



Multiple Locations Conference

Fort Myers, Fla. • Feb. 28 - March 2

Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

Take 5: Vaccine Team

Mike Burns, RPh
Presidents & CEO
AuBurn Pharmacies



Intake



Vaccine Administration Record, Screening, and Patient Consent

Vaccine Requested #1: _____

Vaccine Requested #2: _____

Facility Name: _____ Type: SNF-LTC / AL / IL / H+ / Other Room Number: _____

Patient Name: _____ DOB: _____ Age: _____ Gender: Male / Female

Race: American Indian/Alaskan Native Asian Black/African American Native Hawaiian/Pacific Islander White Other Unknown Ethnicity: Non-Hispanic Hispanic Unknown

Name of Medical DPOA, if other than patient: _____ Phone Number: _____

****IF NOT CURRENTLY AN AUBURN CUSTOMER, PLEASE COMPLETE INSURANCE INFORMATION BELOW: ****
 Commercially Insured Medicare (Medicare ID: _____) Uninsured (SSN: _____)

1) Have you ever had a severe reaction to any vaccine requiring medical attention? If yes, please describe:	YES	NO
2) Are you allergic to eggs, thimerosal mercury, neomycin, PEG, polysorbate, or gelatin?	YES	NO
3) Have you had Guillian-Barre syndrome, seizures, brain or nerve problems?	YES	NO
4) Are you pregnant or planning to become pregnant in the next 3 months?	YES	NO
5) Are you, or anyone in your household, being treated with chemotherapy or radiation for cancer, have HIV/AIDS, any other immune deficiency disorders, or taking oral prednisone or other steroids?	YES	NO
6) Do you have a bleeding disorder or take "blood thinners" like Coumadin or heparin?	YES	NO
7) Have you received any vaccine within the last 2 weeks?	YES	NO
8) Have you been exposed to anyone diagnosed with COVID-19 or influenza in the past 14 days?	YES	NO
9) Are you experiencing any symptoms of illness, including fever, cough, shortness of breath or loss of taste or smell? <i>If the patient is seeking COVID vaccination, please complete Questions 10-12. Otherwise, skip.</i>	YES	NO
10) Date of last COVID Vaccination _____	YES	NO
11) Have you received a monoclonal antibody for COVID-19 in the last 90 days?	YES	NO
12) Have you tested positive for COVID in the last 90 days? <i>If the patient is seeking Pneumonia vaccination, please complete Question 13. Otherwise, skip.</i>	YES	NO
12) Has patient received previous doses of pneumonia vaccine, and if so, what formulation(s) and what date(s)? _____	YES	NO

Please read the following statements and complete section below providing consent:

I consent to Auburn Pharmacy and its staff for my person named at the top of this form to be vaccinated with this vaccine for both the initial and second dose in the series, if applicable. I have been provided the Emergency Use Authorization Fact Sheet or a Vaccine Information Statement prior to vaccination and have the ability to revoke consent at any time. I have had an opportunity to ask questions that were answered to my satisfaction. I believe I understand the benefits and risk of vaccination and ask that the vaccine be given to me or to the person named above for whom I am authorized to make this request. I do hereby authorize Auburn Pharmacy to release information and request payment from Medicare or commercial insurance. I certify that the information given by me in applying for payment is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf. I consent to inclusion of this immunization data in any state immunization registry for myself or on behalf of the person named below.

Is patient able to make their own medical decisions? ___ Yes ___ No If yes, Patient Signature: _____ Date: _____

If no, Medical DPOA Name: _____ Medical DPOA Signature: _____ Date: _____

OR Verbal authorization given to Facility Staff Member: _____ Title: _____ Date: _____

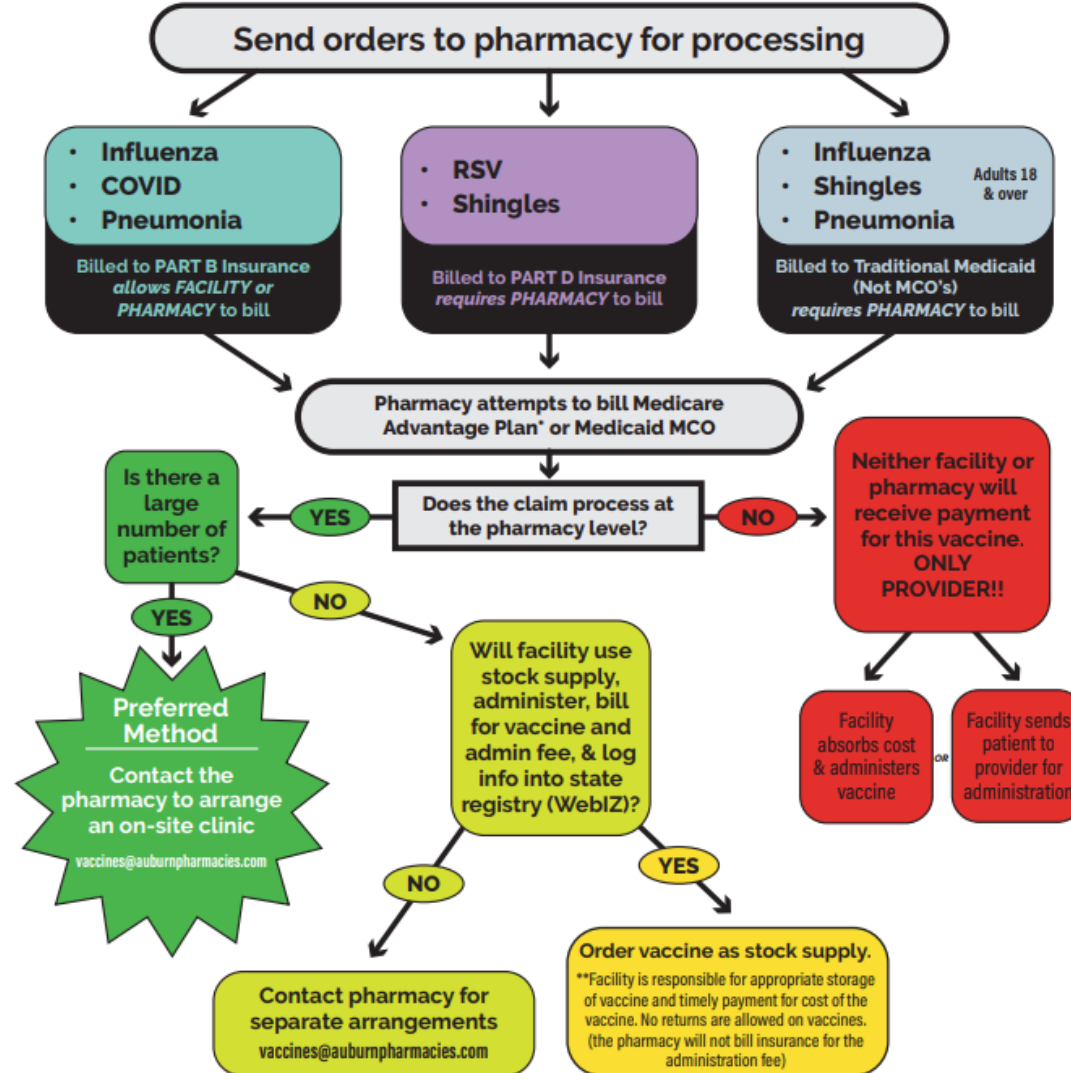
Internal Use Only

Admin Date	Administrator	Admin Signature	Notes/Product Sticker
Vaccine	Notes/Product Sticker	Vaccine	Notes/Product Sticker
LOT/EXP		LOT/EXP	
Manufacturer		Manufacturer	
Dose		Dose	
Location/Route		Location/Route	

Scanned as Rx
 Faxed PCP
 WebIZ/SMV



You have screened the patient, confirmed eligibility, & determined the formulation(s) needed





LTC partnering

Valuable Partners,

We are excited to offer you a new service – a pharmacist solely dedicated to your community's **vaccination needs**. Now, AuBurn Pharmacy can offer on-site vaccine clinics throughout the year at no additional charge to you or your patients. We understand that your time is valuable, and protecting your patients is of paramount importance to all of us. We are here to help!

We are offering the following vaccines for both **residents and staff***:

- Influenza
- COVID
- RSV
- Pneumonia
- Shingles
- ... and others, as requested!

***Staff vaccinations** will require insurance to be presented in advance of vaccination day, and payment provided at the time of vaccination, unless facility has committed to pay for the staff vaccination, at which point, it would be added to your bill.

We are proud to support you along each step of the vaccine process. Our services include:

- Billing vaccines
 - To patient insurances*
 - To facility (for Med A patients or Managed Care stay)
- Administering vaccines (in either a common area or room to room if patients are not ambulatory)
- Reporting vaccinations to the state immunization registry, WebIZ or ShowMeVax

***NOTE:** There are some insurances that will only cover certain vaccines if they are administered by a provider in the provider's office. We will work with your team to address these situations as they arise.

To schedule vaccinations, we require:

- Completion of the **AuBurn Vaccine Administration Form** for all patients eligible for and interested in vaccination
 - Clearly indicate which vaccine(s) are being requested (top section of page)
- Then email that form to us at vaccines@auburnpharmacies.com or fax to 316-201-6273, Attn: Vaccine Coordinator. Once these forms are received, our team will contact you and schedule a date

Please feel free to call or email us with any questions. We appreciate all that you do for your communities and we are pleased to assist you in keeping patients as healthy as possible!



Name, Credentials
Job Title
Pharmacy Name
Address
Phone
Fax



My Team in Action





Better Education = Higher Vaccination Rates



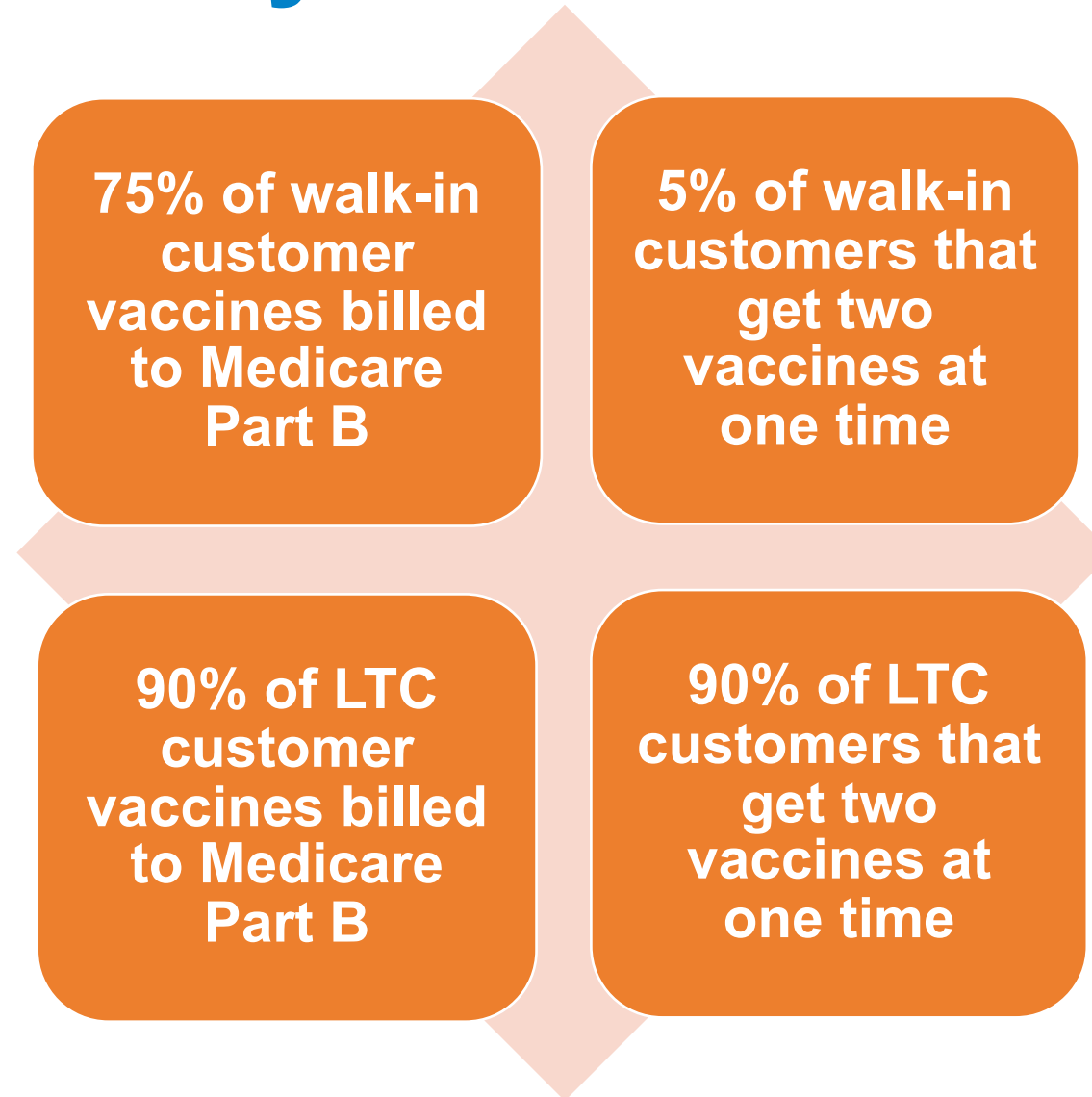
THE PROFIT MARGIN
PER VACCINE RANGES
FROM \$5.27 TO \$66.12.



OVER 60% OF PATIENTS
RECEIVE 2 VACCINES
PER VISIT



Vaccines by the Numbers





Mike Burns, RPh
President and CEO
AuBurn Pharmacies

Implementing Practical Leadership Skills

Scott Pace, PharmD, JD

Owner

Kavanaugh Pharmacy



What does developing leadership mean in our pharmacy?

- Focus on the basics (live Vision and Mission)
- Invest time in learning your employee' strengths/weaknesses AND likes/dislikes
- Don't always dictate, involve where possible
- Hire for your culture



Couple of Tools We've Used

- DiSC Assessment Tool
 - Other personality tests are fine too – create common language
- Yes, And
- Weekly 5 min check in



Don't be overwhelmed

- Leadership skills are like clinical knowledge...you've got to always be learning and you have to practice them!



Scott Pace, PharmD, JD

Owner

Kavanaugh Pharmacy

scott@kavanaughrx.com

How to Get, Keep, and Say Goodbye to Employees

Deborah Kelly, PhD, JD, MA

Partner

Manatt



Learning Objectives

1. Describe the dos and don'ts of using social media in hiring, managing, and terminating employees
2. Explain how to put processes in place that minimize the risk to your business



Slides

Due to copyright rules, the slides for “How to Get, Keep, and Say Goodbye to Employees” cannot be shared.



Blue Ridge Apothecary

peak personalized care

NCPA Multiple Locations Conference
February - March 2024



College of Pharmacy
UNIVERSITY OF SOUTH CAROLINA

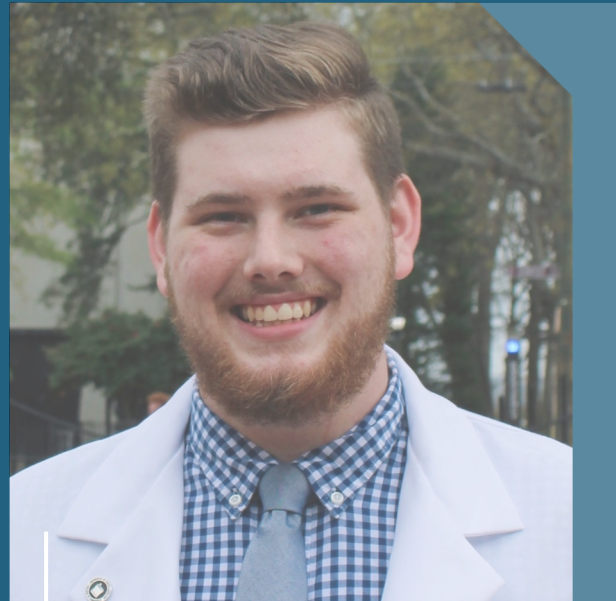
Future Owners

Farehaa Hussain



PharmD

Jacob King



PharmD, MBA

CharLeigh Steverson



PharmD



Greer's Current Standard of Pharmacy

01

Keys To Our Mission and Vision

One-Stop
Shop



Meet and Exceed
Expectations



Patient-Centered
Care



High Standards of Care



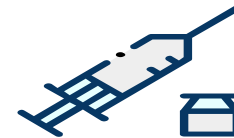
Traditional Dispensing
and Counseling



Home Delivery



Comprehensive
Medication Reviews



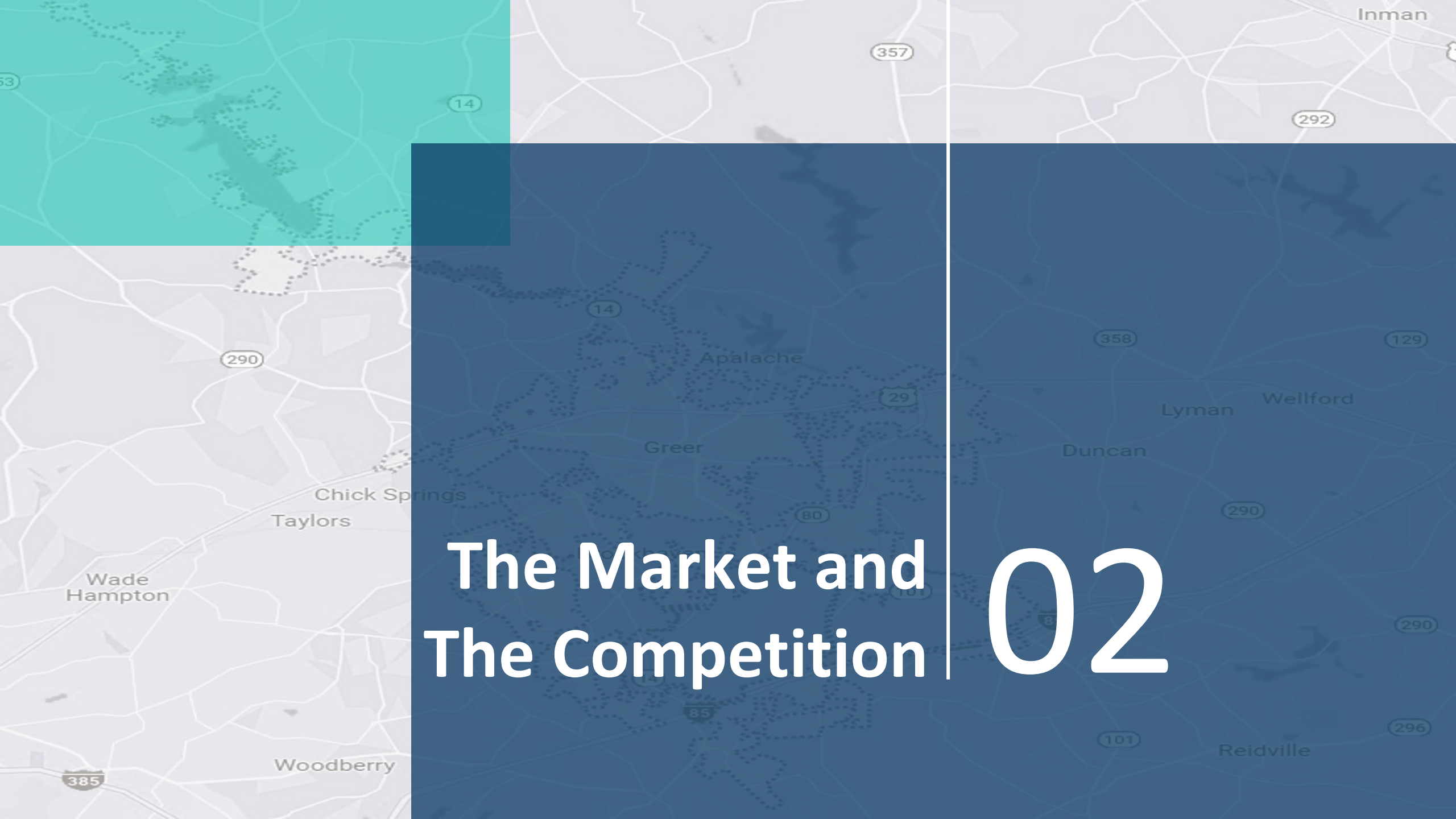
Immunizations



Tobacco Cessation
Counseling



Medication Therapy
Management



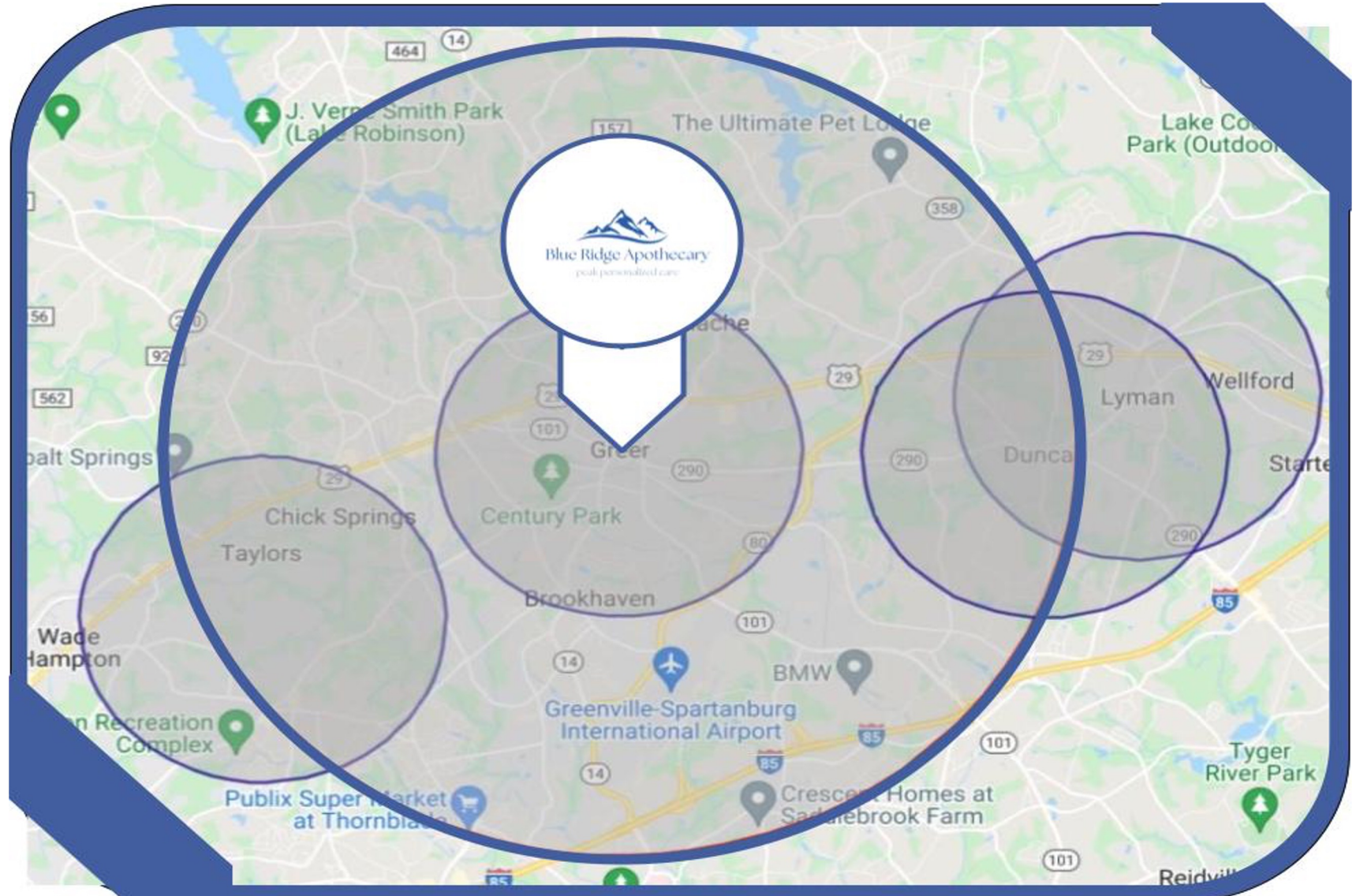
The Market and The Competition

02

What's the market radius look like?

Blue Ridge Apothecary's Market

- Primary market within 5 mile radius of store
- Delivery radius of 5 miles provides baseline coverage
- 3 mile radius around to account for entirety of town
- 10 minute drive or less for patient convenience





What does our market look like?



Affan, 25

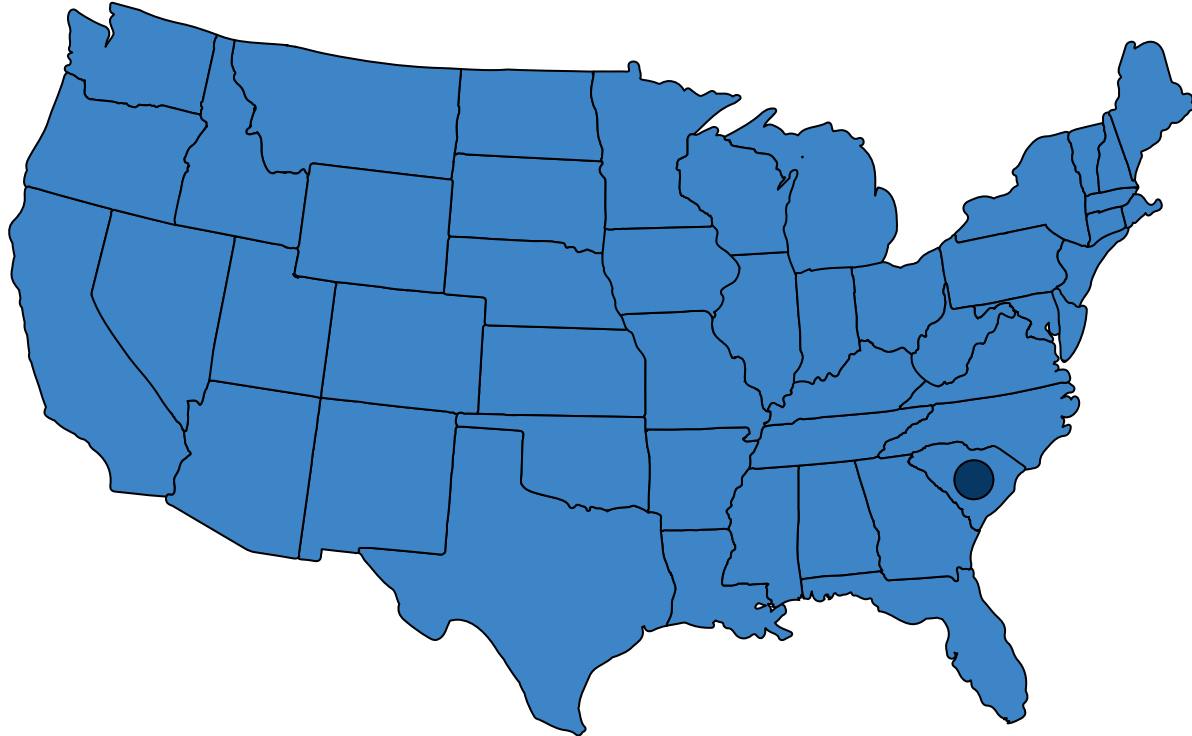


Sarah, 38 and Ty, 36



Lexapro, 2

Why do we need these services?



49th In Cost of Care

41st For Health Outcomes

32nd For Access of Care

Demographic Comparison

Trade Area

Median Age



33.55

Average Household Income



\$65,603

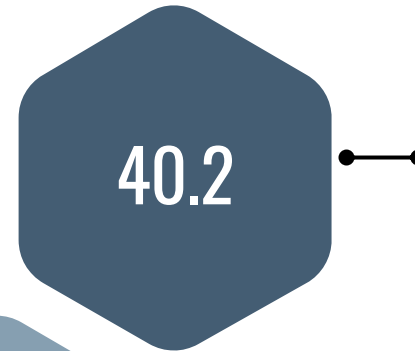
Median Household Size



3.16

South Carolina

Median Age



40.2

Average Household Income



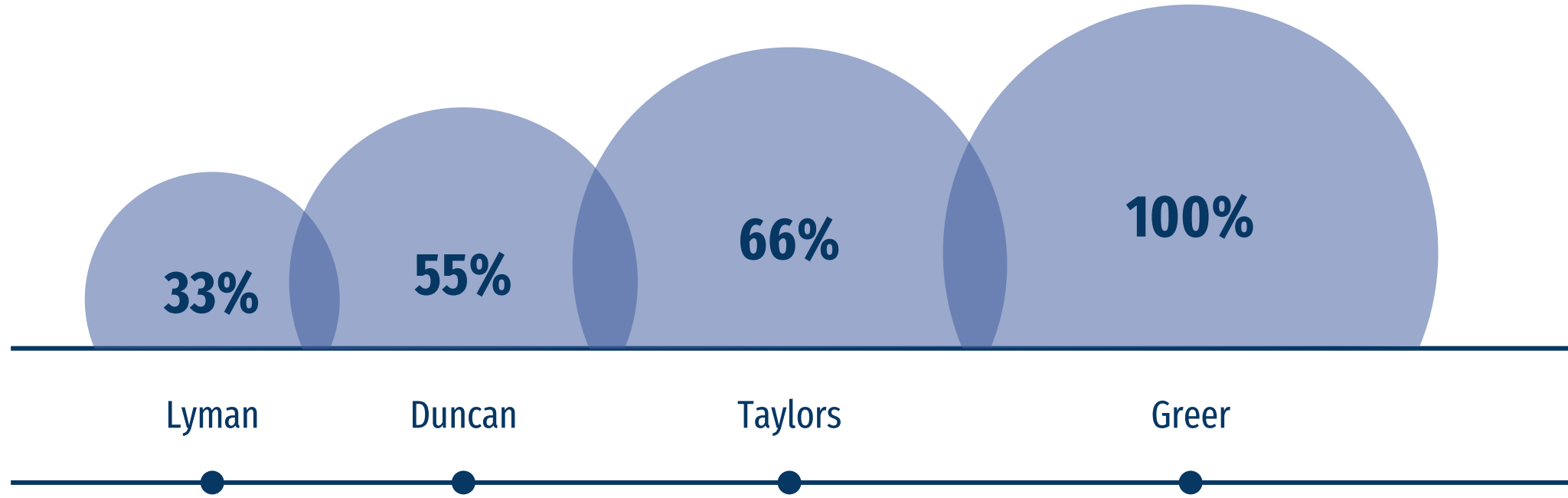
\$59,318

Average Household Size



3.06

Percentage of Market Coverage



Blue Ridge Apothecary

The Patient and Prescription Market

Town	Population	Population in Trade Area ¹	Prescription Volume ²	Potential Prescription Revenues ³
Greer	38,865	38,865	660,705	\$39,391,232
Taylors	23,222	15,327	260,551	\$15,534,041
Duncan	4,041	2,223	37,783	\$2,252,643
Lyman	6,321	2,086	35,461	\$2,114,173
Total	77,449	58,500	994,500	\$59,292,090

1. Based on percent market coverage in previous slide

2. Assuming each patient received 17 prescriptions annually per 2020 NCPA Financial Digest

3. Assuming each prescription is \$59.62 per 2022 NCPA Financial Digest

Competition in the Trade Area

CVS

Three locations
within trade
area

—

Hours recently
reduced in 2/3
stores by one to
two hours per
day

Walgreens

Two locations
within trade
area

—

Hours recently
reduced in one
store, second
store is
temporarily
closed

Walmart

One location
within trade
area

—

Hours recently
reduced by two
hours per day

Mail Order

Liberally
estimated
performance to
value above
Blue Ridge
Apothecary

—

Delivery
available from
FedEx, UPS, and
USPS in area

Status of Market Competition

Pharmacy	Total Rx Filled Daily ¹	Annual Rx Filled ²	Annual Rx Revenue ³	Percent of Total Market
Blue Ridge Apothecary	145	45,240	\$2,697,209	4.55%
CVS	1,750	546,000	\$32,552,520	54.91%
Walgreens	650	202,800	\$12,090,936	20.39%
Walmart	300	93,600	\$5,580,432	9.41%
Mail Order	150	46,800	\$2,790,216	4.71%
Total	2,995	934,440	\$55,711,313	93.96%

1. Summation of values reported from stores in trade area

2. Assuming pharmacy is open 28 days of the month

3. Assuming each prescription is \$59.62 per 2022 NCPA Financial Digest



\$3,580,777

In Rx Revenue Unclaimed in
Market





03

Breakdown of the Cost of Acquisition

Valuation of Pharmacy

Average Gross Profits

\$592,403

15% Sales +
Inventory

\$671,392

\$8 per Annual Rx +
Inventory

\$601,480

Annual Gross Profit

\$690,149

Average of Annualized
Rx Volume

\$561,600

20% Gross Revenue

\$592,403

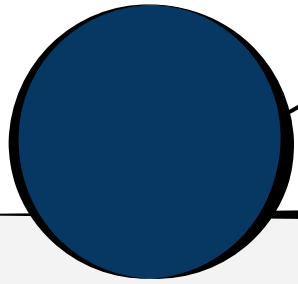
~\$620,000

Summary of Loan Request

Name of Business:	Blue Ridge Apothecary 109 North Main Street Greer, SC 29650
Amount of Loan Request:	\$1,554,080.00
Terms of Loan Request:	25 Year Loan Term 7.75% Fixed Interest Rate Extended line of credit in the amount of \$75,000
Date of Loan Request:	October 14th, 2023

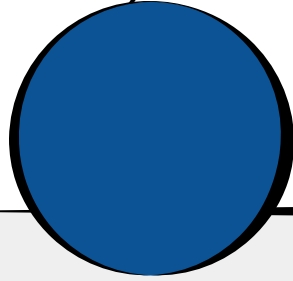
Loan Total

\$1,554,080



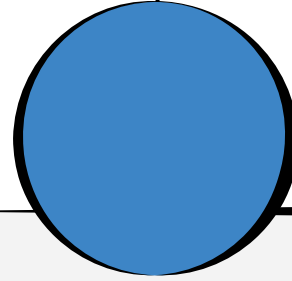
\$620,000

Acquisition of
Blue Ridge
Apothecary



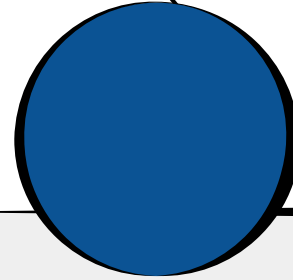
\$550,000

Purchase of
Property and
Building



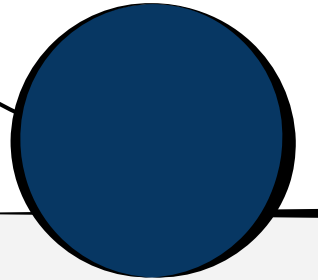
\$25,000

General Building
Renovations



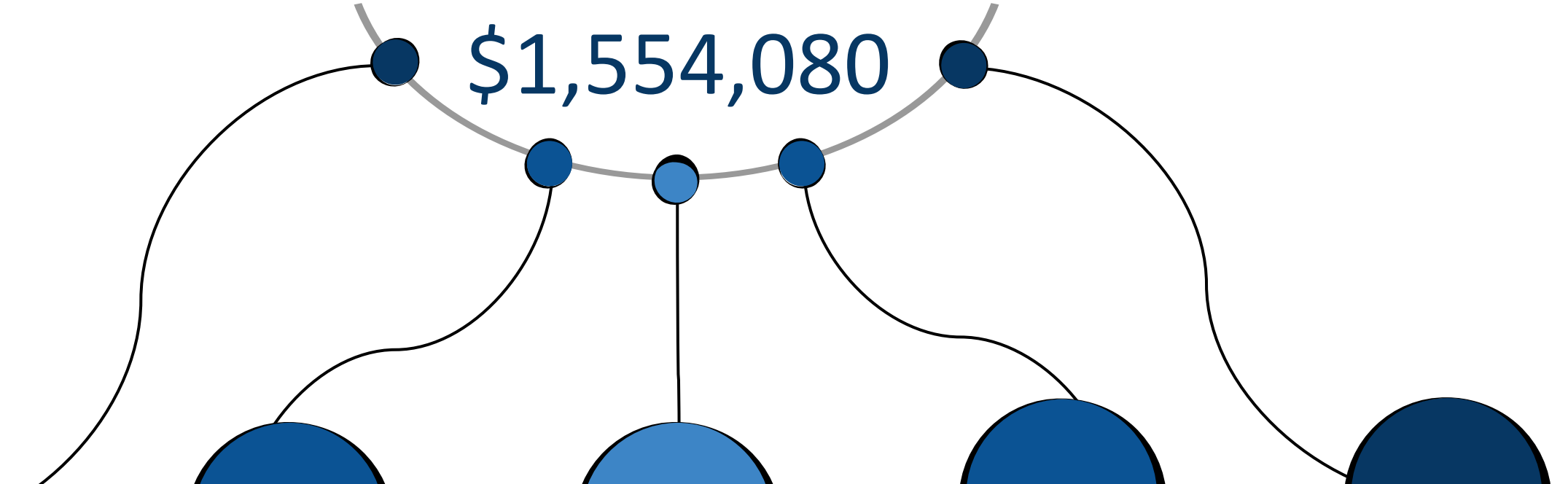
\$30,000

Installation of
Compounding
Lab



\$75,000

Extended Line of
Credit



Keeping Your Loan Secured

**Personal Contribution Worth
19% of Loan Amount**



**Personal Guarantee and Life
Insurance Policy From Each Owner**



**Contributing \$300,000
Worth of Collateral**



**Property Secured as Potential
Collateral**





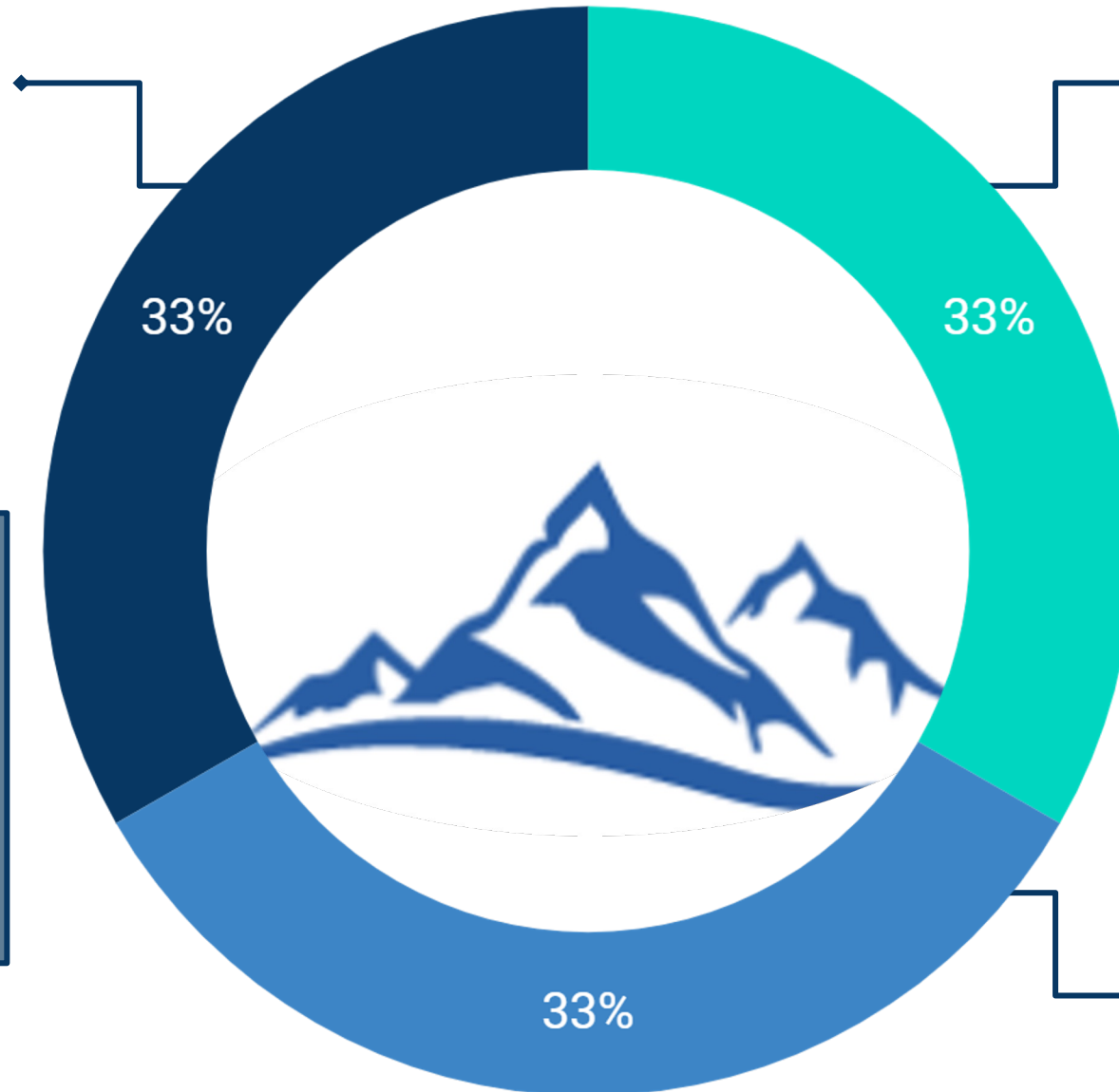
04

Legal and
Business
Structure Post-
Acquisition

Legal Structure

Farehaa
Hussain, LLC

Jacob King, LLC

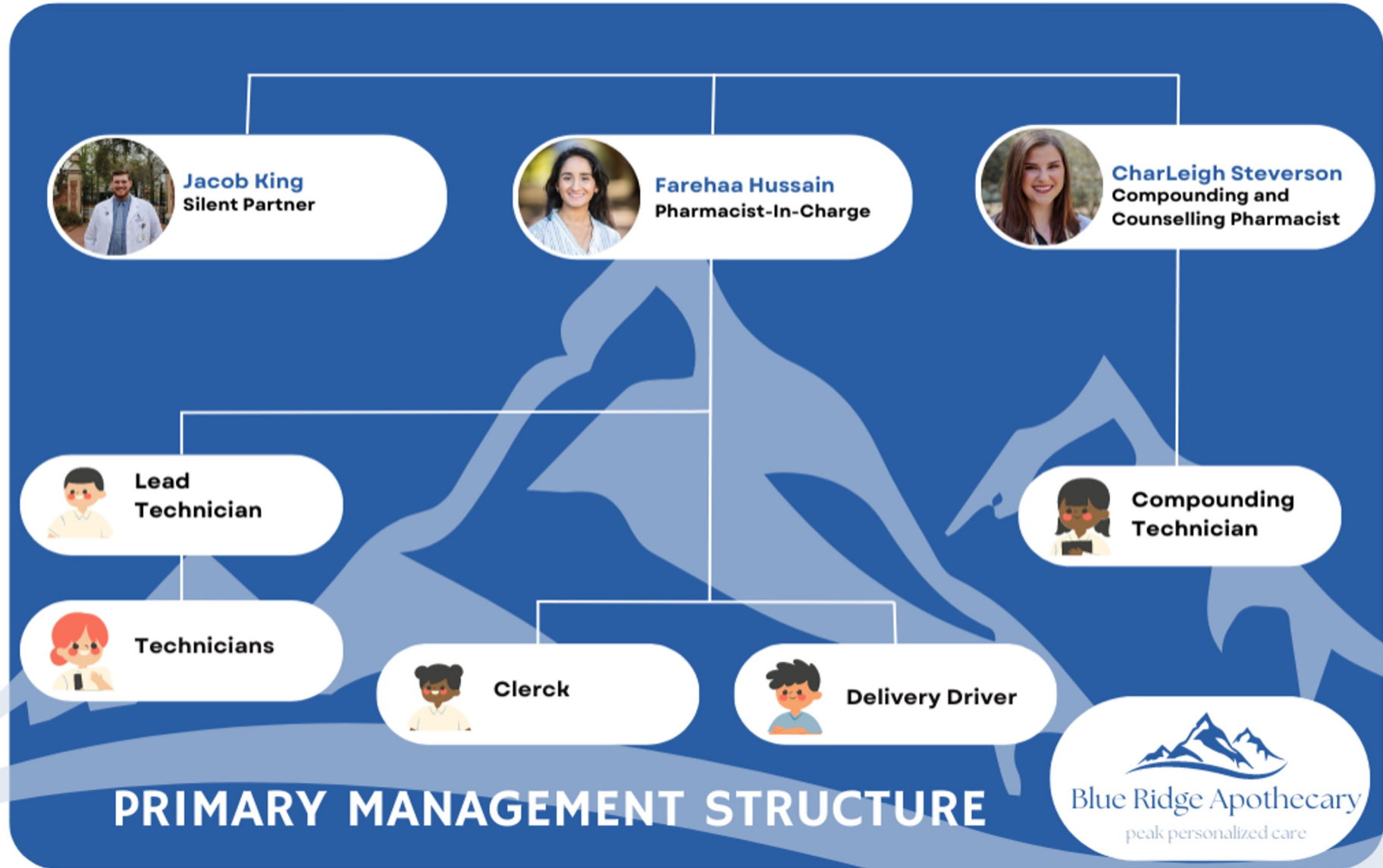


Limited Liability Company (LLC)

- Corporate Veil
- Single Taxation
- Protect Assets of Owners

CharLeigh
Steverson, LLC

Management Structure





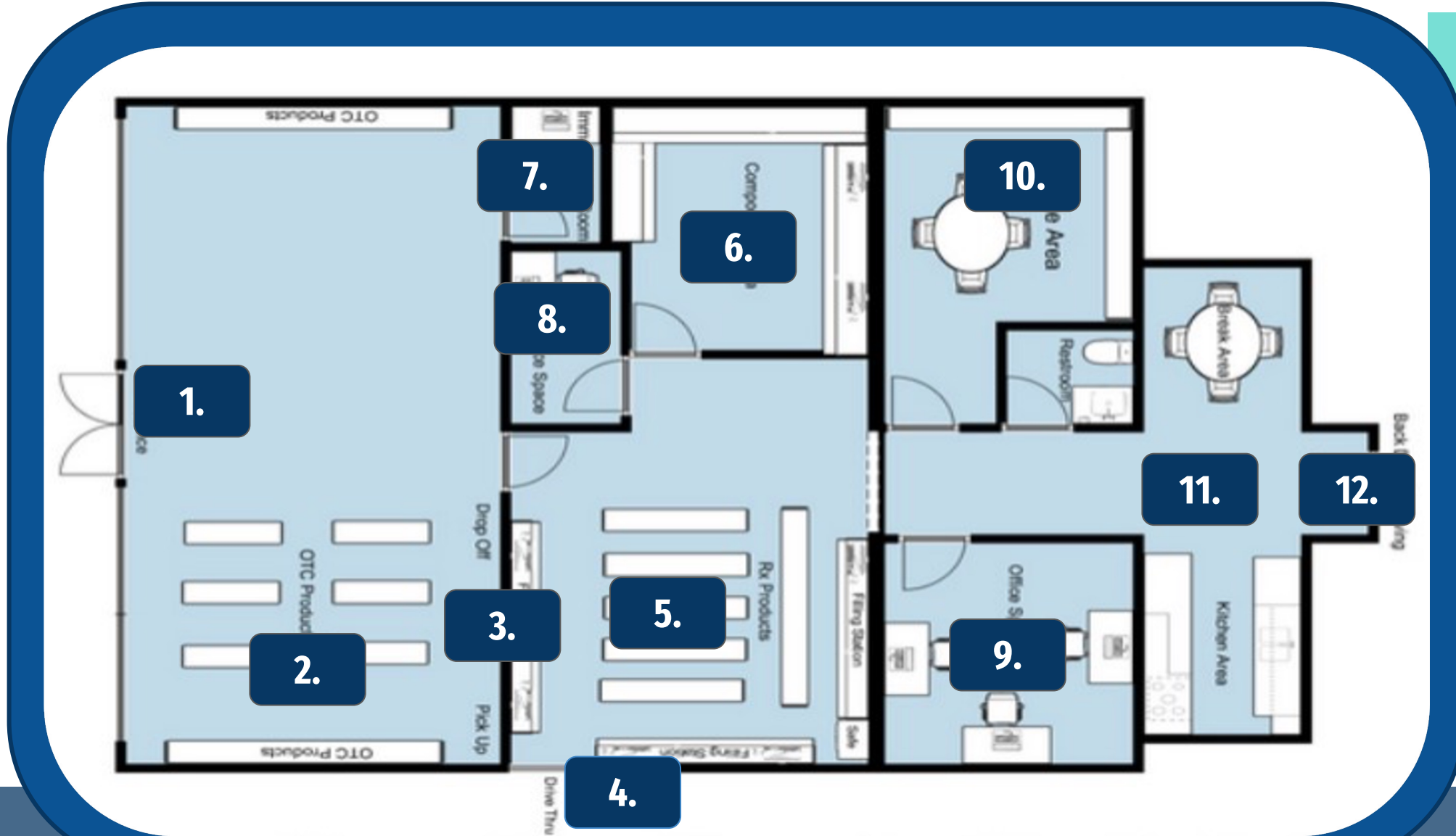
05

A Much
Needed
Change for the
Community of
Greer

Pharmacy Pre-Renovation

Directory

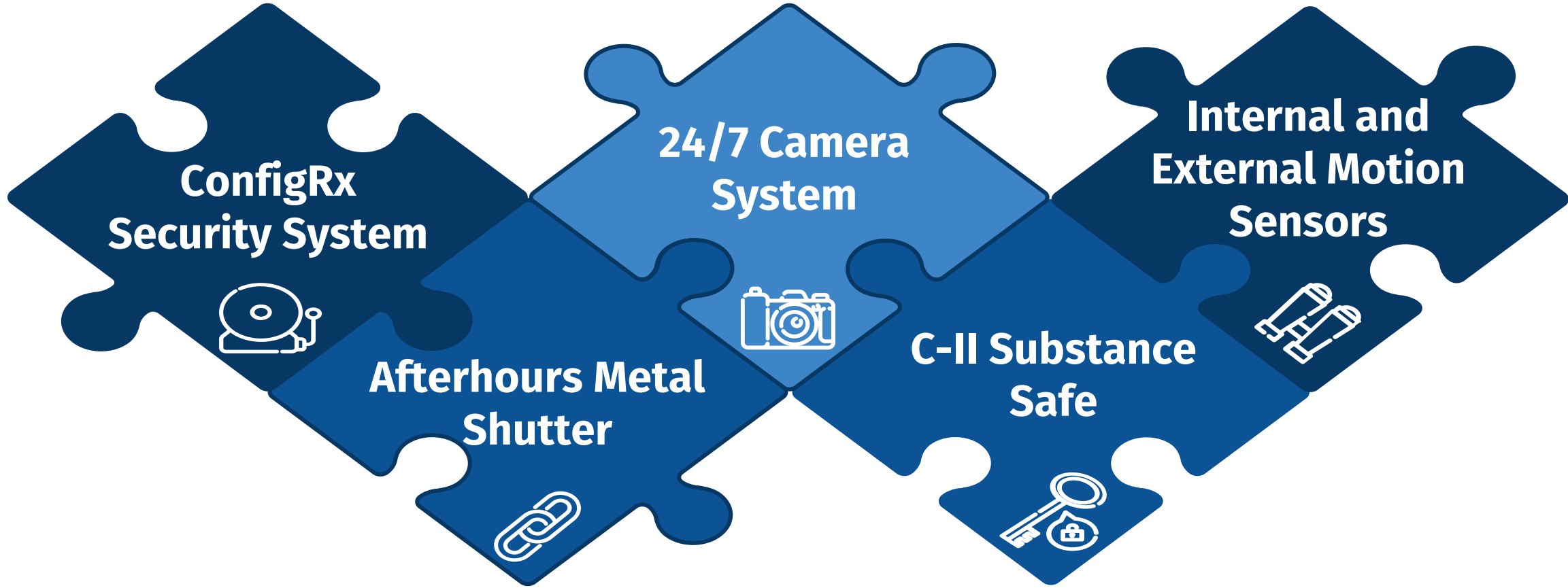
1. Entrance
2. Front End
3. Front Counter
4. Drive Thru
5. Pharmacy Shelves
6. Compounding Room
7. Immunization Room
8. Office
9. Office
10. Storage
11. Break Area
12. Receiving



Pharmacy Post-Renovation



Protecting Your Investment



**Expanding
and
Enhancing
Our Services**

OUR PARTNERS




AmerisourceBergen



Compliant Pharmacy Alliance



Pharmacist Mutual



SC CPESN



Insurance Network

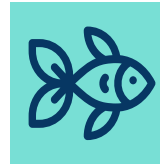


Flip The Pharmacy

Enhancing Current Services



Sterile and Non-Sterile Compounding



Veterinary Compounding



Multilingual Services



Dispill Adherence Packaging



Medication Synchronization

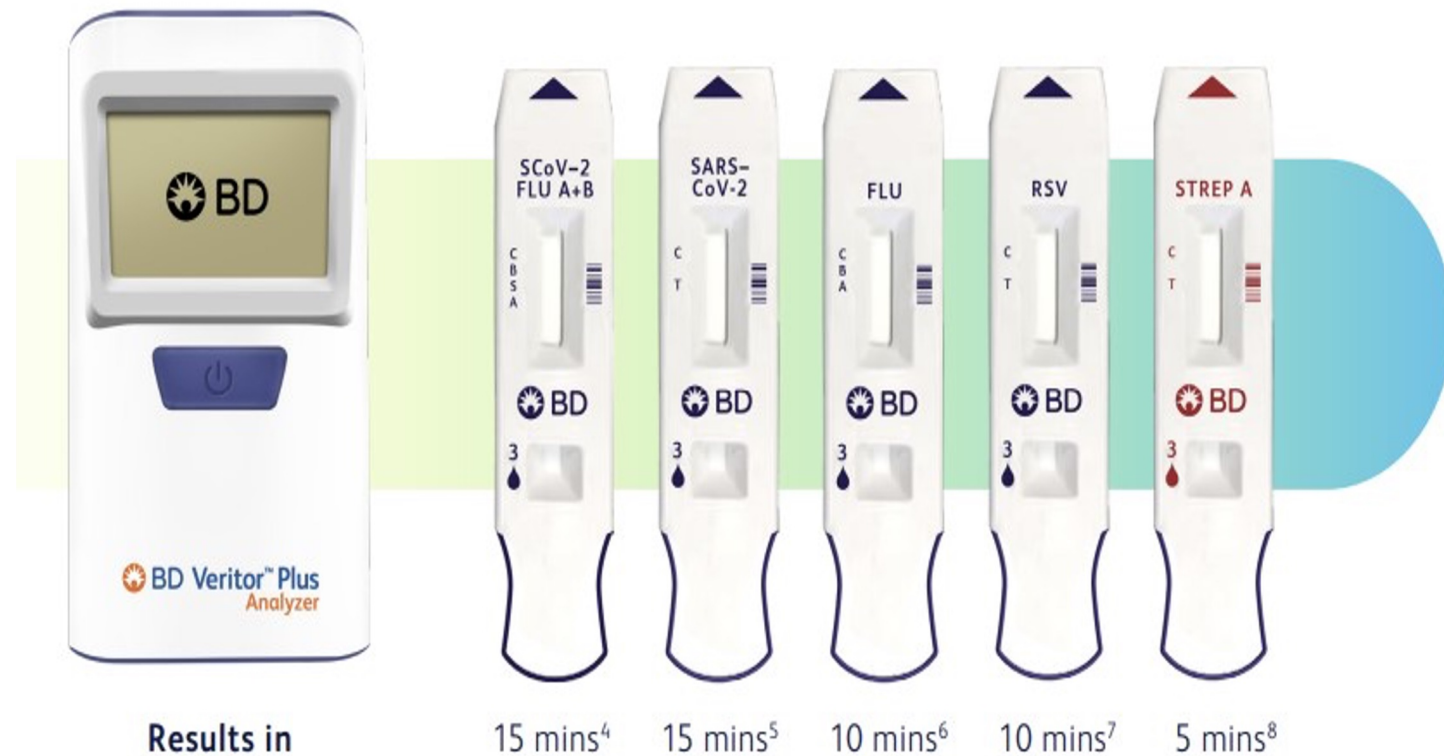
Point of Care Testing and Test-To-Treat Program

Rapid Testing for

- Influenza A+B
- Covid-19
- Combination Flu and Covid-19
- Strep A

Collaborative Practice Agreement with “Main Street Medic” to allow treatment of influenza and strep A

Emergency Use Authorization of Paxlovid to allow treatment of Covid-19



Contraceptive Prescribing and Administration

Pharmacy Access Act

- Each pharmacist to complete certificate program regarding contraception
- Provide each patient with informed consent and self-screening tool
- Patient to be counseled and PCP to be notified
- **Eligibility:** All patients 18 years or older, or less than 18 years of age with evidence of a past contraceptive prescription

South Carolina Hormonal Contraceptive Self-Screening Questionnaire

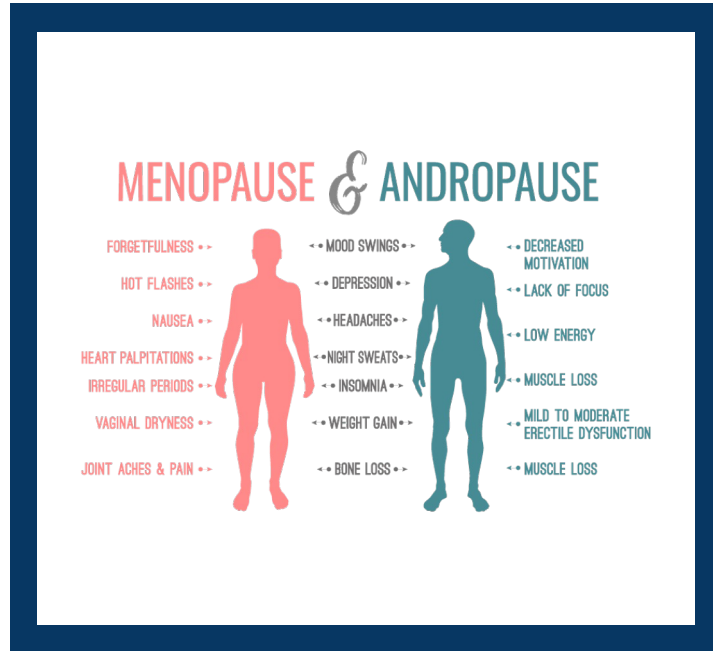
Date ___/___/___ Patient Name _____ Primary Care Provider _____
 Date of Birth ___/___/___ Age _____ Weight _____ Do you have health insurance? Yes / No
 What was the date of your last women's health clinical visit? _____
 Any allergies to Medications? Yes / No If yes, list them here _____
Do you have a preferred method of birth control that you would like to use?
 A daily pill A weekly patch A vaginal ring Injectable (every 3 months)

1	Do you think you might be pregnant now?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2	What was the first day of your last menstrual period?	___/___/___
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Have you previously had contraceptives dispensed to you by a pharmacist?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Do you smoke cigarettes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6	Have you had a recent change in vaginal bleeding that worries you?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Have you given birth within the past 21 days? If yes, how long ago?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Are you currently breastfeeding?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9	Do you have diabetes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Do you get migraine headaches?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10a	If so, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes <input type="checkbox"/> No <input type="checkbox"/>
11	Are you being treated for inflammatory bowel disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes <input type="checkbox"/> No <input type="checkbox"/>
13	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
14	Have you ever had a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	Have you ever been told by a medical professional you are at risk of developing a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
16	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
17	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
18	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
20	Have you had a solid organ transplant?	Yes <input type="checkbox"/> No <input type="checkbox"/>
21	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, (yellow skin or eyes)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
22	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/> No <input type="checkbox"/>
23	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	_____
24	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	If yes, list them here:	_____

Signature _____ Date _____



Bioidentical Hormone Replacement Therapy



Hormone Replacement

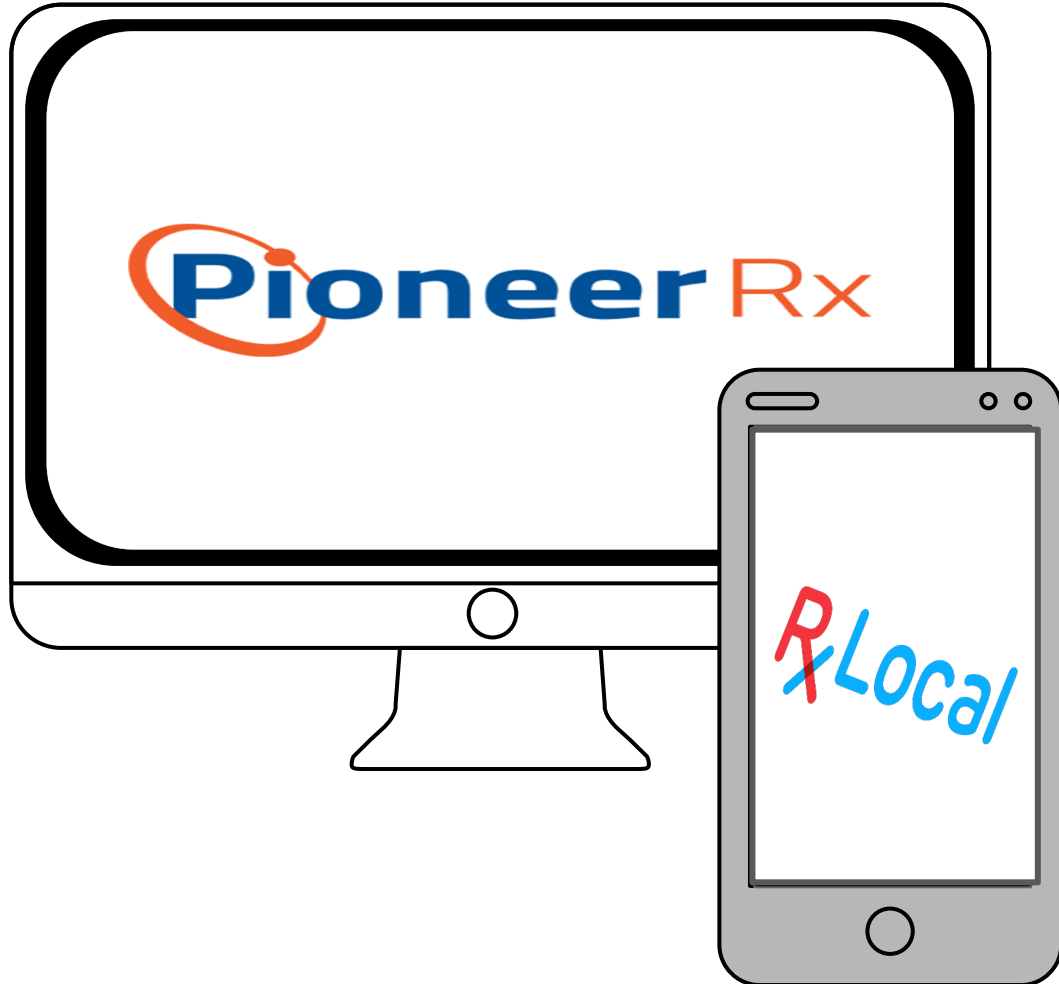
27% of Trade Area is between ages 45 and 65, ~2% higher than the state average



Gender Affirmation

Having access to gender-affirming care has been shown to reduce self-harm and suicidal ideation by 73%

PioneerRx and RxLocal



Dispensing Services

- Dispensing System
- MedSync
- MTM Services
- Care Plan



Development Mobile App Services

- Refill Requests
- Profile Updates
- OTC Ordering



Marketing Overview

Marketing Materials

Physical Materials

- Business Cards
- Road Signs
- Koozies
- Door Hangers
- Local Sports Team Sponsorships
- Branded T-shirts

Digital Materials

- Geofencing Ads on Facebook and Google
- Local Radio Ads
- Moonlight Movie Ads



Marketing Activities



**New Owner's Meet
and Greet Event**



**Greer International
Festival Tabling**



**Annual Freedom
Blast Blood Drive**



**Greer Christmas
Parade Float**

Timeline of New Services

Store

Acquisition

Months 1 - 3:
Good Faith Period



POC Testing

Month 1:
Begin utilization of
POC and Test-to-treat
Services

Store

Renovation

Months 3 - 4:
Construction of new
pharmacy layout



PioneerRx

Months 4 - 6: Pioneer
University and System
Transfer



Pharmacy-Based Contraceptives

Month 6: Begin counseling on
and prescribing
contraceptives

HRT and GAT Program

Month 13: Launch pilot
program for bHRT
services

Compounding - Sterile and Non-Sterile

Month 9: Launch new
compounding services
including veterinary
compounds



**Financial Goals
and
Expectations
For Years 1 - 3**

06

Financial Baseline



Sales	\$2,962,013
Cost of Goods Sold	78.6%
Gross Profit	\$690,149
Total Expenses	\$2,271,864
Net Income	\$100,708

Prioritization of Cash Based Services



Hormone Therapy Counseling

Estimated Revenue per Hour:
\$120

COGS: ~50%

Net: \$60/Hr



Compounded Products

Estimated Revenue per
prescription: \$65.00

COGS: ~40%

Net: \$39/Rx



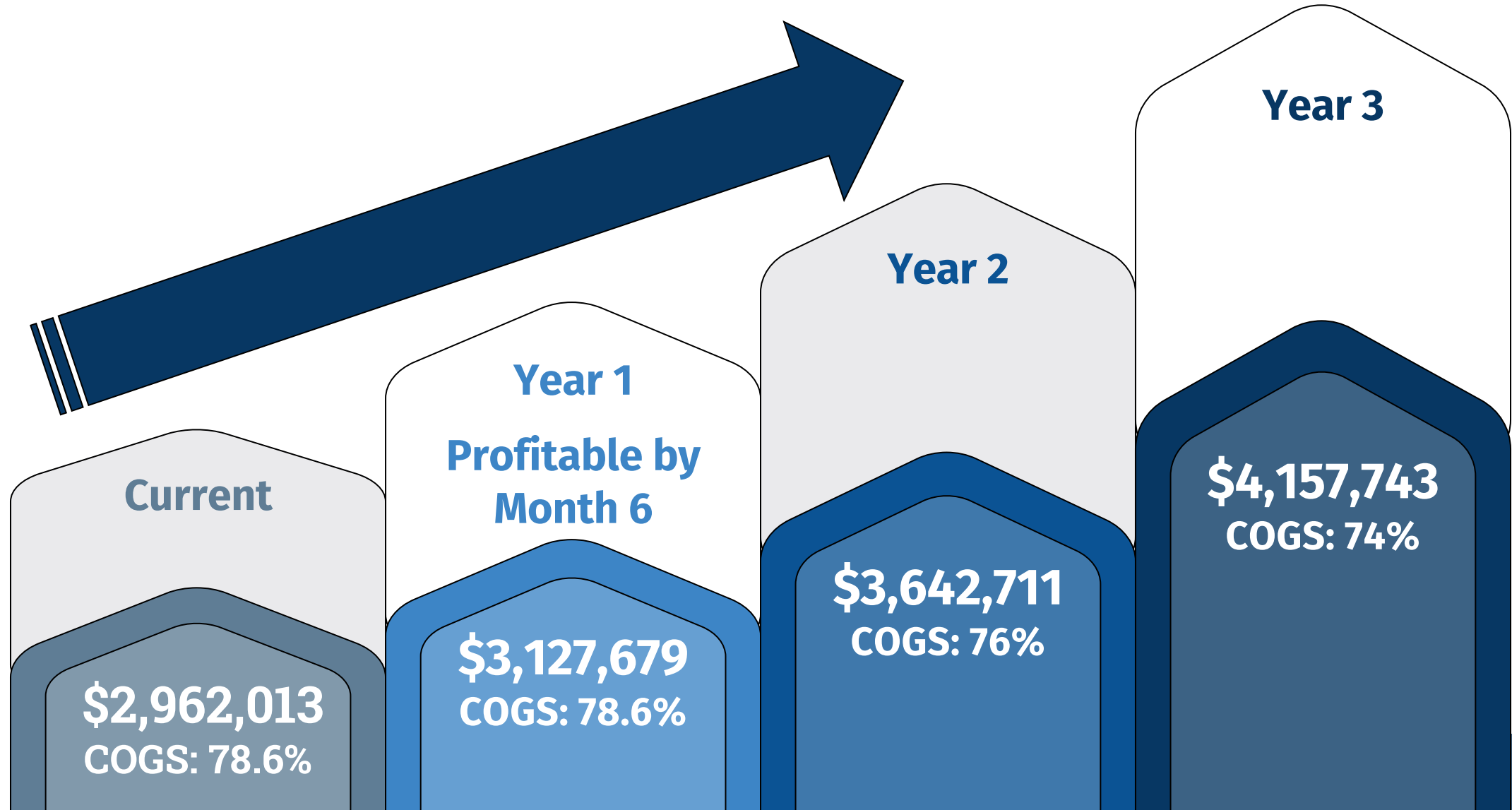
Point of Care Testing

Estimated Revenue per Test:
\$85.00

COGS: ~20%

Net: \$68/Test

Projects Sales and Cost of Goods Sold



The Primary Takeaway



Tenant-Based Revenue



**Estimated Revenue per Business per
Month: \$3,000**

Rent to increase by 5% annually

Return on Investment

\$1,554,080
7.75%
Interest

Your Investment

Protected by
Collateral, Personal
Contribution, and Life
Insurance Policies!

\$11,738 per
Month for
300 Months

Repayment

20% of Net Profits
will be contributed to
pay loan back faster!

~\$2,000,000
Paid in
Interest

Ready to Invest Again

Full loan amount will
be paid in 25 years or
sooner!

Prospective SWOT Analysis

S

Strengths

- Community presence
- Starting customer base
- Proximity to primary and urgent care facilities

W

Weaknesses

- Expansion restricted by building type
- Limited available market share

O

Opportunities

- CPA with Main Street Medic
- Expansion into PrEP and PEP prescribing and administration

T

Threats

- Heavy competition present
- Political opposition to services
- DIR Fee Changes



THANKS!

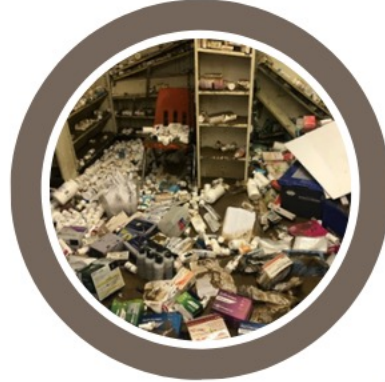
We are happy to accept
any questions at this time!

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The NCPA Foundation improves community-based health care access by supporting efforts that promote the sustainability and growth of independent community pharmacists, the most accessible health care provider, through scholarships, grants, and ownership development.



Donate Today!

The NCPA Foundation, a 501(c)(3) organization, was established in 1953. Contributions are deductible for income tax purposes to the extent permitted under federal tax law (Tax ID: 90-0633086)



Building and Scaling Your LTC at Home Services

Lindsay Dymowski Constantino

Cofounder, President

Centennial Pharmacy Services

LTC@Home Pharmacy Network (CPESN LTC@HOME)



Learning Objectives

1. Discuss opportunities to scale your LTC at home operation across multiple locations.



Let's See Who Is Here....

- How many pharmacies here are retail only?
- How many pharmacies here are LTC only?
- How many pharmacies are combo?
 - Combo at the location level or both retail & LTC in ecosystem
- Who is familiar with LTC@Home?
- Who is billing LTC@Home?

LTC@Home Is....

A sector of pharmacy supporting patients who qualify for LTC level of service, but reside in the community, not in an institutional setting.

Why is it so Important?

Pharmacy

- Provided fair reimbursement based on level of service provided to the patient.
- *QUALITY METRICS*

Provider

- Supported by a team of medication experts to help with care initiatives, gaps, and communication
- *QUALITY METRICS*

Plan

- Has greater pharmacy support in their ecosystem for the patients who are at highest risk.
- *QUALITY METRICS*

Payer

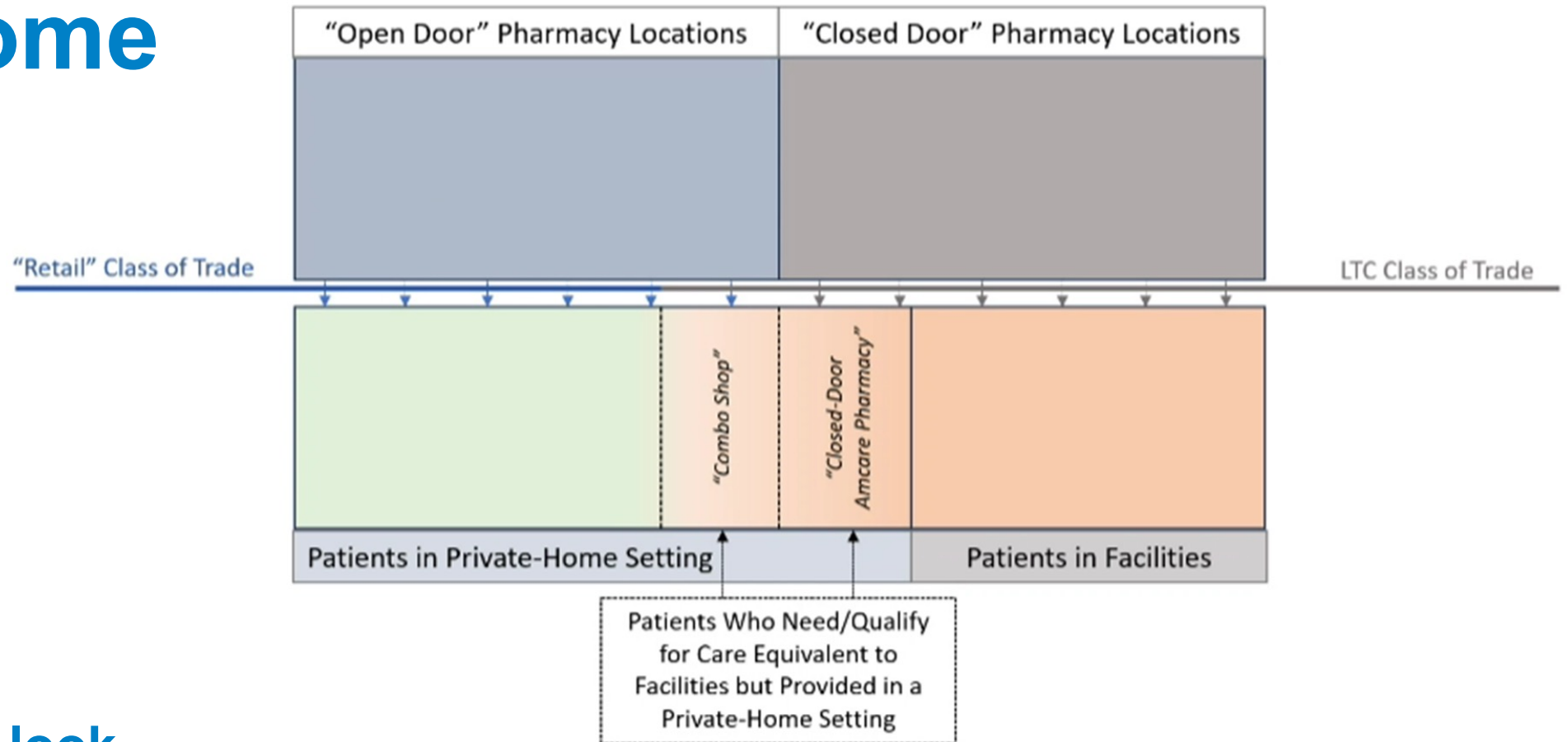
- Has pathways for care and reimbursement structures for programming development.
- *QUALITY METRICS*

Patient

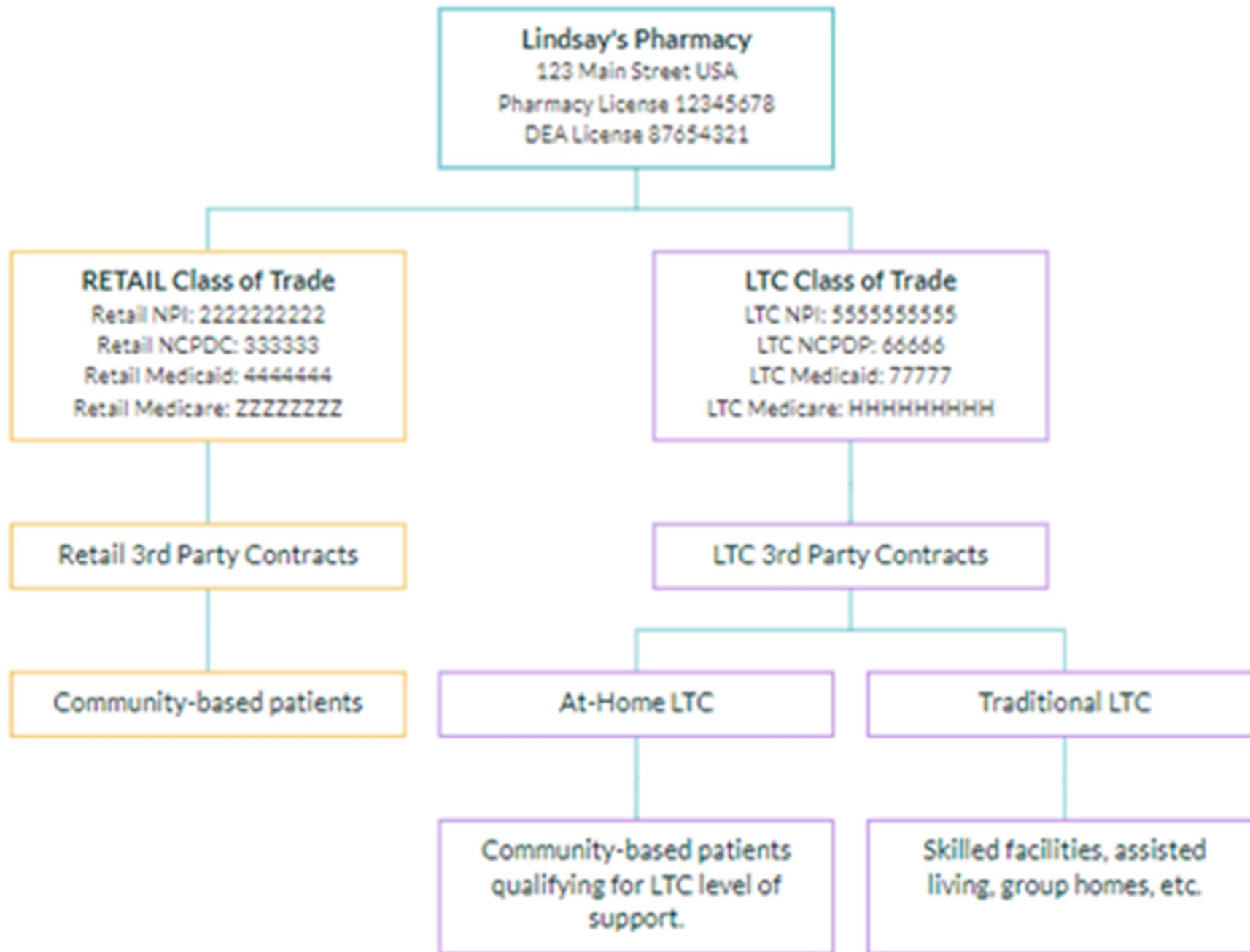
- Has needed LTC level of pharmacy support to help manage chronic conditions and age in place.
- *QUALITY OF CARE*
- *QUALITY OF LIFE*

**EVERYBODY
WINS!**

Where does LTC@Home Fall?



What does that look like operationally?.....

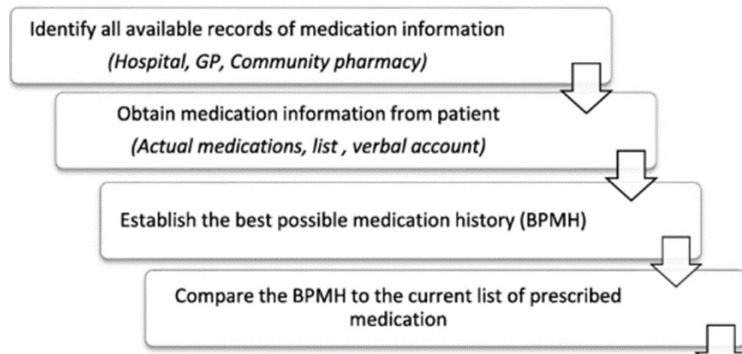


LTC@Home has a unique service set

Service Set	In-House	Outsource	LTC (all)	Unique to LTC at Home
Comprehensive Inventory and Inventory Capacity	Yes	No	Yes	
Pharmacy Operations and Prescription Orders	Yes	No	Yes	
Specialized Packaging	Yes	Limited	Yes	
IV Medications	Yes	Yes	Yes	
Compounding and Alternative Forms of Drug Composition	Yes	Yes	Yes	
Pharmacist On Call (24/7/364)	Yes	Yes	Yes	
Delivery	Yes	Yes	Yes	
Miscellaneous Reports, Forms, and Prescription Ordering Supplies	Yes	No	Yes	
Dispensing Medication Review	Yes	No	No	Yes
Care Coordination with Transition of Care Management	Yes	No	No	Yes
Comprehensive Patient Care Documentation	Yes	No	No	Yes
Emergency Log Books	Only applicable for facility-based long term care services.			
Emergency Boxes	Only applicable for facility-based long term care services.			

LTC@Home Documentation

Dispensing Medication Review



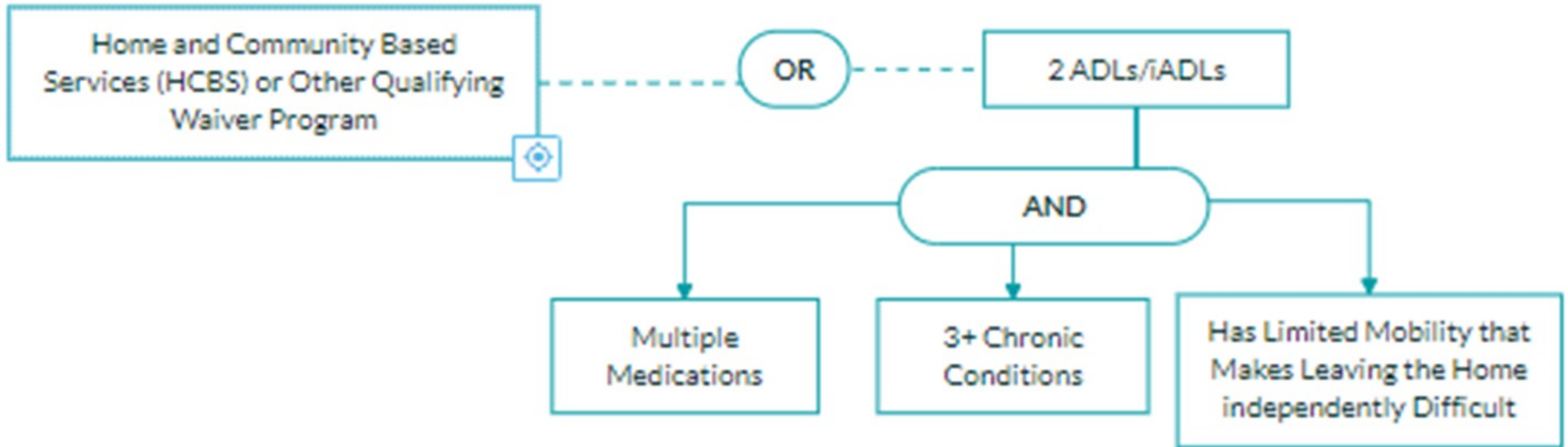
Patient Qualification

Blurred screenshot of a Patient Qualification form, showing various fields and sections.

Medication Acquisition Attestation (Delivery or Pick Up by Agent)

Blurred screenshot of a Medication Acquisition Attestation form, showing various fields and sections.

Who is the LTC@Home Patient?





Hub and Spoke LTC@Home

- The hub-and-spoke model is a strategic approach to service delivery that involves centralizing certain operational functions (hub) while maintaining multiple service locations (spokes) to provide care and support to patients in their homes.
- In the context of LTC at Home Services, the hub serves as the central point for medication fulfillment, coordination of care, and administrative functions, while the spokes represent the satellite locations or branches where patients receive direct care and services.

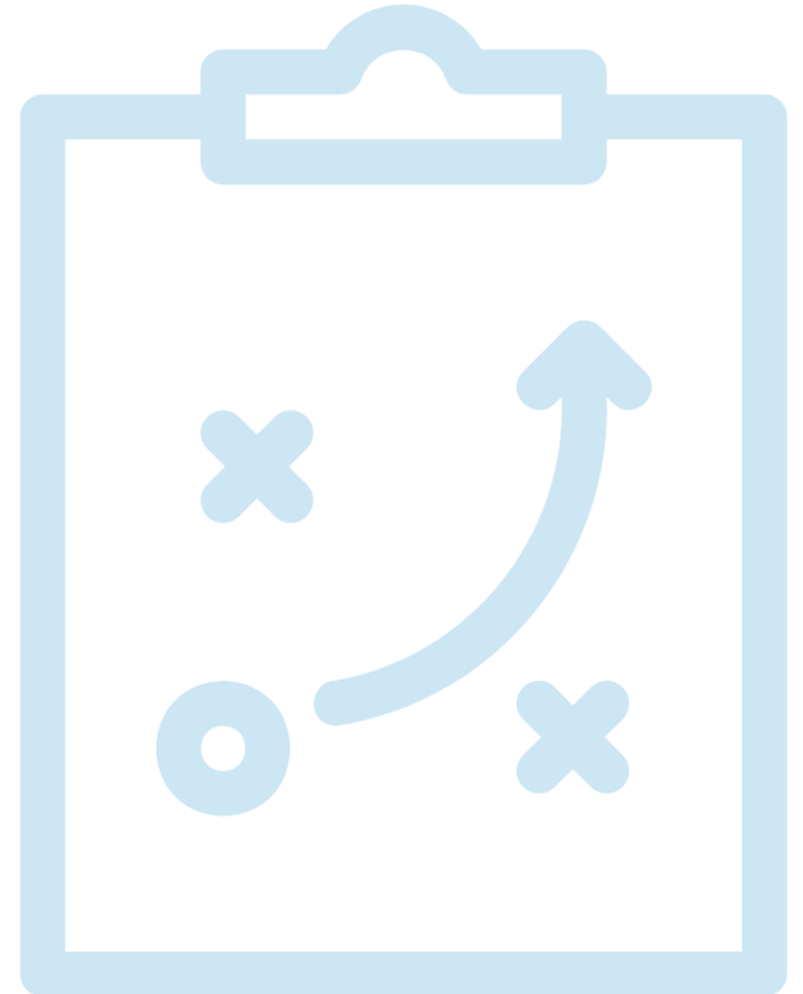


Benefits

- By centralizing medication fulfillment and coordination of care at the hub, pharmacies can achieve economies of scale, optimize inventory management, and streamline operational processes. Bulk purchasing, centralized staffing, and standardized workflows contribute to reducing overall operational costs and maximizing resource utilization across multiple locations.
- By offering a comprehensive suite of LTC at Home Services across multiple locations, pharmacies can attract a larger patient base, increase service utilization, and diversify revenue streams through service fees, reimbursements, and partnerships with healthcare providers.

Logistics

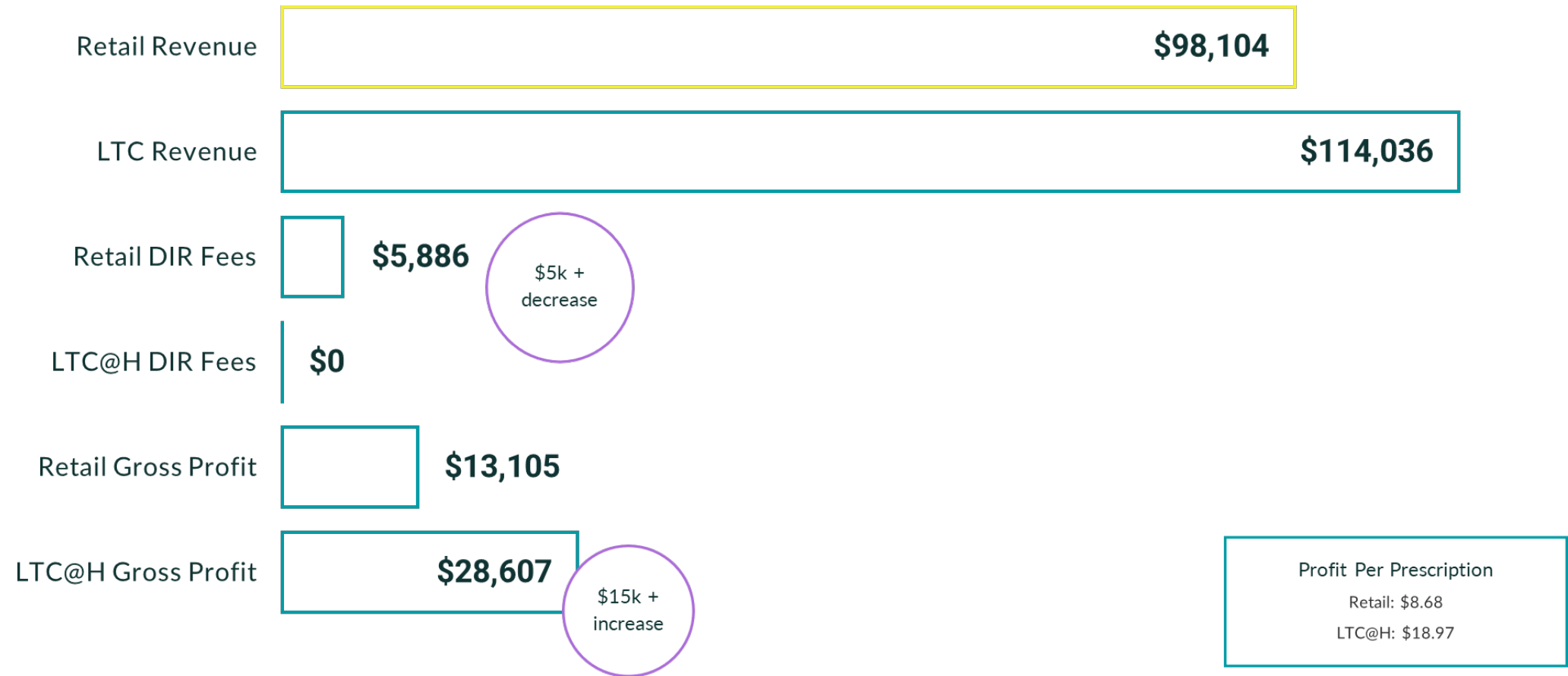
- Prescription Processing: Streamlined prescription processing workflows, electronic prescribing systems, and interoperable communication platforms to facilitate seamless coordination between the hub and spoke pharmacies.
- Scheduling and Routing: Efficient scheduling and routing systems for medication deliveries, clinical services, etc. to optimize resource allocation and minimize travel time and costs.





Is this Worth It for My Pharmacy?

ROI Based on 1 BIN for 1 National Payor - 150 Patients - 1508 RXs - 4 Week Survey



Implementation Strategy

1

Standardizing Processes: Develop standardized protocols, workflows, and quality standards to ensure consistency and efficiency across all locations.

2

Establishing Clear Communication Channels: Implement robust communication channels and protocols to facilitate seamless coordination and information sharing among the hub, spokes, healthcare providers, and patients.

3

Leveraging Technology: Utilize technology solutions such as, cloud PMS, and mobile applications to enhance communication, care coordination, and remote monitoring.

Helpful Resources

- [NCPA LTC Division](#)

- [CPESN LTC@HOME](#)



Lindsay Dymowski Constantino

Cofounder & President Centennial Pharmacy Services

Cofounder & President LTC@Home Pharmacy
Network (CPESN LTC@HOME)

Chief Parental Officer, Household Constantino

Contact:

L.DYMOWSKI@LTCAH.COM

LTC@CPESN.COM



What's ahead for pharmacy benefits?

Ann Lawlor

Vice President Network Contracting & Strategy
Optum Rx United Health Group

Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

This presentation is meant to be informational and not to promote any particular company.



Learning Objectives

1. Describe health equity programs in the community pharmacy space.
2. Identify new options for 2025 for clients to engage with a pharmacy clinically integrated network and medication adherence programs.
3. Identify opportunities for a PBM to improve self serve and admin requirements for community pharmacies.

Key Stats



26,000
Community
Pharmacies



2,414
Directly
Contracted
Agreements



Relationship
with **7**
PSAO's



1,012 Rural
Pharmacies



812 340B
pharmacies

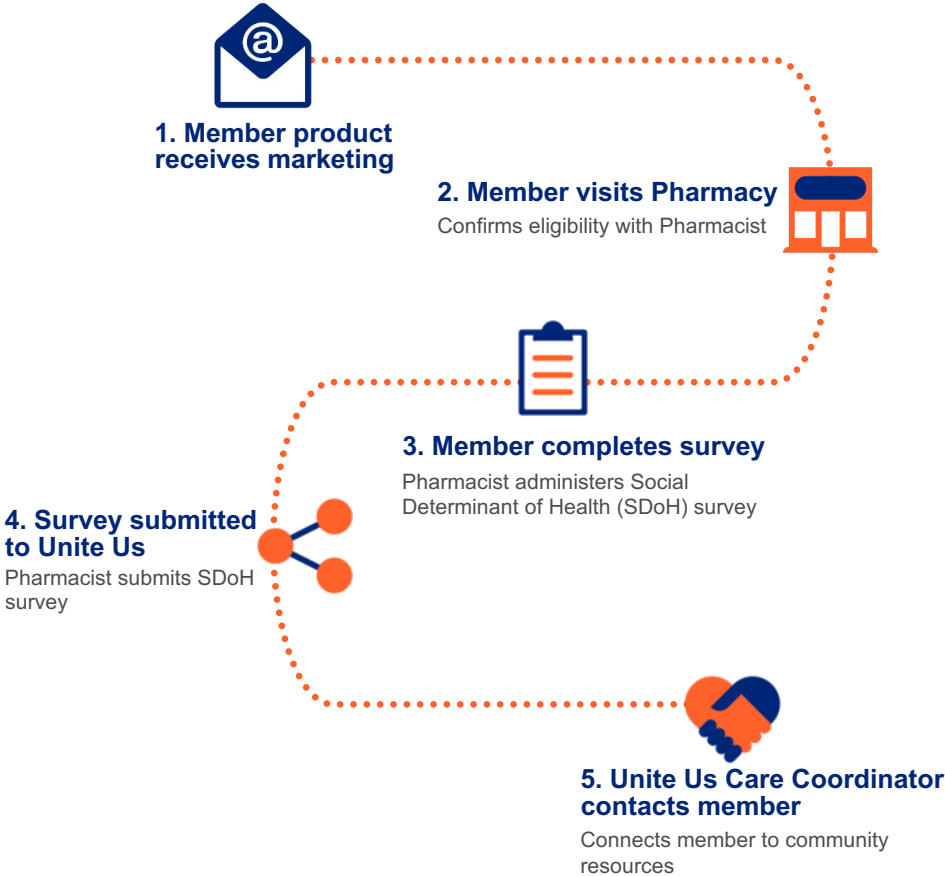


Resource Bridge

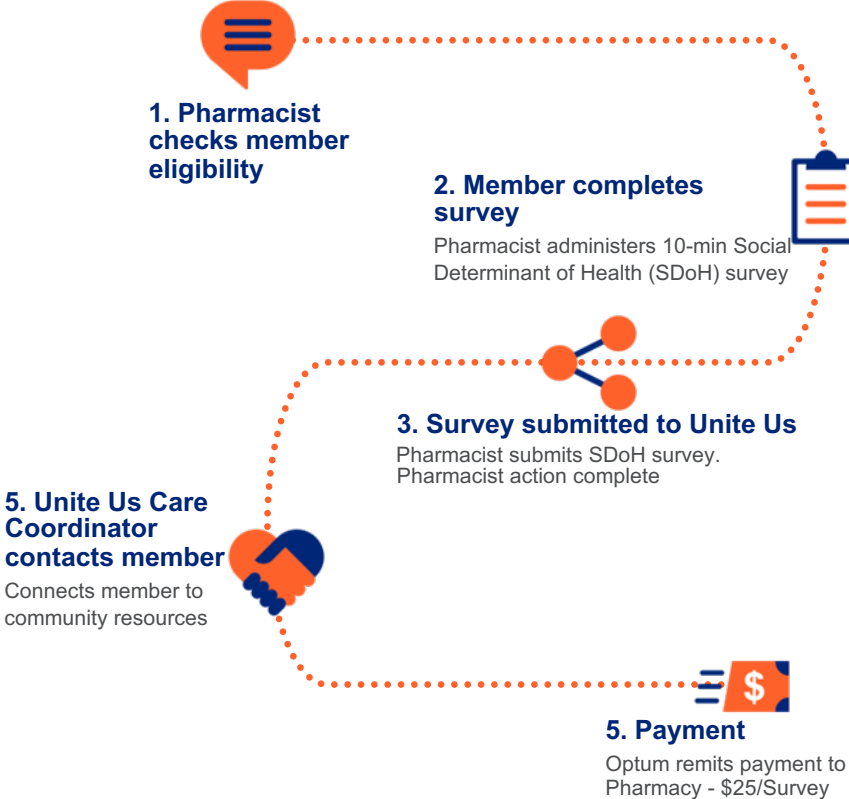
Resource Bridge

Phase	LOBs	Sales Ready Cert	Operational Ready Cert
Product	Commercial (Excluding UHC and UMR), Government and Health Plans	Achieved: Jan 12, 2024	Scheduled: Mar 27, 2024

Member Journey



Pharmacist Journey



Overview

Resource Bridge is designed to address the social determinants of health affecting ORx members and aims to connect members with essential community resources through our partnership with Unite Us.

The Unite Us platform enables pharmacies to play a pivotal role in improving the lives of our members by connecting members with critical needs such as housing, utilities, transportation, and more.

The product also provides supplemental income to partnered pharmacies for their participation in survey administration, providing an additional revenue stream for Health Plans with in-house pharmacies.



Bridge to Wellness

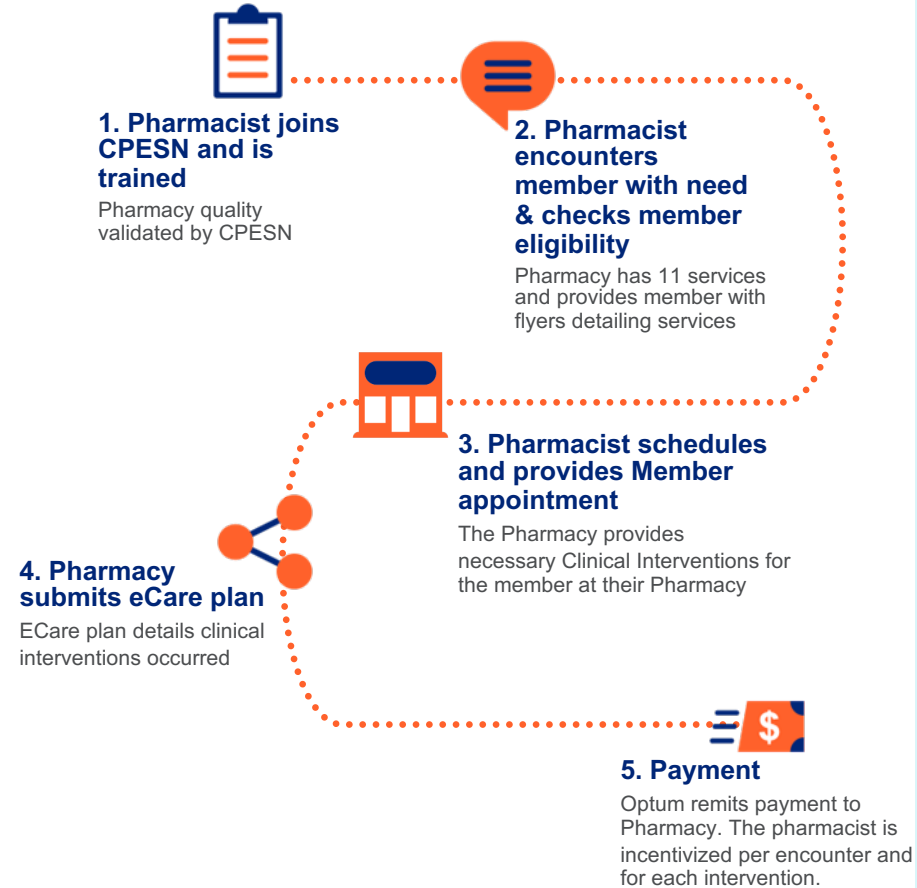
Bridge to Wellness

Phase	LOBs	Sales Ready Cert	Client Implementation
Product	Health-plan/Payers across all Direct Commercial HealthPlan Clients	Achieved: Feb 9, 2024	Target Date: Feb 28, 2024

Member Journey



Pharmacist Journey



Overview

Bridge to Wellness is a product designed to enhance data-driven patient-care opportunities for our clients' members at their pharmacy.

Bridge to Wellness delivers high-touch, provider - administered medication services that closes gaps in care, promotes medication adherence and improves health outcomes through more accessible clinical engagement by a licensed pharmacist.

The program is a partnership between Optum Rx and CPESN USA, a clinically integrated network (CIN) of pharmacy providers organized as a network of ~ 3,500 local community pharmacies. Our product offering supports the goal of bolstering independent pharmacies by enhancing their scope of services and leveraging the expertise of Pharmacists who interact with members more frequently, improving health outcomes and decreasing health care costs through effective disease management solutions provided at a lower cost-of-care than traditional clinical settings.

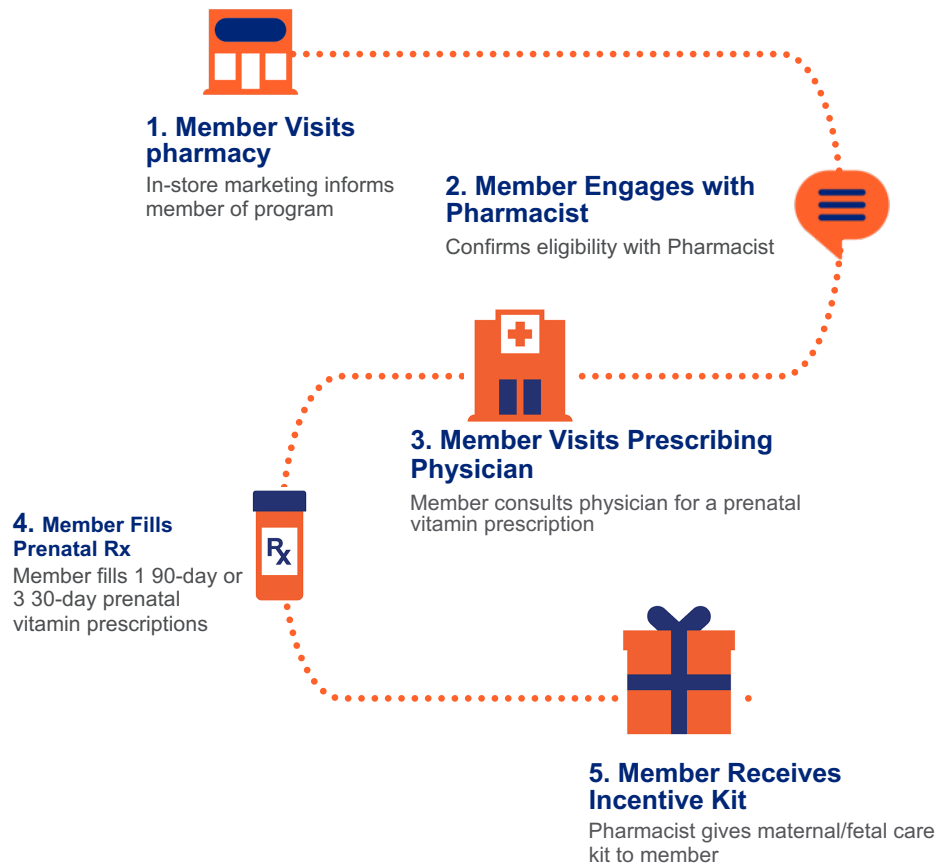


Bridge to Healthy Baby

Bridge to Healthy Baby

Phase	LOBs	Sales Ready Cert	Operational Ready Cert
Pilot	<ul style="list-style-type: none"> Pilot – All Product - TBD 	TBD	TBD

Member Journey



Pharmacist Journey



Overview

The Bridge to Healthy Baby pilot is a health equity program administered by OptumRx and focused on promoting prenatal healthcare and adherence to prenatal vitamins.

The pilot aims to incentivize pregnant OptumRx women of all lines of business to attend prenatal provider care appointments and adhere to a prescription prenatal vitamin regimen to improve infant and maternal health outcomes. The initiative offers maternal care accessories and wallet cards for the Maternal Mental Health Hotline to mothers who fill one 90-day or three 30-day prescriptions for prenatal vitamins.

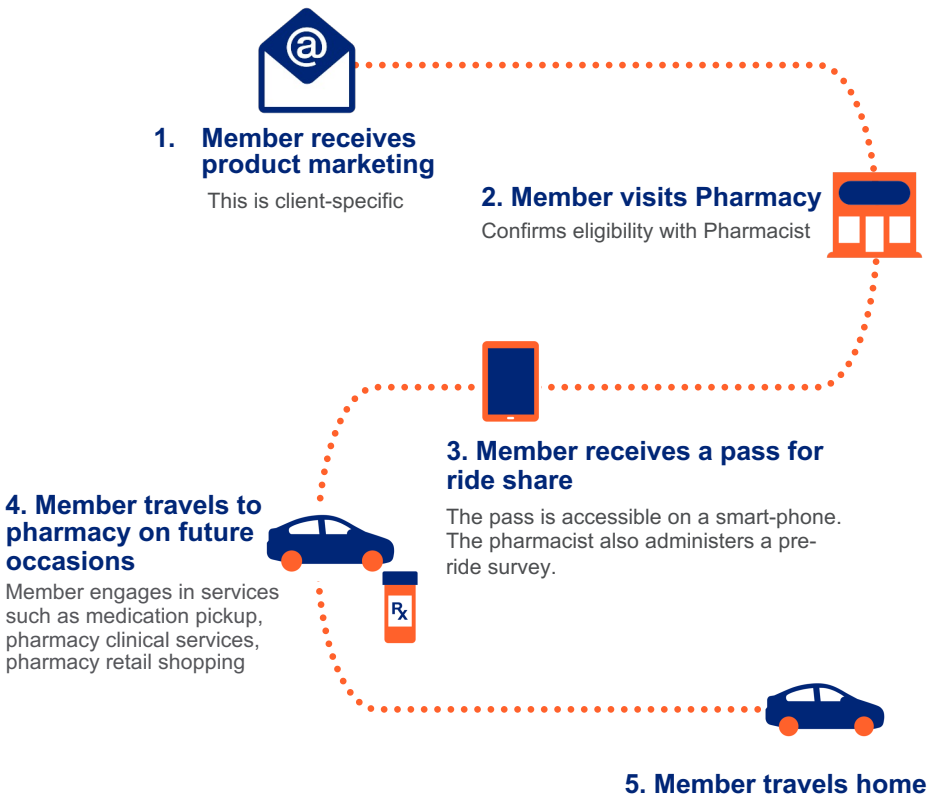


Bridge to Pharmacy Care

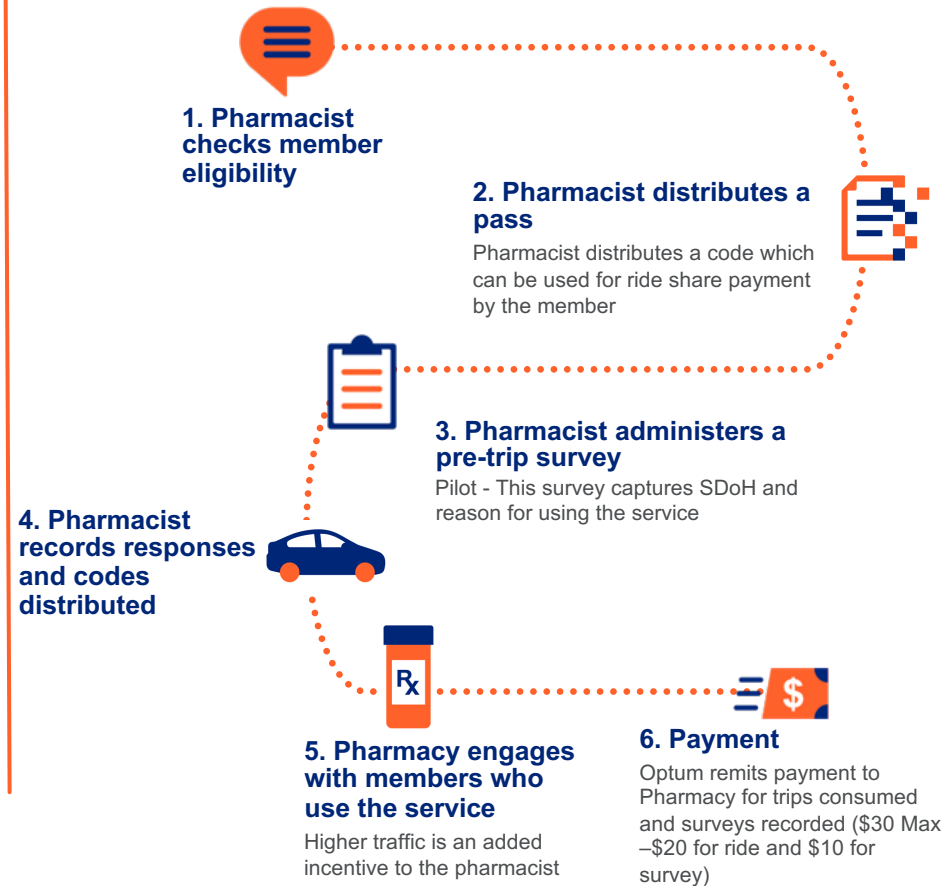
Bridge to Pharmacy Care

Phase	LOBs	Sales Ready Cert	Client Implementation
Pilot	Commercial, Medicare, and Medicaid	Target Date: 10/01/2024	Target: 12/15/2024

Member Journey



Pharmacist Journey



Overview

Bridge to Pharmacy Care is a Health Equity innovation in the pharmacy setting. The product removes friction for Optum Rx members who may be impacted by pharmacy deserts through facilitating rides to and from the pharmacy, with the help of the pharmacy staff.

Optum Rx facilitates payment and creates ride share access to share with the pharmacy. The member receives their ride share pass and then has autonomy in when they schedule their visit and return trip during business hours.

Pharmacists are provided supplemental income opportunities when they enable ride share access to the pharmacy.



Bridge to Provider Care

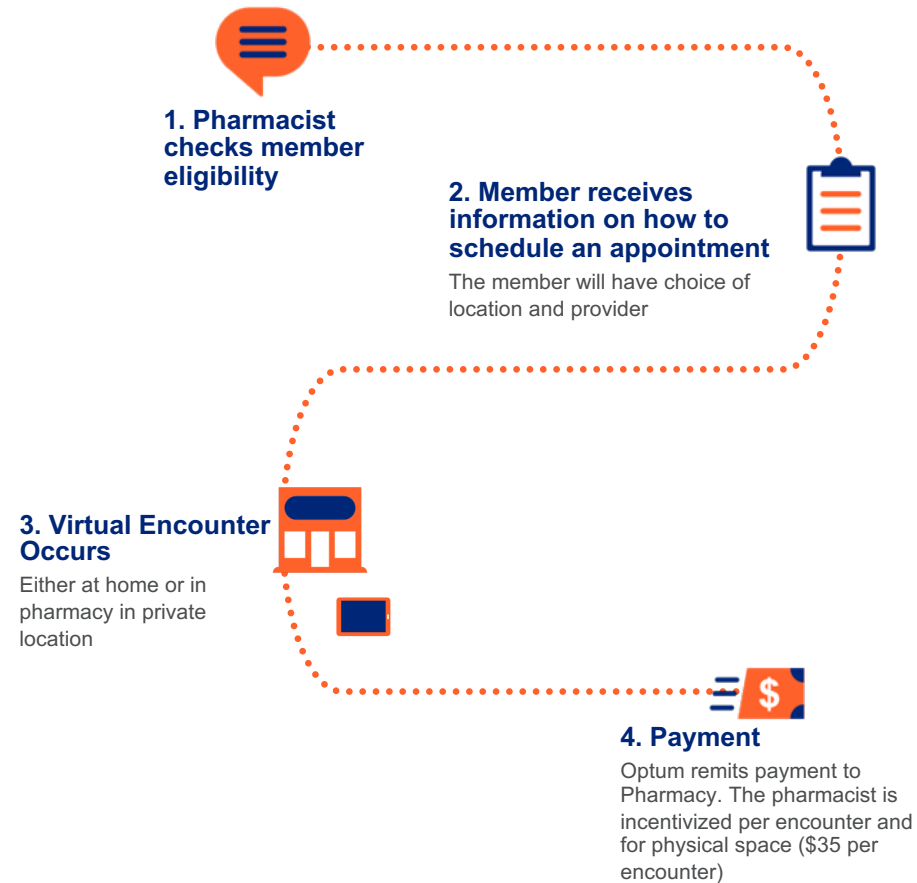
Bridge to Provider Care

Phase	LOBs	Sales Ready Cert	Client Implementation
Pilot	Health-plan/Payers across Commercial, Medicare, and Medicaid	Target Date: 10/01/2024	Target Date: 12/15/2024

Member Journey



Pharmacist Journey



Overview

Bridge to Provider Care is a health equity innovation in the pharmacy space that seeks to bridge disparities in access to care. The product enables telemedicine at the pharmacy through multiple telemedicine partners, offering members the ability to engage with acute care services with more ease. After learning of the service, the members can then choose to participate in virtual appointments at home or at the pharmacy in a privacy location.

Optum Rx acts as a connector between the pharmacy and providers to enable access for members. Optum Rx will provide incentive for pharmacists for designating a space for virtual encounters and facilitating appointments.



Community Pharmacy Support Services

Community Pharmacy Support Services

Payment Predictability/Assistance with Cash Flow

Improved reporting for PSAOs with new fields for ease of claim identification



Processing payments to pharmacies every (3) three days



Lowered credentialing fees by 33%



Reporting/ Transparency

Supply chain support via predictive analytics for RSV, Flu & COVID-19 instances



Offering reconciliation services to Independents at discounted pricing through Change Healthcare



Enhancements to the 835 electronic remittance file for ease of claim reconciliation



Provider Portal developments for real time and self-serve options



Enhanced Engagement

Optum Rx leadership has established a meeting cadence with pharmacy associations including IPA, APhA, NCPA



Voice of the Pharmacy campaign – one on one meetings with Independent pharmacy owners



Coming Soon

Transaction fees assessment



MAC appeal review



PBM Pharmacy Council



Pharmacy Newsletter



Overview

Optum Rx is focused on improving relationships with our PSAO/ Independent Pharmacy Partners.

At the end of 2022, we began engaging key contacts to assess pain points and develop a strategic plan. Thus, launching our Community Pharmacy Support Services.



Ann Lawlor
Vice President Network
Contracting & Strategy
Optum Rx United Health Group

How Biosimilars are Changing The Way You Practice

Trenton Thiede, PharmD, MBA

President

PAAS National[®]



Learning Objectives

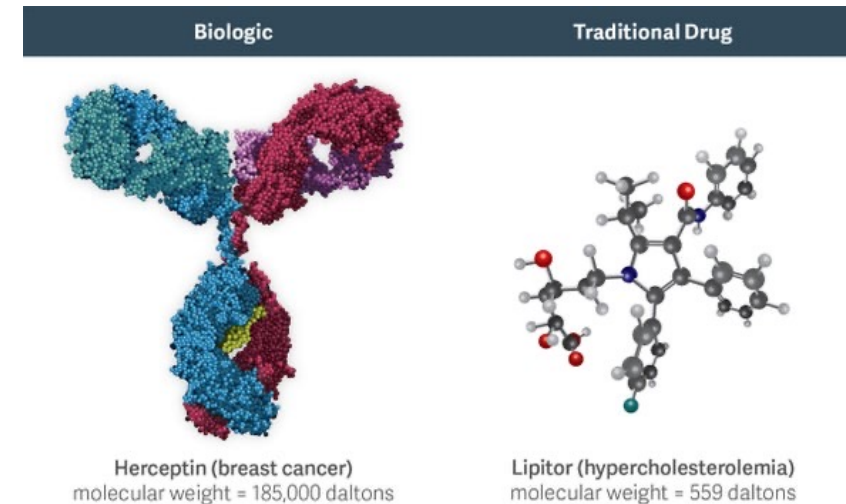
1. Identify biosimilars and their interchangeability.
2. Discuss the fundamentals of DAW codes with biologic drugs.



Biologics

Background

- Insulin products were re-classified in March 2020 as “biological products” as per Section 351 of the Public Health Service (PHS) Act
 - Also re-classified other small protein drugs such as human growth hormone and pancreatic enzymes
- Goal was to allow regulatory pathway for increased competition to decrease prices





Biologics

Background

- Biologics no longer located in FDA Orange Book
 - Brand drugs approved under NDA
 - Generic drugs approved under ANDA



The Orange Book
The publication Approved Drug Products with Therapeutic Equivalence Evaluations



**APPROVED
DRUG
PRODUCTS**

WITH

**THERAPEUTIC
EQUIVALENCE
EVALUATIONS**

37th EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2017



Biologics

Background

- Now located in the FDA Purple Book
 - Biologic products approved under BLA
 - There are no “generics” or “AB ratings”

The screenshot shows the top navigation bar of the FDA Purple Book website. On the left is the FDA U.S. Food & Drug Administration logo. On the right is a 'Purple Book Glossary' link, a search bar, and a menu icon. Below the navigation bar is a purple banner with the text 'Purple Book Database of Licensed Biological Products' and decorative icons of various biological products. To the left of the main content area is a sidebar with links: 'Purple Book Homepage', 'About Purple Book', 'User Guide', 'FAQs', 'Patent List', and 'Download Purple Book Data'. The main content area contains two paragraphs of text and a search box. The first paragraph states that the database contains information on all FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products. The second paragraph states that the database also contains information about all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER). The search box contains the text 'Enter at least 3 letters' and a magnifying glass icon. Below the search box is a link for 'Advanced Search'. At the bottom right of the page, it says 'Database last updated: February 13, 2024'.

FDA U.S. FOOD & DRUG ADMINISTRATION

[Purple Book Glossary](#)

Purple Book

Database of Licensed Biological Products

[Purple Book Homepage](#)

[About Purple Book](#)

[User Guide](#)

[FAQs](#)

[Patent List](#)

[Download Purple Book Data](#)

The Purple Book database contains information on all FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products.

The Purple Book also contains information about all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER).

Enter a product's proprietary (brand) name or the nonproprietary (proper) name to find biological products. As you type, a list of potential results will begin to appear below the search box based on what you are typing. Click on a product from the auto-populated results list below to view the results page. The results page for your selected product will include all biological products that share a core name (*i.e.*, biosimilar, interchangeable, reference, and related biological products).

Enter at least 3 letters

[Advanced Search](#)

Database last updated: February 13, 2024



Biologic Terminology

Type	BLA License Type	Like an Orange Book...	Example
Reference Product	351(a)	Brand drug	Lantus [®]
Biosimilar	351(k) biosimilar	B-rated generic Must obtain prescriber approval to substitute	Rezvoglar [™] (now interchangeable)
Interchangeable Biosimilar	351(k) interchangeable	A-rated generic	Semglee [®]
Unbranded Biologic	Approved under reference product BLA	Authorized generic NOT found in Purple Book	Insulin glargine-yfgn



DAW Codes

Code	Abbreviated Description	*Use with caution according to state law and third-party payors
0	No Product Selection Indicated - <u>Default</u>	
1	Substitution Not Allowed by <u>Prescriber</u>	
2	Substitution Allowed – <u>Patient</u> Requested Product Dispensed	
3	Substitution Allowed – <u>Pharmacist</u> Selected Product Dispensed	
4	Substitution Allowed – Generic Drug or Interchangeable Biosimilar Not In Stock	
5	Substitution Allowed – Brand Drug or Reference Product Dispensed as a Generic or Interchangeable Biosimilar	
6	Override - Do not use without Plan approval	
7	Substitution Not Allowed – Brand Drug or Reference Product Mandated by Law	
8	Substitution Allowed – Generic Drug or Interchangeable Biosimilar Not Available in Marketplace	
9	Substitution Allowed by Prescriber but Patient's <u>Plan</u> Requests Brand or Reference Product	



DAW Codes

- NCPDP published updates to DAW code definitions to reflect biosimilars (May 2022)

Code	Abbreviated Description	NCPDP Description	Interpretation
0	No Product Selection Indicated <u>Default</u>	This is the field default value that is appropriately used for prescriptions for single source brand, single biologic, co-branded/co-licensed, generic or interchangeable biosimilar products. DAW 0 is not appropriate for a multi-source branded product with available generic(s) or for a reference product with interchangeable biosimilar(s).	<ul style="list-style-type: none">• Per NCPDP guidance, the use of DAW 0 would be appropriate for items such as:<ul style="list-style-type: none">○ Ubrelvy™, Levemir®• Per NCPDP guidance, the use of DAW 0 would NOT be appropriate for items such as:<ul style="list-style-type: none">○ Advair Diskus®, Lantus®• NCPDP, and PBMs, diverge from typical application of DAW 0



DAW Codes

- NCPDP published updates to DAW code definitions to reflect biosimilars (May 2022)

Code	Abbreviated Description	NCPDP Description	Interpretation
9	Substitution Allowed by Prescriber but <u>Plan Requests</u> Brand or Reference Product	This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic or interchangeable biosimilar substitution is permitted, but the plan's formulary requests the brand or reference product. This situation can occur when the prescriber writes the prescription using either the brand, reference product, generic or interchangeable biosimilar name and the product is available from multiple sources.	<ul style="list-style-type: none">• Used when the plan's formulary requests the brand or reference product when a generic or interchangeable biosimilar is available• If payer status changes, revert to billing the lowest cost alternative



DAW Codes

Interchangeable Biosimilar Application

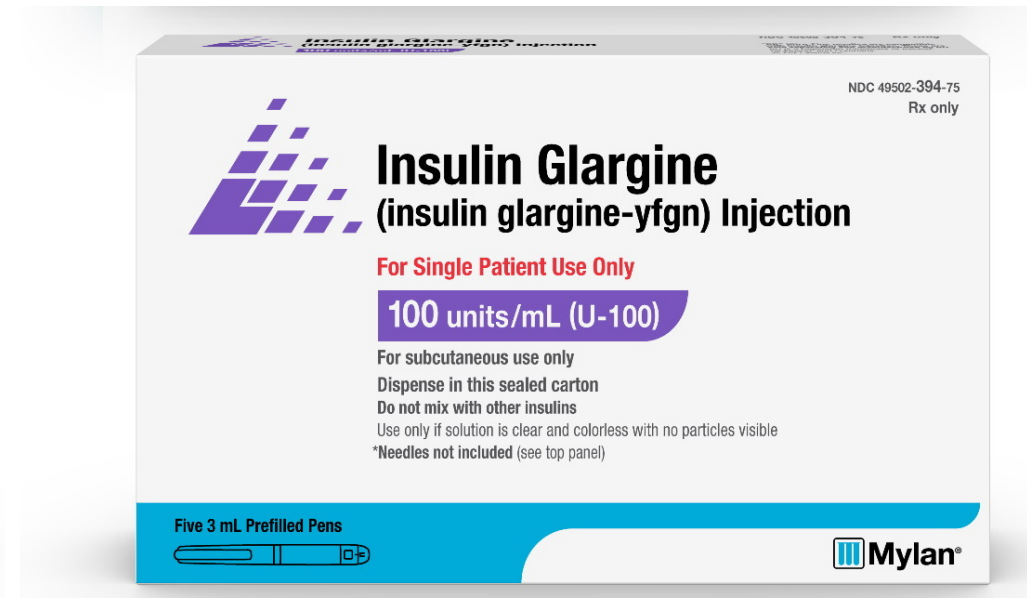
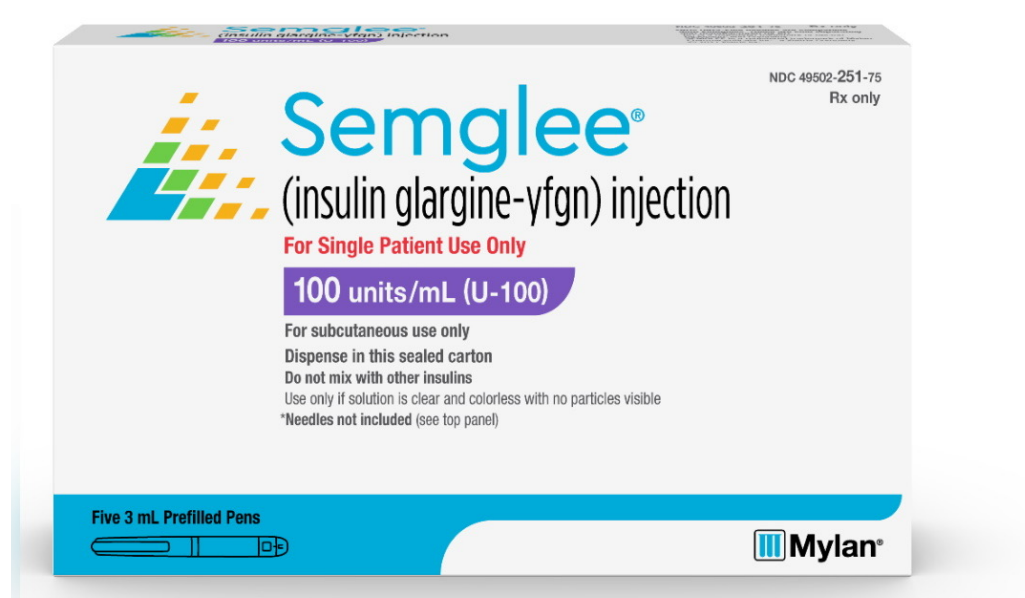
Prescribed Drug	Substitution Allowed?	Dispensed/Billed Drug	DAW Code (408-D8)
Reference Product	Allowed	Interchangeable Biosimilar	0
Reference Product	Not Allowed	Reference Product	1
Reference Product	Allowed	Reference Product	2-9
Interchangeable Biosimilar	Allowed	Interchangeable Biosimilar	0
Interchangeable Biosimilar	Not Allowed	Interchangeable Biosimilar	1
Interchangeable Biosimilar	Allowed	Reference Product	2-9



Equivalent Biologics

Insulin Glargine Substitution

Insulin glargine-yfgn unbranded can be interchangeably substituted for Semglee or Lantus





Biologic Products - Unbranded Biologics

Unbranded biologics can be identified by matching the BLA # of the reference product and the unbranded biologic.

NIH U.S. NATIONAL LIBRARY OF MEDICINE REPORT ADVERSE EVENTS | RECALLS

DAILYMED ALL DRUGS | HUMAN DRUGS | ANIMAL DRUGS | MORE WAYS TO SEARCH ▼

Enter drug, NDC code, drug class, or Set ID

HOME + NEWS FDA RESOURCES + NLM SPL RESOURCES + APPLICATION DEVELOPMENT SUPPORT HELP

INGREDIENTS AND APPEARANCE

SEMGLEE insulin glargine-yfgn injection, solution			
MARKETING INFORMATION			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761201	11/15/2021	

INGREDIENTS AND APPEARANCE

INSULIN GLARGINE insulin glargine-yfgn injection, solution			
MARKETING INFORMATION			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761201	11/16/2021	



Interchangeable Biosimilars

Insulin Glargine Substitution

- FDA approved the first interchangeable biosimilar product July 2021
 - Semglee[®] (insulin glargine-yfgn)
 - Permits pharmacy-level substitution (without prescriber approval)
- Substitution regulated at state level
 - See website below for resource on state laws for biosimilar interchangeability
 - All 50 states allow, some nuances (e.g., prescriber notification)



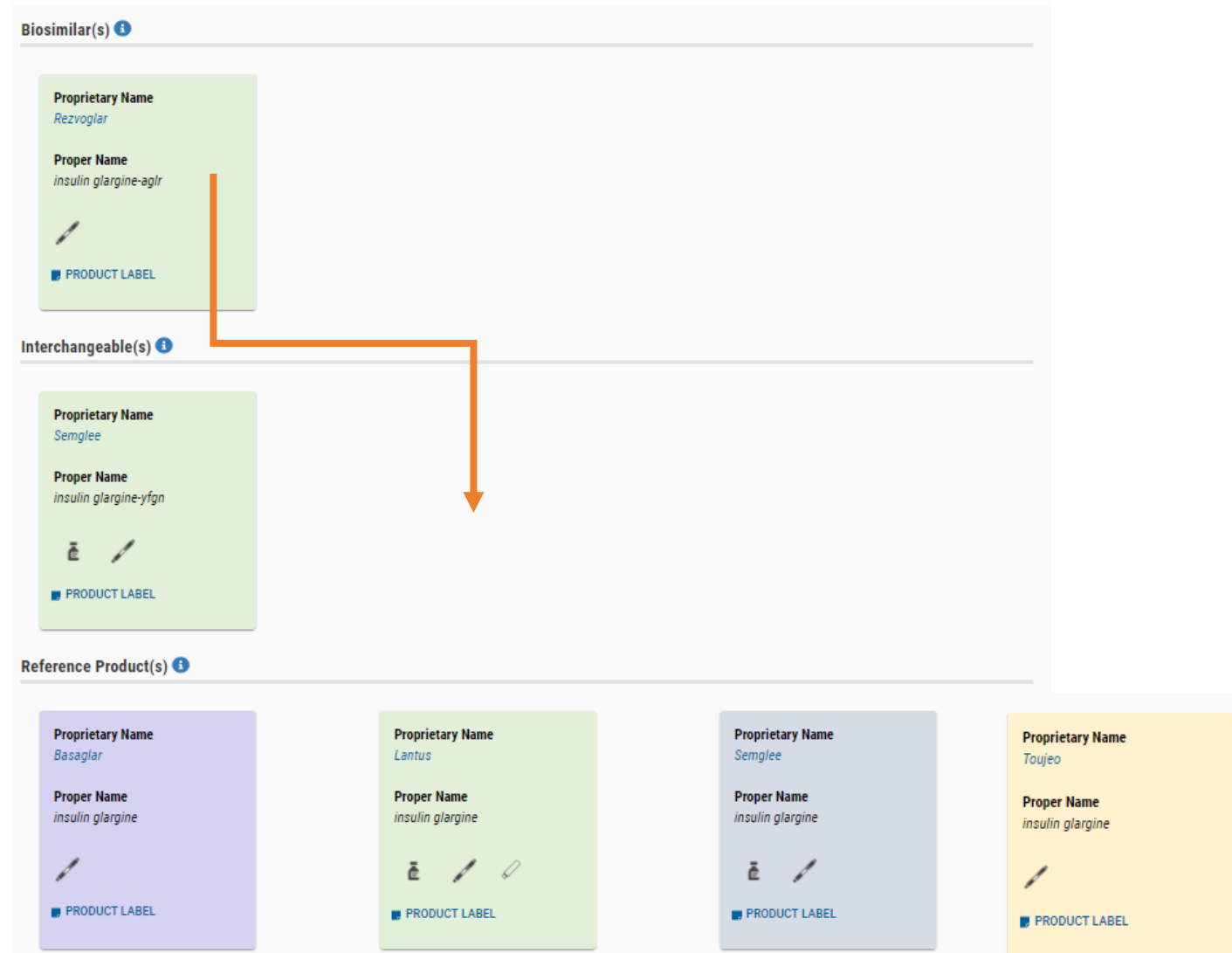
Interchangeable Biosimilars

Prescription written as:	Okay to substitute WITHOUT prescriber approval (if allowed by state law)				
	Lantus[®] BLA 021081 <i>Reference Product</i>	Insulin glargine (Winthrop) BLA 021081 <i>Unbranded biologic</i>	Semglee[®] BLA 761201 <i>Interchangeable Biosimilar</i>	Insulin glargine-yfgn (Mylan) BLA 761201 <i>Unbranded biologic</i>	Basaglar[®] BLA 205692 <i>Reference Product</i>
Lantus [®]	Yes	Yes	Yes	Yes	No
Semglee [®]	Yes	Yes	Yes	Yes	No
Basaglar [®]	No	No	No	No	Yes
Insulin glargine	Yes, however consider clinical context – has patient been on a product previously?				



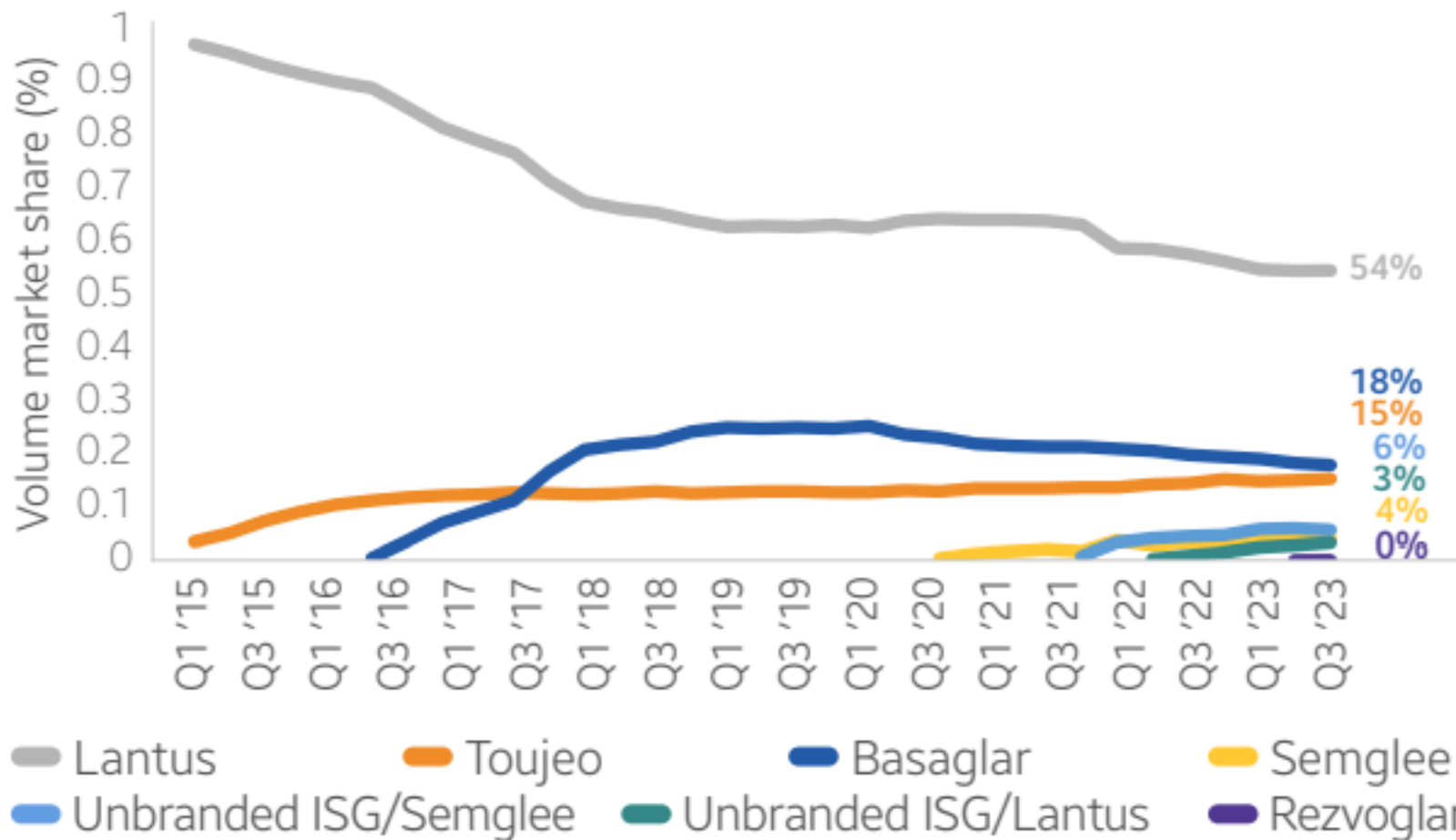
Interchangeable Biosimilars Insulin Glargine Substitution

Matching color cards indicate a biological product is biosimilar to or interchangeable with a reference product





Insulin Glargine Volume Market Share





Adalimumab Biosimilars

Humira currently has 7 biosimilars approved by the FDA and 2 interchangeable biosimilars

The screenshot displays a database interface for Adalimumab products, categorized into three sections: Biosimilar(s), Interchangeable(s), and Reference Product(s). Each product entry is shown in a purple-bordered box with the following fields: Proprietary Name, Proper Name, and a PRODUCT LABEL icon.

Category	Proprietary Name	Proper Name
Biosimilar(s)	Amvita	adalimumab-avto
	Adalima	adalimumab-avnd
	Avio	adalimumab-avjz
	Aytmaz	adalimumab-avbz
	Idacio	adalimumab-avcf
	Yufyma	adalimumab-avty
	Yufyma	adalimumab-avjt
Interchangeable(s)	Adimase	adalimumab-avtb
	Cymze	adalimumab-avbm
Reference Product(s)	Humira	adalimumab



Adalimumab Biosimilars

Product	Company	Launch Date	Concentration	Interchangeability Designation Approved	Citrate free
Abrilada™	Pfizer	November 2023	Low (50MG)	No ²	Yes
Amjevita™	Amgen	Jan 31, 2023	Low (50MG)	No ³	Yes
Cyltezo®	Boehringer Ingelheim	July 1, 2023	Low (50MG)	Yes ⁴	Yes
Adalimumab-adbm	Boehringer Ingelheim	October 2, 2023	Low (50MG)	Yes	Yes
Hadlima™	Organon/Samsung Bioepis	July 1, 2023	Low (50MG)	No ⁵	No
Hadlima™	Organon/Samsung Bioepis	July 31, 2023	High (100MG)	No ⁶	Yes
Hulio®	Mylan/Viatris/Biocon/Fujifilm Koywa Kirin	July 31, 2023	Low (50MG)	No	Yes
Adalimumab-fkjp	Biocon	July 1, 2023	Low (50MG)	No	Yes
Hyrimoz®	Sandoz/Novartis	July 1, 2023	Low (50MG)	No ⁸	No
Adalimumab-adaz	Sandoz	July 1, 2023	Low (50MG)	No	No
Hyrimoz®	Sandoz/Novartis	July 1, 2023	High (100MG)	No ⁸	Yes
Adalimumab-adaz	Sandoz	July 1, 2023	High (100MG)	No	Yes
Idacio®	Fresenius Kabi	July 2023	Low (50MG)	No ⁷	Yes
Yuflyma®	Celltrion	July 1, 2023	High (100MG)	No	Yes
Yusimry™	Coherus BioSciences	July 1, 2023	Low (50MG)	No	Yes

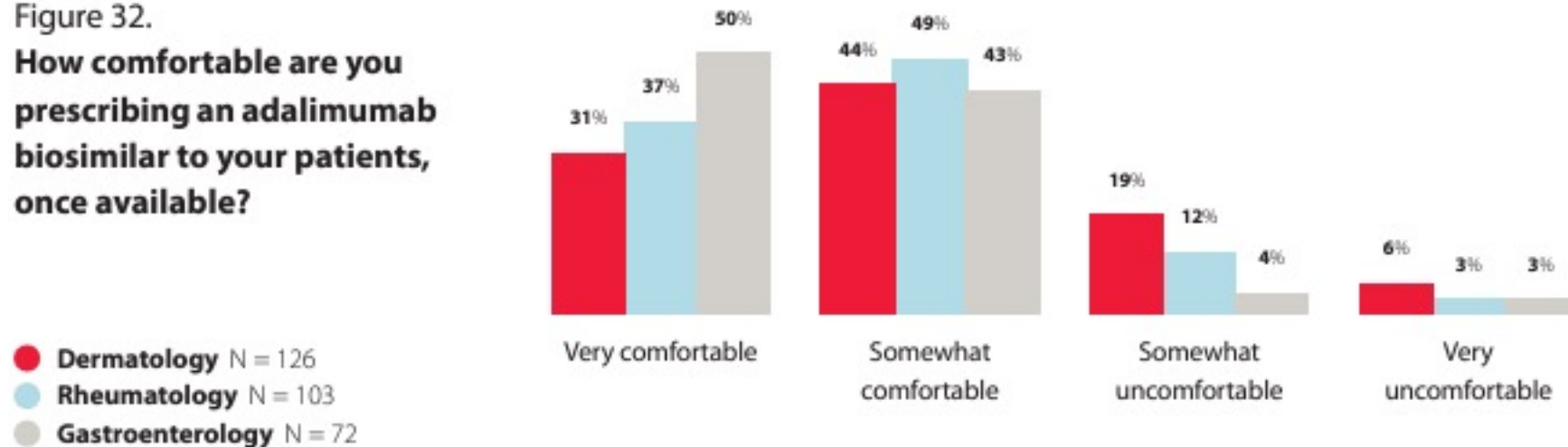


Adalimumab Biosimilars

93% of gastroenterologists said they are at least somewhat comfortable prescribing adalimumab biosimilars compared to 86% for rheumatologists and 75% of dermatologists.

Gastroenterologists reported the highest comfort levels with adalimumab biosimilars compared to dermatologists and rheumatologists.

Figure 32.
How comfortable are you prescribing an adalimumab biosimilar to your patients, once available?



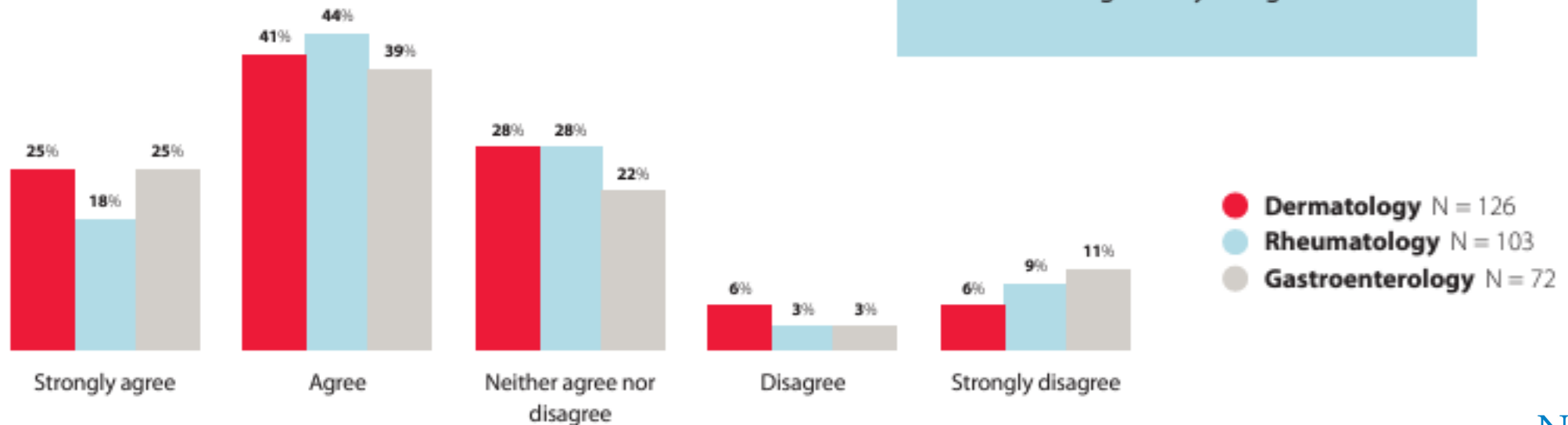


Adalimumab Interchangeable Biosimilars

Figure 38.

To what extent do you agree with the following statement? I will only feel comfortable prescribing an adalimumab biosimilar if it has the interchangeability designation.

Over 60% of providers across all therapeutic areas will only feel comfortable prescribing an adalimumab biosimilar if it has an interchangeability designation





Payors – OptumRx

In terms of coverage for the autoimmune therapy Humira (adalimumab), Optum Rx has excluded several biosimilars, including: Adalimumab-fkjp, Hadlima, Hulio, Idacio, Yuflyma and Yusimry. In June 2023, Optum Rx had indicated that it would offer access to three biosimilars of the blockbuster It treats patients with rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, ulcerative colitis and plaque psoriasis. The three that will be offered include:

- * Sandoz’s Hyrimoz and adalimumab-adaz, both high concentration treatments, their high-list and low-list products, respectively.
- * Boehringer Ingelheim’s Cyltezo, the first interchangeable biosimilar, and its low-list price version, adalimumab-adbm
- * Amgen’s Amjevita, both high-list and low-list versions, which were added earlier this year.

Optum Rx will include these biosimilars on the standard formulary on parity with Humira. All four products will be on Tier 2 of standard formularies with prior authorization required and quantity limits upon launch, an Optum Rx spokesperson had said previously.



Payors – Cigna

Effective Sept. 1, 2023, Cigna Healthcare will prefer the following biosimilar products alongside HUMIRA on its national preferred, standard, performance, and legacy commercial formularies:

- Cyltezo (Boehringer Ingelheim), the first FDA-approved interchangeable biosimilar to HUMIRA, low-concentration formulation.
- Adalimumab-adaz (Sandoz), high-concentration formulation, unbranded.
- Hyrimoz (Sandoz), high-concentration formulation.

In addition to the preferred biosimilar products above, Cigna Healthcare will also add Hadlima (Organon), both high- and low-concentration formulations, as preferred alongside HUMIRA on its value, advantage, and total savings formularies.



Payors – CVS Caremark

CVS Caremark accelerates biosimilars adoption through formulary changes

CVS Caremark announced that effective April 1, 2024, Humira will be removed from its major national commercial template formularies and Humira biosimilars will be covered.



Sandra Levy
Senior Editor

1/3/2024

CVS Caremark, a CVS Health company, late Jan. 4 announced that effective April 1, 2024, AbbVie's Humira will be removed from its major national commercial template formularies and Humira biosimilars will be covered.

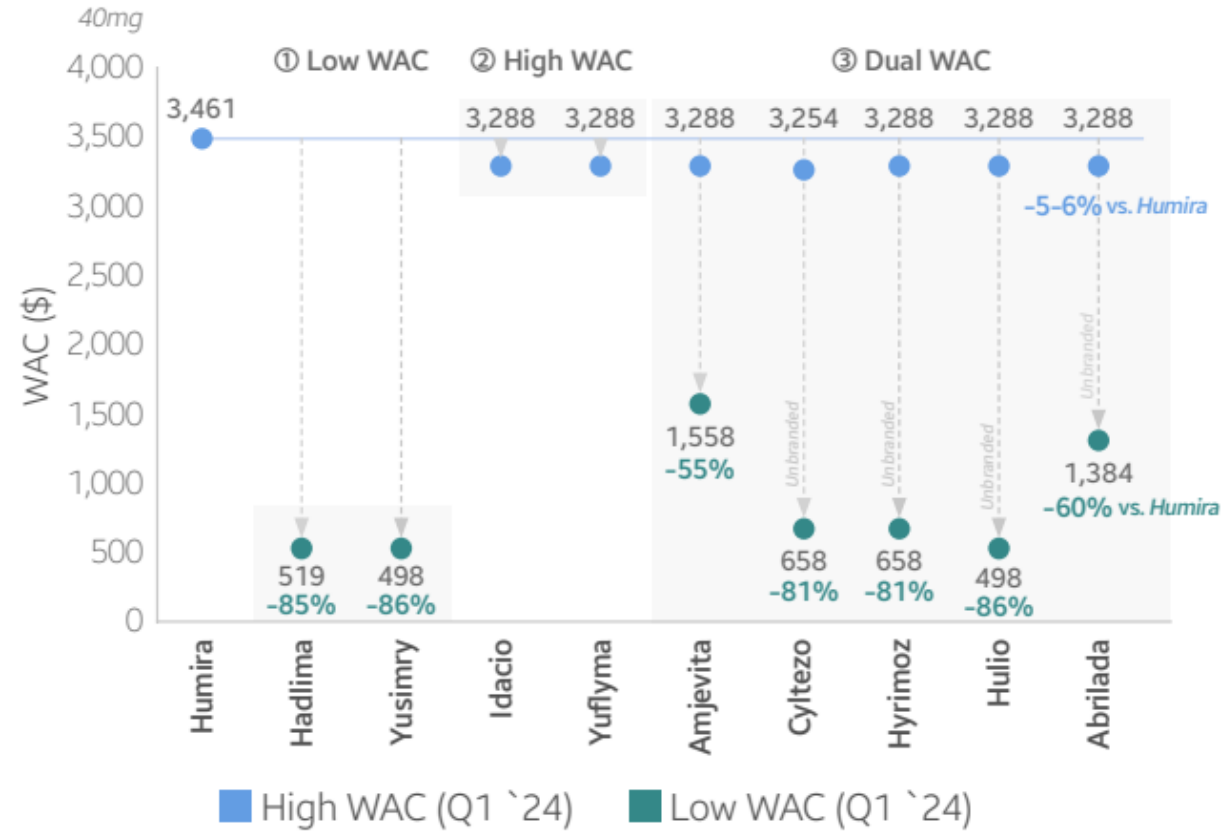
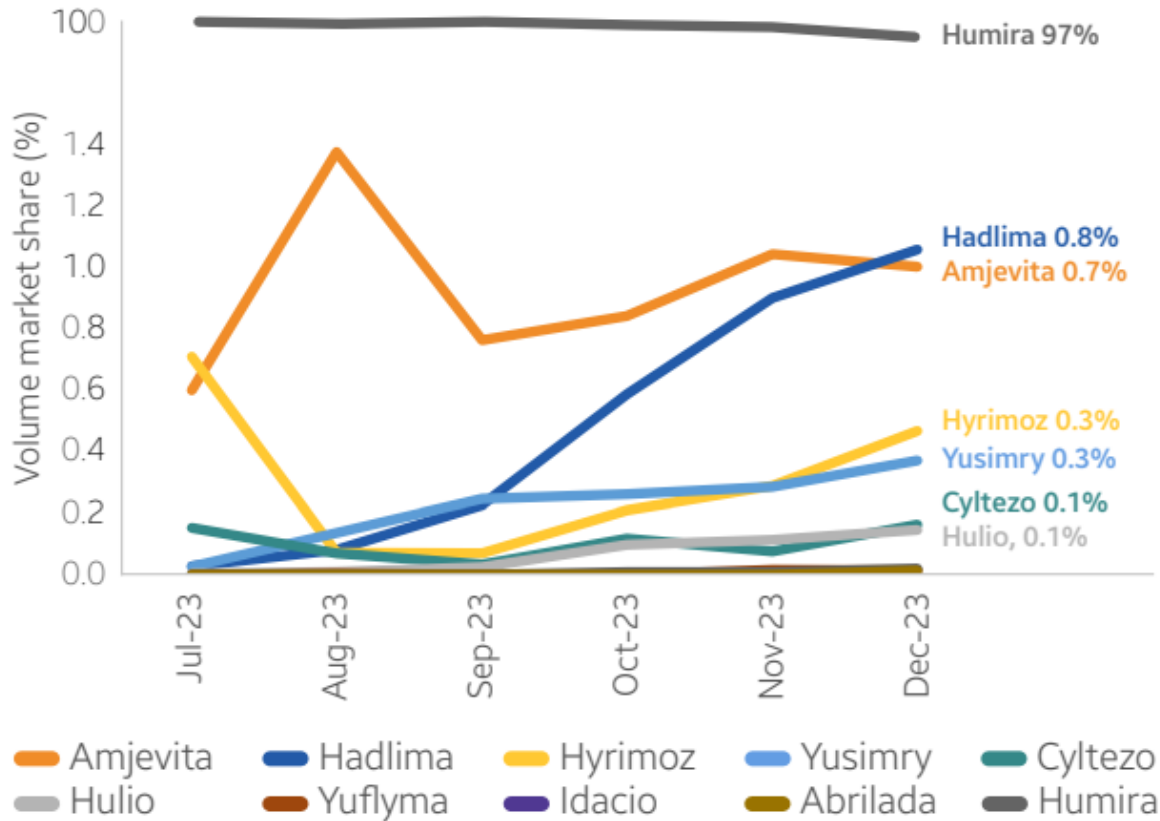


Payors – CVS Caremark

The company also announced that AbbVie, as part of its continued commitment to access, has entered into an agreement to supply Cordavis, a CVS Health company, with a committed volume of co-branded Humira. This will provide another treatment option for adalimumab patients and aligns to the CVS Caremark focus on customer choice and seamless member experience, per the brand. The Cordavis Humira product will be available in the second quarter. Cordavis Humira provides additional options for payors, the company noted.



Adalimumab Market Share and WAC





Potential IRA Impact on Biosimilar Development

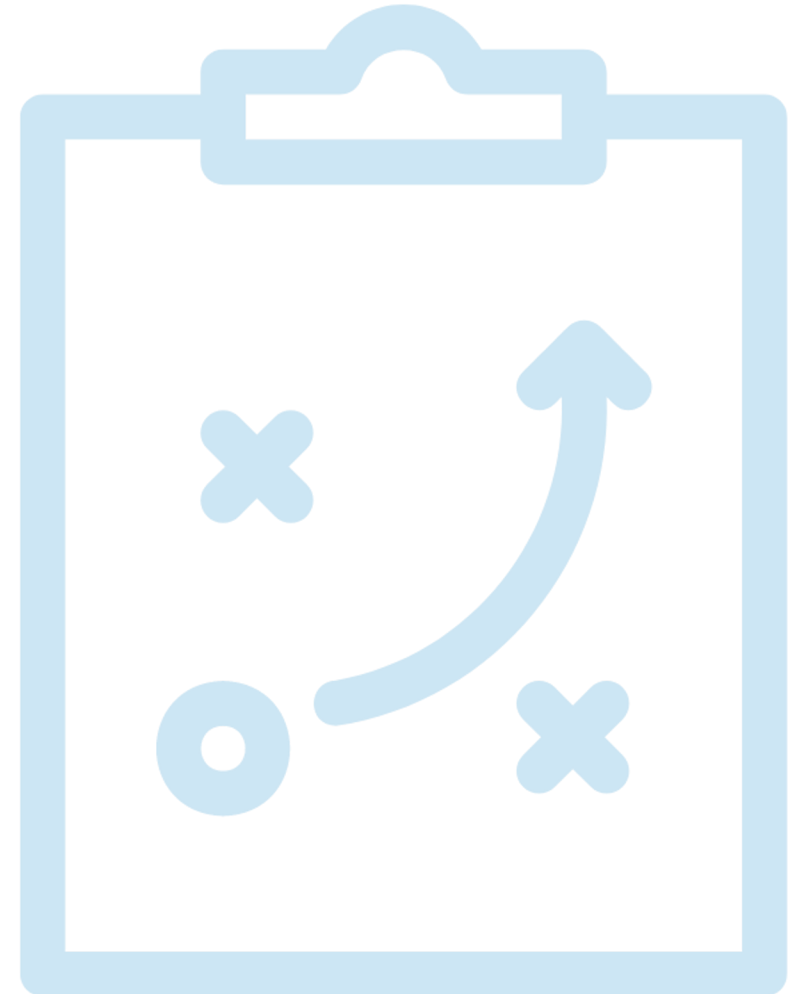
- Biosimilar development can take nearly a decade and cost upwards of \$300 million
 - Development begins years before patent protections and market exclusivity are lost
- IRA allows CMS to impose price controls with 2 years' notice
 - No reliable way to predict which biologics will be selected for price controls
- Congress enacted a “special rule” allowing a two-year waiver before a brand biologic product is selected for price-setting if there’s a high likelihood of biosimilar competitors

Your Next Steps:

Matching color cards in the purple book convey biosimilarity, not interchangeability

Unbranded biologics are considered identical to their respective reference product and have matching BLAs

Consider DAW codes for reference products with interchangeable biosimilars





Trenton Thiede, PharmD, MBA
President, PAAS National®
trent@paasnational.com