be reliable for customers at any cost.
02	Scalability	What is the scalability of the business?	Proposed	Try to increase a scale performance by increase storage capability	The scale capacity of the system is not limited. In fact, it needs to store old history as well.
03	Usability	How to use this system?	Proposed	Customers who have authorization	It is user friendly and easily

#	Non-Functional Requirements	Question	Status*	Additional Info	Response
				can use the system without any problem.	accessible for customers and providers. It shouldn't be a sophisticated and high level system. It is designed that any customer in different knowledge or background should understand and operate the system without prior knowledge or training.
04	Serviceability	How often is the system serviced?	Proposed	Same as maintainability, there is peredical system service before it crashes	Service and update of the system is periodical. There is a technical team for this purpose only.
05	Utility	How can this business become more useful?	Proposed	Accessed by anyone authorized by both FDA and prescription medication providers.	Increase the number of customers by making this business more easily accessible and prevent any illegal action such as protecting confidential documents and information.
06	Regulatory	What are the rules and regulations this business does not compromise?	Proposed	Regulation is mandatory for this system/business specially focusing on privacy and confidentiality policies	HIPAA and FDA policies are well protected by both customers and providers.
07	Maintainability	How often does the system maintain or update?	Proposed	System maintainability is performed by authorized and fully skilled people who have experienced the system very well.	Maintenance is periodic to have a reliable system. Same as serviceability, service and update of the system is

#	Non-Functional Requirements	Question	Status*	Additional Info	Response
					periodical. There is a technical team for this purpose only.
08	Security	How secure is the system ?	Proposed	Online system security option available which responds to any illegal activity within a short period of time, and notify the system security team.	Security is the main concern regarding privacy and confidentiality of customers. Our team
09	Manageability	Is the system easily manageable for both customers and prescription medication providers?	Proposed	Managed by authorized providers with limited and customers without limited access.	The system is managed by both customers and prescription medication providers. It also needs two authentication to update and manage customer accounts in the system.
10	Data Integrity	How is data integrated among customer accounts, pharmacies, outside providers and delivery companies?	Proposed	Data integrated with approved systems or outside providers anytime across the nation.	The system integrated data with outside providers and provided a better and affordable price to customers.
11	Capacity	How much customer data is the system capable of storing?	Proposed	Capacity of storage is not limited. Plus, the system stores patient/customer history without any system or time latency.	Same as scalability, The scale capacity of the system is not limited. In fact, it needs to store old history as well.
12	Availability	Does the system work/available anytime, any environment and location?	Proposed	As long as the internet is available, the system is available anywhere in the world 24/7.	The system is available across the nation without latency. It is not limited by location and country that is approved by FDA.
13	Interoperability	Is this system portable with other related systems?	Proposed	Any system which is approved by FDA can integrate	It is connected or portable with systems that

#	Non-Functional Requirements	Question	Status*	Additional Info	Response
				and exchange information through their system to this business.	provide prescription medication at an affordable price. However, it requires a strong secured system.
14	Environmental	Does the system contribute a positive impact to the environment?	Proposed	Since it is an online business there is a positive impact to the environment by reducing carbon footprint.	The system works in any environment without time or data latency.
15	Company Growth	What is the future growth for the number of customers and pharmacies?	Proposed	Captured to ensure the solution provided can accommodate the projected number of customers	The solution provided should be able to accommodate any number of people in America retrieving a prescription.
16	Access Business	How many Pharmaceutical Solutions can access this business?	Proposed	Since any pharmacy licenses are approved by the FDA, any pharmacy can be involved.	On average over a thousand users will be able to simultaneously gain access to the system.
17	Order Medication	Where will your customers order prescription medication?	Proposed	Anywhere they can access customer account	Customers can access their account from home.
18	Online Customer Access	How will your users access the online customer account?	Proposed	From phone, computer or over the phone.	The users will access the system through the internet.
19	External Vendor Access	Will external vendors need access to the business?	Proposed	External vendors are closely work with pharmacies and customers to ensure fast and reliable delivery	External vendors such as the foreign suppliers will have access to parts of the system, in order to communicate to the pharmacy.
20	Delivery	Delivery delay: Is there a delay during delivery?	Proposed	Customers need their prescription drugs on time. Therefore, customer accounts are	If the system was brought down it would be difficult to operate because the system requires communication between multiple

#	Non-Functional Requirements	Question	Status*	Additional Info	Response
				frequently modified by the pharmacy and outside providers.	entities in order to prepare the prescription. A backup and restore would be required once the system goes down to preserve the data.
21	Training	Training: Employee training is mandatory?	Proposed	Seasonal training is mandatory. specially, new laws and HIPAA policies trainings will provide for employees	The providers such as the doctors and hospital systems will need training.This will be done so they understand the proper ways to input the prescription information. Customers can also receive tutorial training for how to operate within their account.

4.4 Information Availability Requirements

Doctor/provider :- Will have access only to his patients medication records.
Patients:- patients will have access to their own prescription and nonprescription drug history.
Pharmaceutical Solution Inc.:-

Customer service agent: - accesses patients information if authentication code is provided by the patient.
Service Desk:- access patients information if authentication code is provided by the patient.
Business Manager:- Access records unonomized. Cannot access individual patient information.
Case Manager:- can access, alter and authenticate patients' accounts.

4.5 Availability (NA)

Since Pharmaceutical Solution Inc. is on a proposal stage, it needs to pass FDA license approval. Therefore, it is not available at this time.

4.6 Data transformation and Calculations

Data transformation is the process of changing the format, structure, or values of data. Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard requires healthcare facilities to store data in a national standard. To reduce paperwork and streamline business processes across the health care system, HIPAA and subsequent legislation set national standards for electronic transactions, code sets and unique identifiers operating rules. We also believe that data transformation will help our business which is more dependent on data analytic. Uniformity of data coding will also benefit easy comparison, manipulation and analysis of data from different sources. As we are comparing prescription drugs from different countries with different codes (or no codes at all) we need to transform foriegn data to fit US coding systems.

Complying with Administrative Simplification standards (ASETT) saves cost. ASETT—the Administrative Simplification Enforcement and Testing Tool—allows our organization to test transactions, both within our organization and with our business trading partners' transactions. ASETT can be used to file a complaint if our organization has any noncompliant business trading partners.

Prescription Drugs:
In the US we have a unique identifier for each prescription drug, National Drug Code (NDC). Drugs are identified and reported using a unique, 10-digit three-segment number called the National Drug Code (NDC) which serves as the FDA's identifier for drugs. FDA publishes the listed NDC numbers in the NDC Directory which is updated daily. Drug establishments are required to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded or processed for sale in the U.S. at their facilities.

The first set of numbers in the NDC identifies the label (manufacturer, repackager or distributor). The second set of numbers is the product code which identifies dosage or strength. The third set identifies package code (package sizes and types).

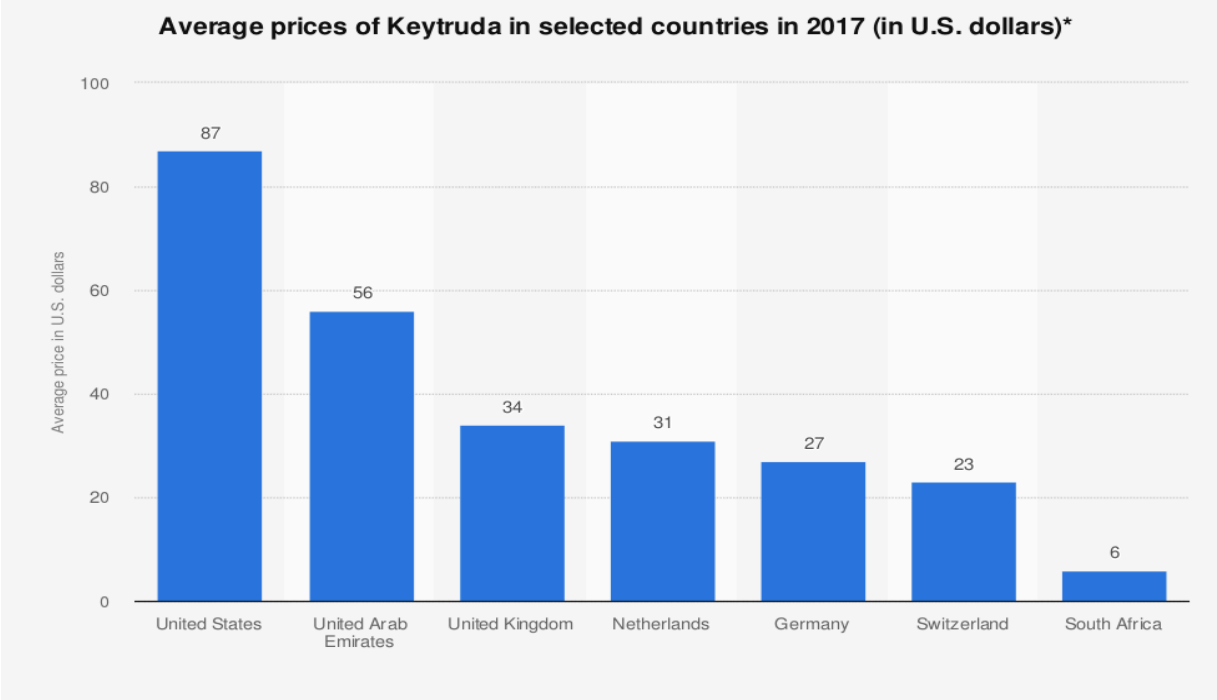
However, our data "Prescription Drugs Prices In Israel 2007-2021" we have Medication_Name, Package_Size, Max_Retailer_Price, Max_Consumer_Price, Max_Consumer_VAT_Price and Year

W used KEYTRUDA as an example to show how our system recognizes prescription drug:

Product ID 0006-3026_064f791c-8110-49ad-9d6b-770dec7ccbd5
NDC 0006-3026
Product Type Human Prescription Drug
Proprietary Name KEYTRUDA
Generic Name Pembrolizumab

Dosage Form Injection, Solution
Route of Administration INTRAVENOUS
Marketing Start Date 2015-01-15
Marketing Category BLA / BLA
Application Number BLA125514
Labeler Name Merck Sharp & Dohme Corp.
Substance Name PEMBROLIZUMAB
Active Ingredient Strength 25 mg/mL

Therefore, data from other countries will be transformed into FDA standard NDC. We will use https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm to transform the name of prescription drug into NDC.



Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
A and D	11523-1314-1	11.09 mg/g, 110.09 mg/g	CREAM	TOPICAL	part347	Bayer HealthCare LLC.	11523-1314	Dimethicone and Zinc Oxide	DIMETHICONE; ZINC OXIDE	HUMAN OTC DRUG	12/25/2009	N/A
A and D	11523-1314-2	11.09 mg/g, 110.09 mg/g	CREAM	TOPICAL	part347	Bayer HealthCare LLC.	11523-1314	Dimethicone and Zinc Oxide	DIMETHICONE; ZINC OXIDE	HUMAN OTC DRUG	12/25/2009	N/A
A and D	11523-1314-3	11.09 mg/g, 110.09 mg/g	CREAM	TOPICAL	part347	Bayer HealthCare LLC.	11523-1314	Dimethicone and Zinc Oxide	DIMETHICONE; ZINC OXIDE	HUMAN OTC DRUG	12/25/2009	N/A
A and D First Aid	11523-7204-1	136.4 mg/g, 469.9 mg/g	OINTMENT	TOPICAL	part347	Bayer HealthCare LLC	11523-7204	Lanolin and petrolatum	LANOLIN; PETROLATUM	HUMAN OTC DRUG	06/04/2003	N/A
A and D Original	11523-0096-5	136.4 mg/g, 469.9 mg/g	OINTMENT	TOPICAL	part347	Bayer HealthCare LLC.	11523-0096	Lanolin and Petrolatum	LANOLIN; PETROLATUM	HUMAN OTC DRUG	04/22/2021	N/A

The NDC Directory contains only information submitted to FDA in SPL electronic listing files by labelers. (A label may be either a manufacturer, including a repackager or relabeler, or, for drugs subject to private labeling arrangements, the entity under whose own label or trade name the product will be distributed.)

- Package data can be found in the Packages file, linked by the ProductID field.
- Reference code names (translations) are included instead of the codes themselves.
- Fields that have multiple values are identified with an “MV” after their name. Values are concatenated together by a semi-colon “;”.
- If the term NULL appears after an element name, it means there may be records where no value is provided

Pharmacies:-
In most cases the foriegn pharmacy filling the prescriptions may be different from the label. In the US we have a unique identifier of each pharmacy, UCPDP_ID. NCPDP_ID is the unique, national identification number assigned by the National Council for Prescription Drug Programs (NCPDP) to every licensed pharmacy in the United States and its territories. NCPDP 5-digit numeric value only.

Therefore, we will transform the name of the foriegn pharmacy to a 5 digit numeric value by preceding a three digit country code.

Healthcare Providers Data
National Provider Identifier Standard (NPI):- NPI is a 10-position, intelligence-free numeric identifier (10-digit number). This means that the numbers do not carry other information about healthcare providers, such as the state in which they live or their medical specialty.

The Centers for Medicare & Medicaid Services (CMS), under the Department of Health and Human Services (HHS), has created an online NPI registry (nppes.cms.hhs.gov) where a physician, other health care provider, or organization can access NPI information. This is part of the same National Plan and Provider Enumeration System (NPPES) web site on which the NPI registry is completed.

NPIs will be used to identify health care providers on prescriptions, in internal files to link proprietary provider identification numbers and other information, in coordination of benefits between health plans, in patient medical record systems, in program integrity files, and in other ways. HIPAA requires that covered entities use NPIs in standard transactions. NPIs simplify electronic transmission of HIPAA standard transactions. All health care providers who are HIPAA-covered entities, whether individuals or organizations, must get an NPI.

As all providers will be based in the US. Two categories of health care providers exist for NPI enumeration purposes: Entity Type 1 (Individual) and
Entity Type 2 (Organization).

Price comparison:
The bread and butter of this business is to identify and provide affordable prescription drugs. Therefore, proper and up-to-date price information is required. Pharmacies are required to update price changes regularly. Once a customer placed an order pharmacies cannot change prices upward or downward.

All prices will be stated in US Dollar. Foriegn pharmacies bear the risk of currency fluctuations.

4.7 Data loading and Sequencing

- The National Drug Code (NDC) will be loaded first. Test indexing and information accuracy.

- FDA publishes the listed NDC numbers in the NDC Directory which is updated daily. Drug establishments are required to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded or processed for sale in the U.S. at their facilities. The first set of numbers in the NDC identifies the label (manufacturer, repackager or distributor). The second set of numbers is the product code which identifies dosage or strength. The third set identifies package code (package sizes and types).

Data	Description	Data format
Proprietary Name	Product Trade Name or Catalog Name is generally supplied by the manufacturers (also known as “labelers” or “firms” for purposes of listing. Limited to a maximum of 100 characters.	Text
NDC Number	A unique 10-digit, 3-segment number. identifies the labeler, product, and trade package size.	Number

Dosage Form	The complete list of dosage	Number and Text
Routes of Administration	Swallowed, injunction, external application etc…	Text
Active Ingredient(s)	Active Ingredient(s)	Text
Strength	For products with a single active ingredient, the indicated strength is the strength of that active ingredient. For multiple active ingredient products, the strength is either "COMBO" or a concatenation of the multiple strengths.	Text
Unit	Abbreviations for units	Number and Text
Package Size and Type	Package size and types appear in the NDC Directory as reported by the firm.	Number and Text
FDA approved application number	Signifies that this product has been approved by FDA for marketing based upon a review of the safety and effectiveness of the drug	Number

The National Council for Prescription Drug Program Identification (NCPDP_ID) will be loaded with pharmacy information and tested for accuracy. Pharmacy information will contain the following.

Data	**Description**	**Data Format**
NCPDP_ID	Unique identifier of the pharmacy	Number
Address	Physical address of the pharmacy	Text and Number
Telephone No.	Contact telephone number of the pharmacy	Number

We will not load healthcare providers and customers data beforehand. Each healthcare provider will create an account and load basic informations

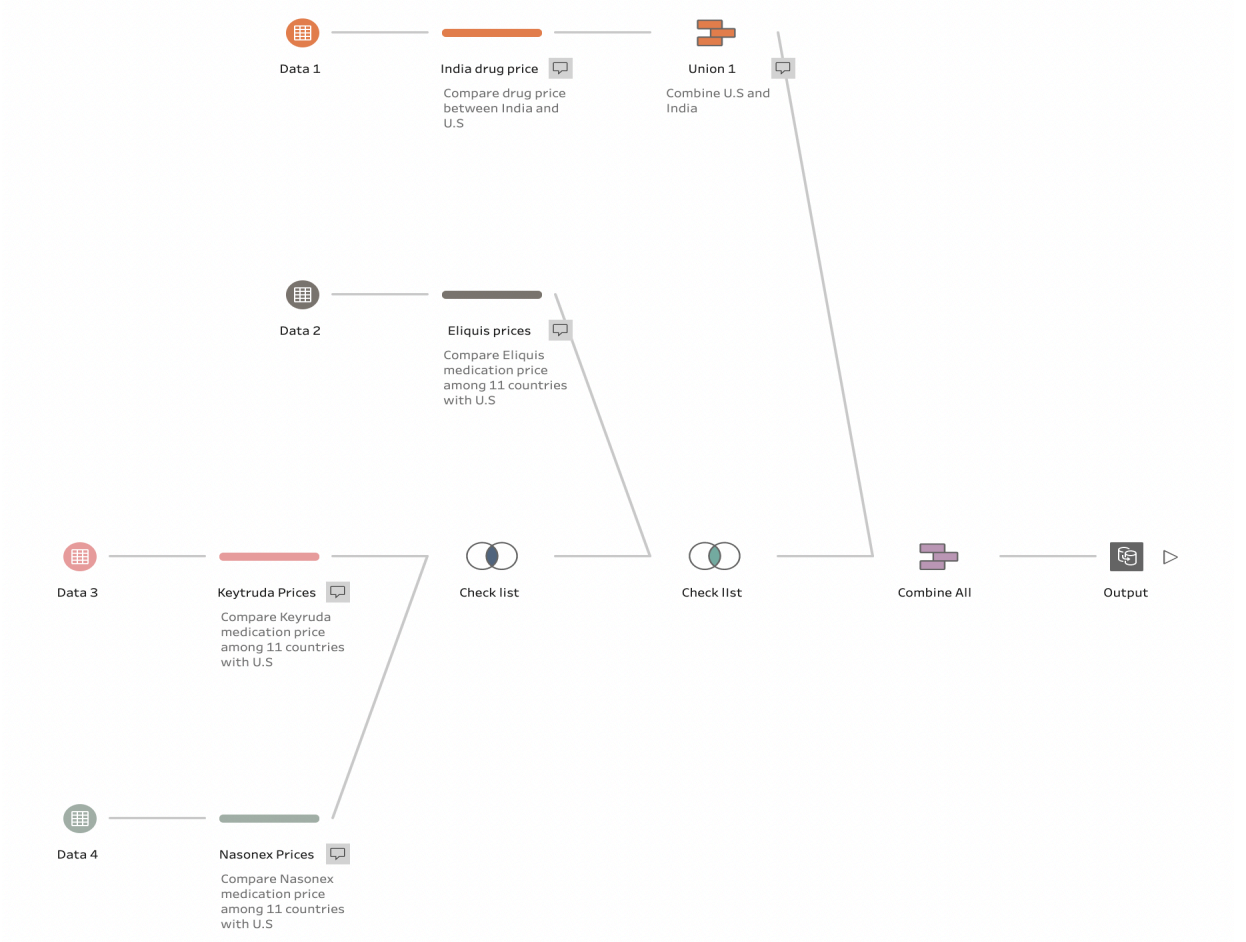
Providers and physicians will have two step login processes.
Providers/Physicians enter National Provider Identifier (NPI). NPIs will be used to identify health care providers on prescriptions, Then choose a physician user and enter a password. Physicians may report primary and secondary taxonomy codes in the NPI application. For instance, a family medicine physician specializing in adolescent medicine might report a primary code for family medicine, 207Q00000X, and a secondary code for adolescent medicine, 207QA0000X. HIPAA requires that covered entities use NPIs in standard transactions. NPIs simplify electronic transmission of HIPAA standard transactions. All health care providers who are HIPAA-covered entities, whether individuals or organizations, must get an NPI.

Name	Description	Data Format
NPI	Intelligence-free numeric identifier (10-digit number)	Number
NPI Type	Identify if the NPI belongs to an organization or individual	Drop down menu (Individual, Organization)
Taxonomy Codes	A unique 10-character code that designates physician's or healthcare organization's classification and specialization.	Drop down menu Listing all taxonomy codes
First Name	Physician's first name	Text (can left blank if NPI belongs to an Organization
Last Name	Physican's last name	Text (can left blank if NPI belongs to an Organization
Organization Name (LBN, DBA, Former LBN or Other Name)	Healthcare Organization's name	Text (can left blank if NPI belongs to an individual provider
Address	Provider's address	Text and number

City	Providers City	Dropdown menu if selected after the state
State	Provider's practicing state	Dropdown menu will appear to choose from.
Postal Code	Zip code of provider's address	Number (5 Digits)
Address Type	This is to identify if the address provided is primary or secondary address	Dropdown menu will appear to choose from

4.8 Logical Data structure

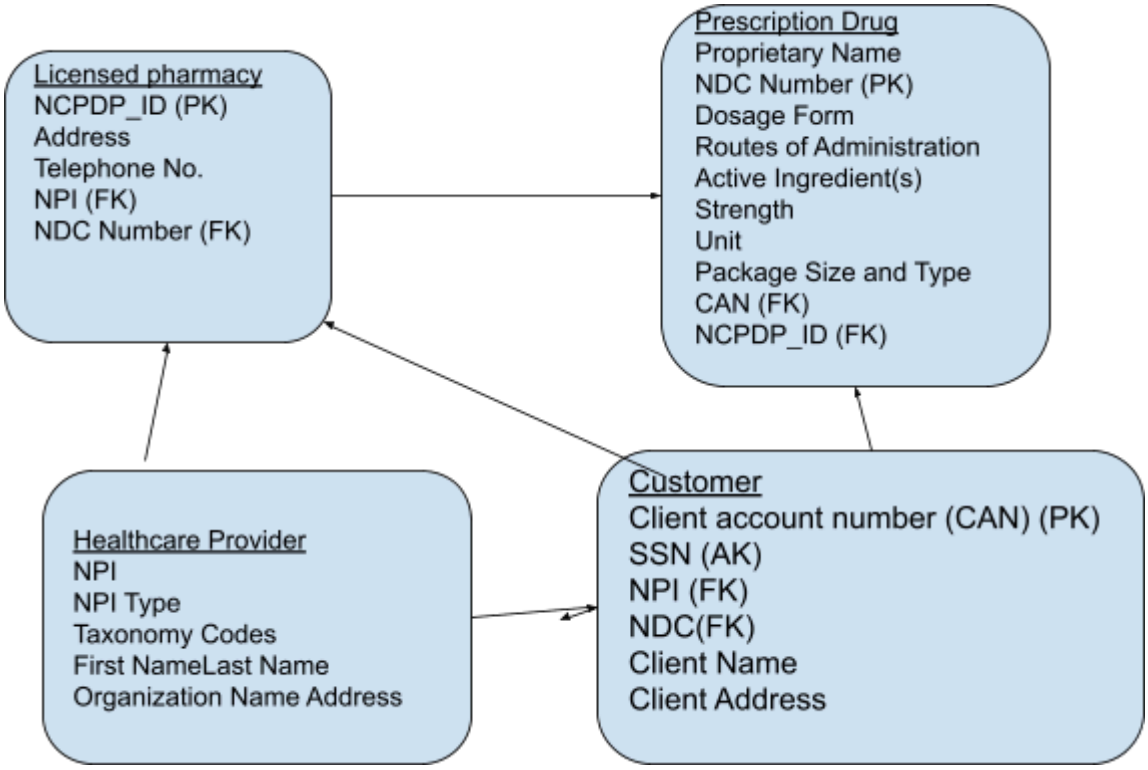
The next Tableau Prep Builder image indicates how we gathered data from Statista for different prescription drugs from different countries in order to compare prices in the U.S. The final outcome is merging these data and creating excel data containing affordable prices of prescription drugs on the market.



Entities

Our model consists of four entities as described in section 2 and 3 above.

1. Licensed pharmacy: Primary key NCPDP_ID
2. Prescription drug : Primary key NDC
3. Providers and physicians: Primary key NPI
4. Customer: Primary Key SSN and alternate key CAN (Customer account number)



Initially we will have four Entities,

- Licensed Pharmacy: has a primary key NCPDP_ID and two forign Keys and NDC.
- Prescription Drug: has one primary key and three fioriegn keys NDC, CAN and NCPDP.
- Healthcare provider: has one Primary key, NPI and two foriegn key CAN (or SSN) and NDC.
- Customer: has one primary and one alternate key, SSN and CAN. Additionally will have three foriegn keys. NPI, NDC, NPI and NCPD_ID.

Customer's Account page contains CAN (Customer Account Number, customers' full name, address, medical history, order history, credit card number (optional), phone number, social security number(optional), authentication, and limited authorization(only accessed by the primary physician and the customer only).
Doctor's page contains the NPI, full name, license number, address and contact information.
Pharmacy page contains the name of the NCPDP_ID, pharmacy, address, contact, authorization number, outside prescription drug providers list, contact information of providers,

FDA approved license, doctors list with contact information, customers list with contact information and orders history.
Prescription Drug contains Proprietary Name, NDC Number, Dosage Form, Routes of Administration, Active Ingredient(s), Strength, Unit, Package Size and Type, and FDA approved application number.

4.9 Physical Data Storage

The data that is needed will be stored on the cloud. We will be accessing information from multiple databases in order for the system to operate this project. The company will not have a server in the building. It is important to note that all storage or handling of patient information, will be compliant with HIPAA (The Health Insurance Portability and Accountability act of 1996) protocol. This was an act put in place to make sure that patient information is not disclosed without the patient's consent. Some HIPAA requirements that will be complied with include, storing all medical records where there is "controlled access", and restricted from unauthorized users. In addition it is required that all patient health information stored in any physical location or on any physical device should be backed up to a non-physical location in the cloud to prevent loss or deletion of the patient's data"(NordicBackup.com). Amazon Web Services (AWS) will be used to store and access the databases containing patient information. They are a useful cloud partner for processing, storing, and transmitting protected health information. Amazon Web Servers are also HIPAA compliant, and considered among the best hosting servers for healthcare purposes. The company that this project is being run for, will come to a business associate addendum with Amazon. This is an agreement made with a cloud partner, that outlines specific responsibilities each side has, regarding the protection of patient health information. The Amazon Simple Storage Service (S3) will be implemented for the project. Some examples of Amazon Simple Storage Service use cases include, building a data lake, backing up important data, and archiving data, and running cloud-native applications.

Filters:

Role based filtering will be used to help protect patient health information. The application server can check the roles of the user when they make a request to view information. For example, patients would be blocked from seeing personal information about their providers or physicians in the database. They would also be filtered out from having access to information about other patients. If a patient requests this information, the software will check the patient's role in the database, and verify whether or not access will be allowed. In order to set the role-based data it is important to. Oauth authorization tokens will be given to users that contain their roles. A user sends their Oauth token when they make a request to the server. If the user does not have access to the requested information, the server will return a forbidden error.

4.10 Security needs

This system will contain sensitive information about patients' medical and personal history. It will be important to build a system that is secure and protects PHI (Patient Health Information). The system will incorporate a password encryption under Amazon Web Server Methods,which will be vital for this purpose. The Amazon Simple Storage System used will include numerous encryption features.The key management service allows for more control over data encryption keys.The company will also have access to American Web Services Cloudtrail. American Web Services Cloudtrail will audit your AWS account and record or monitor activity.

. This will be the format used for all forms of user passcodes and identifications within the system. This includes patient users, pharmacy users, and physician/provider users. The next aspect that will be addressed is access and authorization. Patients will have full access to their accounts. This is where they can find their prescription, and select what delivery method they prefer. In order to gain access to their account they will need to enter their email, and eight digit passcode. The customer will be taken to a page where they are asked whether or not they are a physician, pharmacy or patient. Once they click patient, the customer will then be taken to a new page where they need to enter their customer ID key that was assigned to them when they created the account and social security number. There is also an authentication system installed for when customer users select a prescription for delivery. When a customer clicks their assigned prescription and chooses their delivery method, they will have a 10 digit code sent to their email. They will need to enter this code before they are able to submit their delivery request. Providers/Physicians will have limited access to the system. Providers will need to create their own eight digit passcode in order to log in. They will also need to use their own National Provider Identifier. In order to enter information into customer accounts the provider will fill in their NPI (National Provider Identifier). This will allow the provider to gain access to their main system account. They are also required to create an eight digit passcode when they first register within the system. The providers will then use the social security number of their patient in order to find their account. In order to access the account a verification system will be replaced. The provider will need to request for confirmation where they will be directed to a patient library. This is where they are able to verify the patient name, which will grant them limited access to fill in prescription information on the patient user account. Pharmacys will also be granted access to the system. Pharmacies will be required to enter in a key ID assigned to them and a username of their choice in order to gain access. They will be taken to the screen where they are asked whether they are a patient, provider/physician, or pharmacy. The pharmacy will then enter their NCPDP_ID. These methods will provide strong security in eliminating threats, and protecting user information.

5. Supporting Information

5.1 Assumptions

Currently, it is illegal for individuals to import drugs into the U.S. for personal use. The reason is because the FDA does not have a proper legal tool to regulate, approve or control the manufacturing distribution and sales of in the U.S. A drug approved for use in another country but not approved by the FDA would be considered an unapproved drug in the U.S. and, therefore, illegal to import. the FDA cannot ensure the safety and effectiveness of medicine purchased over the Internet from foreign sources.

Our assumption is that Pharmaceutical Solutions Inc., will succeed in its effort to lobby congress to enact a law that allows FDA regulate foriegn sources who export prescription drugs through U.S. companies and its internet distributions.

5.2 Exclusions

As a business advisor or consultant, it is too early to address how long it takes this project to get in action and start making profit to the stakeholders and business groups. Since, the project should pass FDA regulations before starting the business abroad, there is no estimated time to bring effective revenue at this time. Moreover, the project starts with a capital of one million dollars. However, this amount is not guaranteed. Either it is enough or it needs an additional budget. Therefore, it is not a time to mention or address these two issues to the stakeholders at this time.

5.3 Training Requirements

Training should be given on how to comply with all relevant state regulations. Training is also required on the national and international laws and regulations. This includes the U.S. Health Insurance Portability and Accountability Act of 1996, known as HIPAA.

Additional training is required regarding the storage, protection and use of patient’s information.

Cybersecurity training is required.

Employee users will be trained by tutorials within the site. Employee training will be mandatory under HIPAA training policies. The system will be straightforward on how to access a patient's medical records. It should not be hard to navigate or complete tasks with. The training will provide detailed videos on how to enter a patient's prescription information as well. Other topics that will be included in employee user training include, understanding patient rights, password management, and confidentiality requirements. There will be system engineers hired on the project to assist with any technical issues. They will also be able to answer any questions that users may have about the general functions of the system.The Customer Users will receive detailed preparation on how to operate the system. There will be tutorial training sessions that describe how users will work within the system. The tutorials will include video directions on user controls. This includes information on how to access their prescription and customize how they want it sent to them. Customer users will be instructed on the security of their account, and what needs to be done in order to authenticate it.

Customer training will be optional.The system will have practice quizzes for employee users to test their knowledge.

5.4 Review Records

This is the last stage, however there is no review record yet.

6. Revision History

This is the final stage and reviewed by fellow business managers and Professor Joseph Taylor during the presentation.

7. Abbreviations

The following table contains common abbreviations that are used in this document.

Abbreviation	Description
ASETT	Administrative Simplification standards
BI	Business Intelligence
FDA	Federal Drug Administration
HIPPA	Health Insurance Portability and Accountability Act of 1996
KBQ	Key Business Questions
NFR	Non-functional Requirements
NDC	The National Drug Code
SQL	Structured Query Language
UML	Unified Modeling Language

8. Glossary

The following table contains unique terms and their descriptions that are used in this document.

Term	Description
Authentication	The process or action of proving or showing something to be true, genuine, or valid.
Authorization	The action or fact of authorizing or being authorized.
Pharmaceutical	A compound manufactured for use as a medicinal drug.
Preliminary	Denoting an action or event preceding or done in preparation for something fuller or more important.

References

Affairs, O. O. (n.d.). Personal Importation For Import Program. Retrieved from https://www.fda.gov/industry/import-basics/personal-importation#:~:text=The FDA cannot ensure the,legal sources in the U.S.

Girish Malhotra, P. (2018, February 16). Comparison of Drugs Prices: US vs. India; Their Manufacturing Costs and Opportunities to Improve Affordability. Retrieved from https://www.americanpharmaceuticalreview.com/Featured-Articles/347177-Comparison-of-Drugs-Prices-US-vs-India-Their-Manufacturing-Costs-and-Opportunities-to-Improve-Affordability/

Konstantin, T. (2021, January 06). Prescription Drugs Prices In Israel 2007-2021. Retrieved from https://www.kaggle.com/thomaskonstantin/prescription-drugs-prices-in-israel-20072021?select=TM_2021.csv

Mikulic, M. (2021, March 26). Consumer price index: Prescription and nonprescription drugs U.S. 2020. Retrieved from https://www.statista.com/statistics/187253/us-consumer-price-index-for-prescription-drugs-from-1960/

Mikulic, M. (2021, September 20). Drug prescription volume U.S. Retrieved from https://www.statista.com/statistics/238702/us-total-medical-prescriptions-issued/

Mikulic, M. (2021, March 11). Five or more prescriptions within one month U.S. 1988-2018. Retrieved from https://www.statista.com/statistics/492282/us-population-with-5-or-more-prescriptions-within-one-month/

Mikulic, M. (2019, November 26). Prescription drug prices opinions U.S. 2019. Retrieved from https://www.statista.com/statistics/1074645/opinions-prescription-drug-prices-us/

Mulcahy, A. W. (2021, January 28). Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries. Retrieved from https://www.rand.org/news/press/2021/01/28.html

Sabanoglu, T. (2021, December 02). Total number of retail prescriptions filled annually in the U.S. 2013-2025. Retrieved from https://www.statista.com/statistics/261303/total-number-of-retail-prescriptions-filled-annually-in-the-us/