340B Past, Present & Future

hfma louisiana chapter
healthcare financial management association

Speakers

John Bretz
Director of Strategic Relations, SUNRx

Christopher Combs
Regional Sales Manager, SUNRx

Aaron K. Lott, PharmD
President, AuthorityRX
SUNRx Guest Speaker

John Bretz

340B – The Past

DIRECTOR OF STRATEGIC RELATIONS AT SUNRX

Chris Combs

340B – The Present

REGIONAL MANAGER
AT SUNRX

Aaron Lott

340B – The Future

PRESIDENT AT
AUTHORITYRX

Who is SUNRx

SUNRx is a 340B service, technology-enabled organization supporting 340B Covered Entities across the US

Vision

SUNRx delivers pharmaceutical and technology-related solutions that improve the value of healthcare. We provide superior outcomes to those we serve through innovative solutions, systems, and services that provide transparency and promote choice in decision making.

Mission

We will transform our stakeholder's experiences and financial outcomes through relentless pursuit of knowledge and innovative healthcare services.

Partnership

SUNRx is the exclusive 340B TPA Partner for LHA members.

What We Offer

- Split Billing
- Contract Pharmacy
- Uninsured Prescription Discount Card
- Referral Capture
- Specialty Pharmacy
- Advanced Claims Capture

Who We Serve

- Hospitals
- Health Centers
- Pharmacies

Mike Mouisset

Louisiana Hospital Association
and CEO at Sharcor

*SUNRx is endorsed by the Louisiana hospital Association

Disclaimer

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As always, you should consult your legal counsel with any questions or concerns.

Agenda

- What is 340B? a historical perspective . . .
- Current 340B Market Conditions
- Innovations in 340B
- Optimizing 340B Savings

What is 340B?
a historical perspective…

What is 340B?

Veteran Health Care Act of 1992 ***requires*** pharmaceutical manufacturers whose drugs are covered by Medicaid to provide discounts on outpatient covered drugs purchased by eligible entities serving the nation's most vulnerable patient populations.

Eligible entities enrolled in the program receive 340B discounts for drugs prescribed in outpatient areas.

The program is overseen by Health Resources and Services Administration (**HRSA**), administered by the Office of Pharmacy Affairs (OPA).

340B Eligibility & Registration

- 340B Designation
  (FQHC, DSH, CAH, SCH, RRH, Cancer, Children's, etc.)
- % DSH (only for hospitals)
- Clinics
  (must be on cost report, worksheet B part II, lines 88-93)

Hospital Type	Minimum DSH %
Disproportionate Share (DSH)	>11.75%
Critical Access (CAH)	N/A
Freestanding Cancer (CAN)	>11.75%
Pediatric (PED)	>11.75%
Rural Referral Center (RRC)	≥8%
Sole Community (SCH)	≥8%

Registration to Participate in 340B

- In order to participate in the 340B Program, eligible covered entities must register in the 340B database during one of the quarterly registration periods.

Contracted Pharmacies

- Registered once fully executed agreements are in place.

Register On-Line >>

Register	Start Date
January 1-15	April 1
April 1-15	July 1
July 1-15	October 1
October 1-15	January 1

340B Key Concepts

- Split Billing - Realize savings through replenishment at discount (purchases)
- Contract Pharmacy – Create revenue stream from spread between 3rd party reimbursement and cost to replenish drugs
- Drugs are not purchased at 340B, they are replenished
  - Inventory is owned by Pharmacy
  - Drugs are replenished at 340B prices / cost [AKA, accumulations]
  - Drugs are shipped to Pharmacy through CE/Hospital's wholesaler account
  - Wholesaler invoices are paid by 340B Covered Entity (hospital)
- Claims Capture
  - 340B Eligible Claims [CE, Providers, Services Areas, Profitable, duplicate discount]
  - Referral Claims Capture [claims prescribed by Specialists]
  - Fall out Claims [Eligibility, Time frame (12 months), new service areas)
- Data feeds
  - EMR eligibility files (flat file or HL7)
  - Future adds, adjustments

How high are the discounts?

Provides the 3rd deepest discount on pharmaceuticals, trailing only behind the Department of Defense and Veterans Healthcare Administration contracts or Federal Supply Schedule (FSS)

340B Discount range(s)

At least 52% off catalog or WAC prices

25% to 35% savings off Group Purchasing Organization (GPO)

Savings are often most significant for brand name drugs

Example:

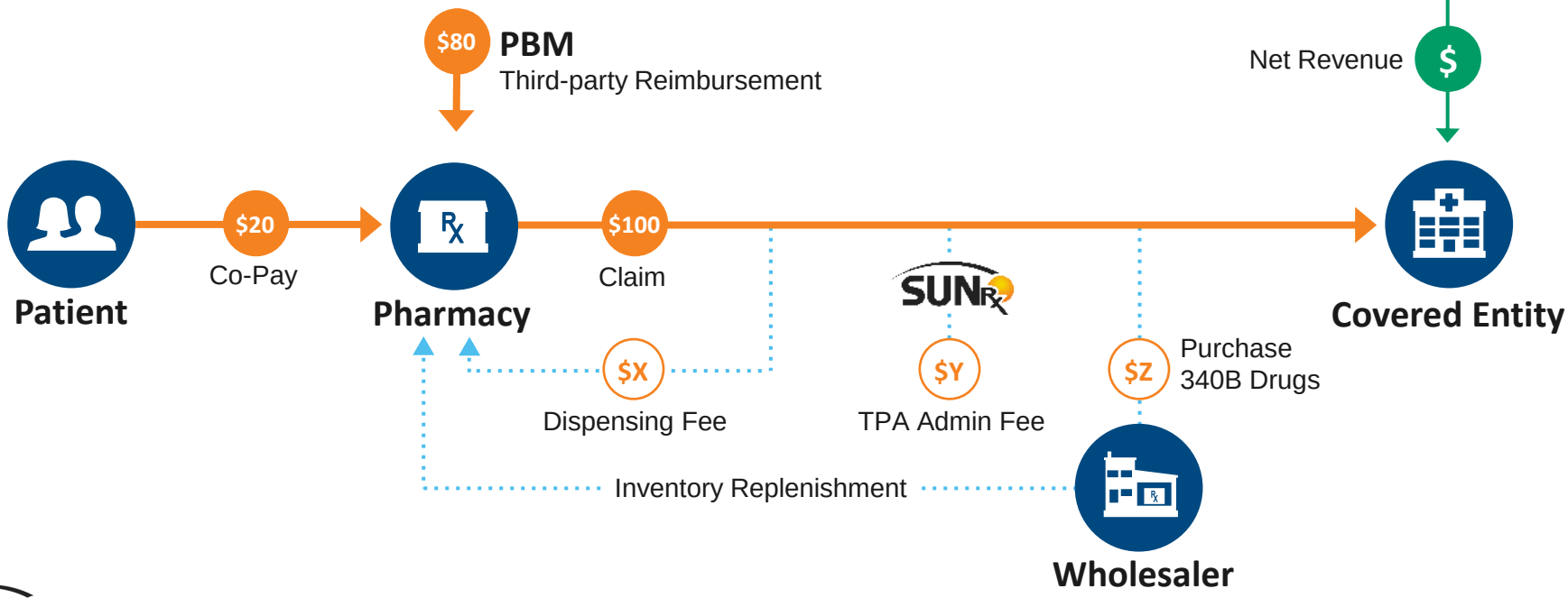
Jardiance 25mg [30 tablets/1 month supply]

- Catalog price: $1,366.50
- 340B price: $0.30

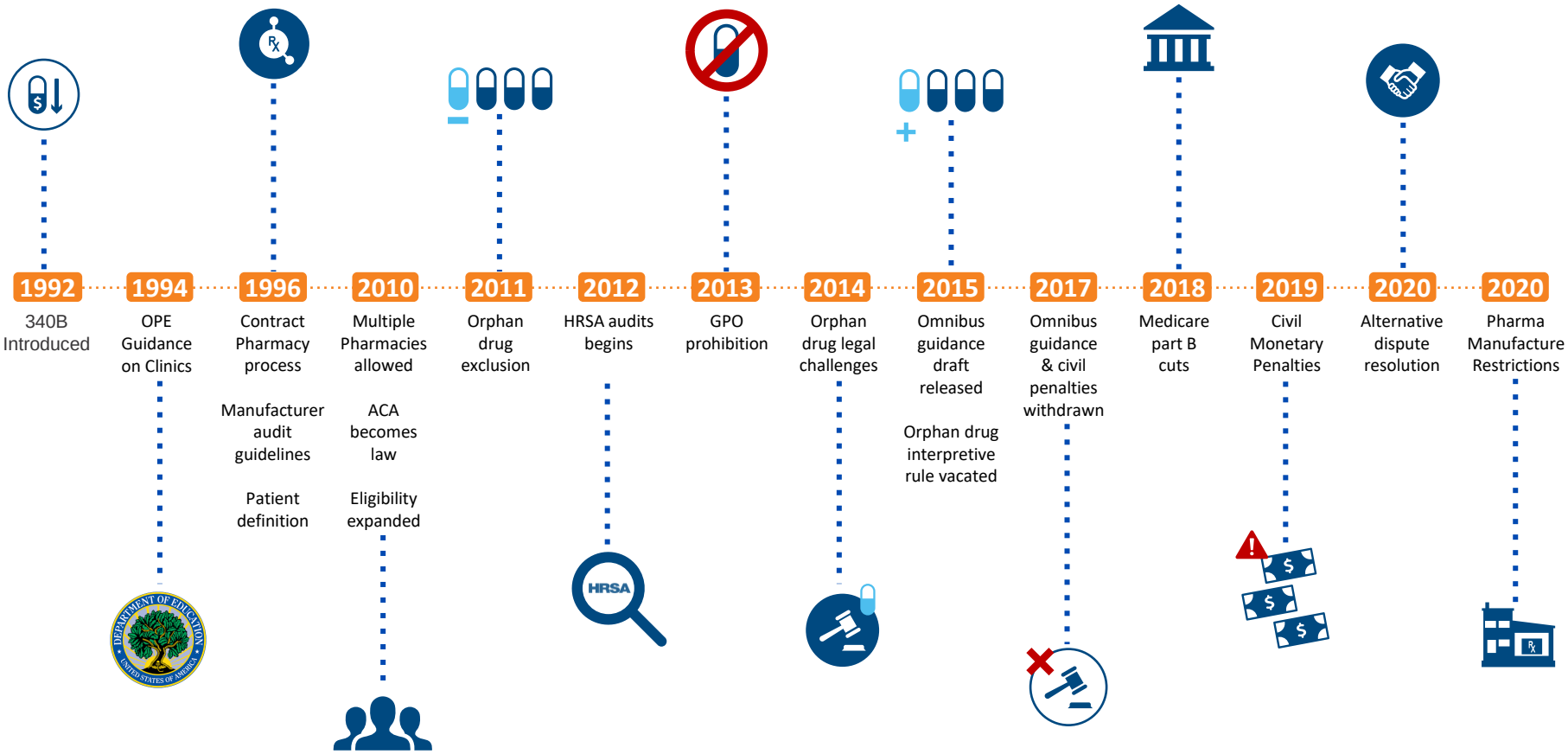
EXAMPLE

Cash Flow of 340B Savings derived from 3rd Party Payors

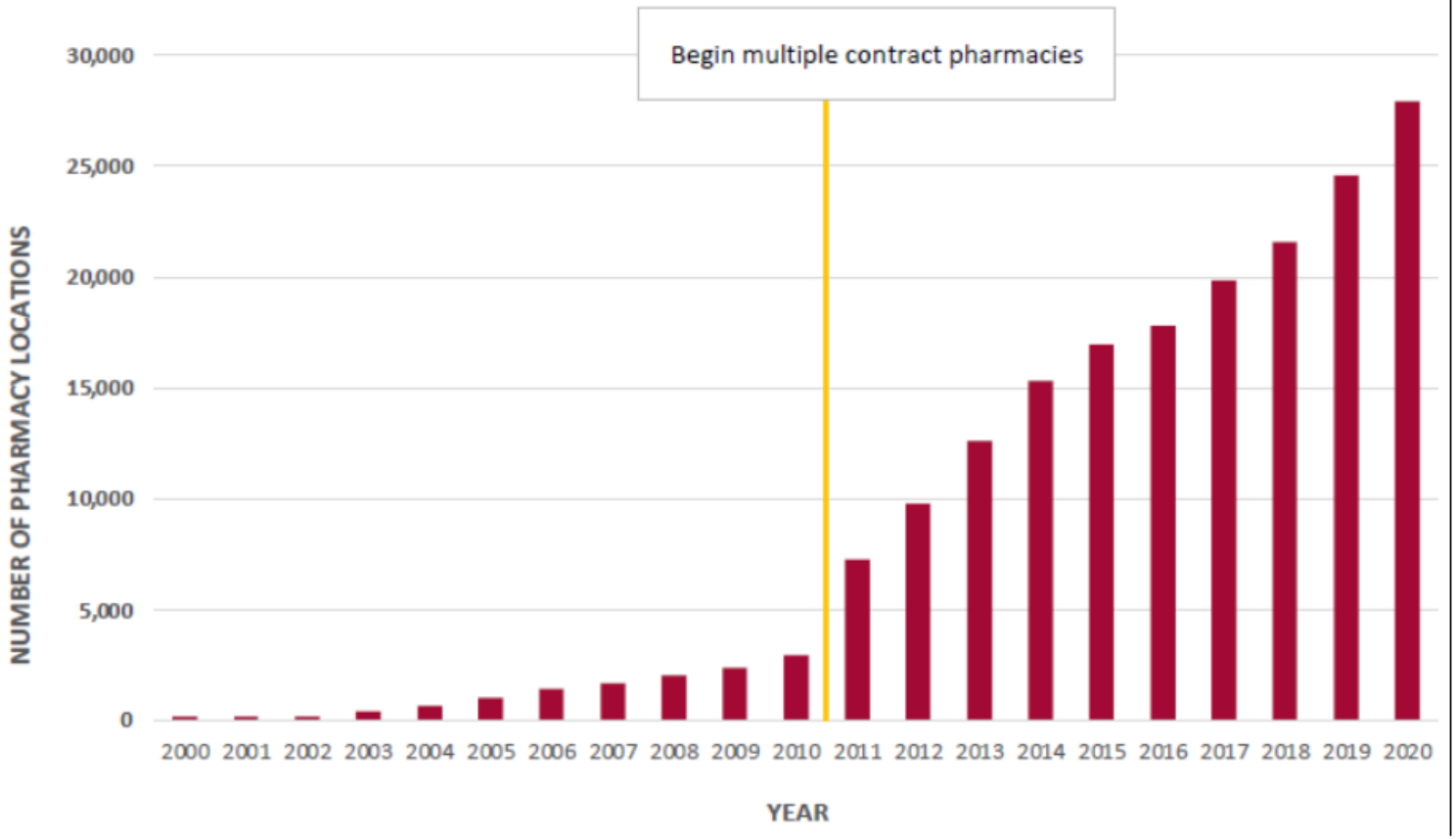
Sample 340B Claim	
Co-Pay	$20
Third Party Reimbursement	$80
Claim Coming Back to Covered Entity	**$100**
Dispensing Fee	$X
TPA Admin Fee	$Y
340B Replenishment	$Z
Net Revenue to Covered Entity	**$100 - $X - $Y - $Z**



340B History

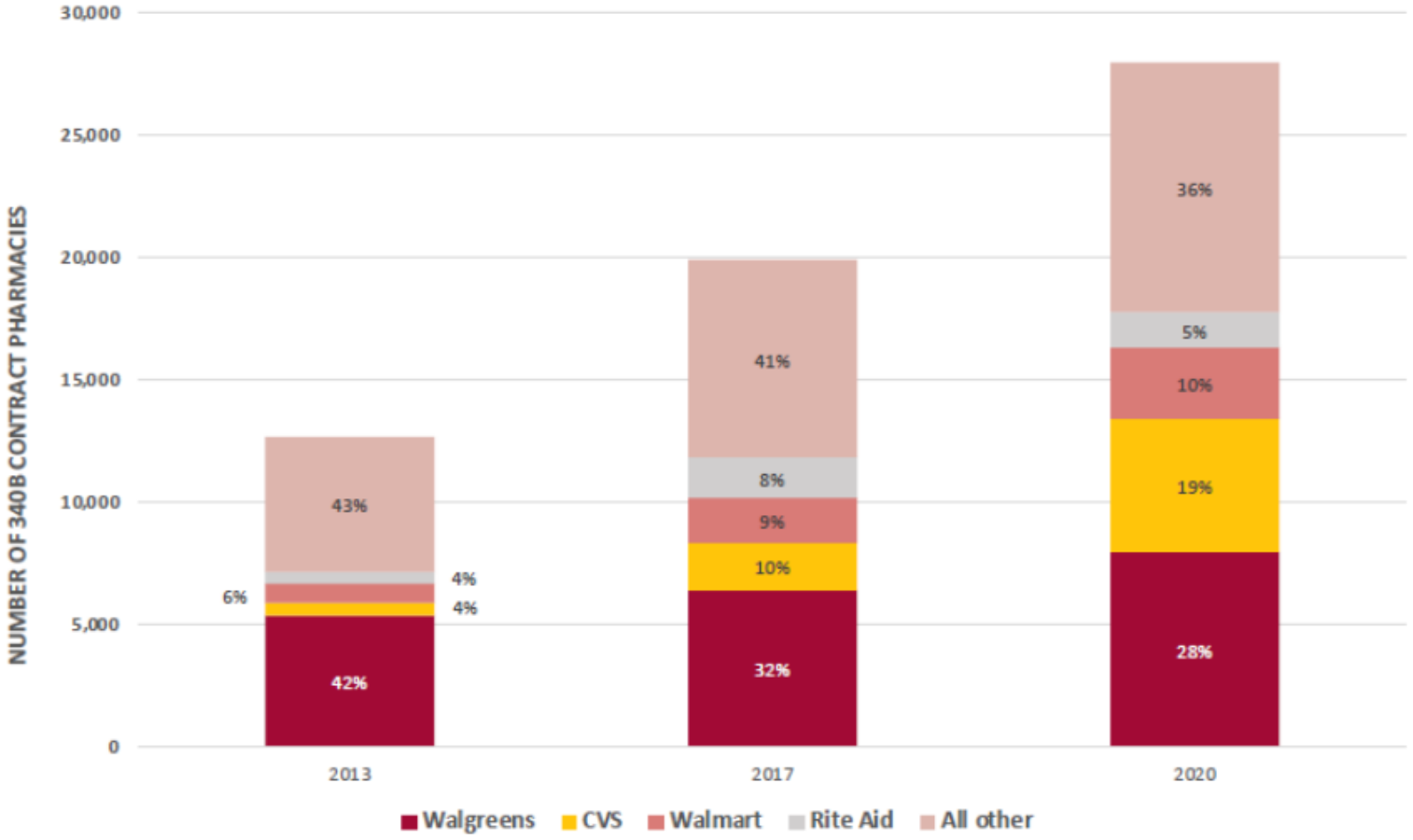


Number of Contract Pharmacies and Major Chain Detail



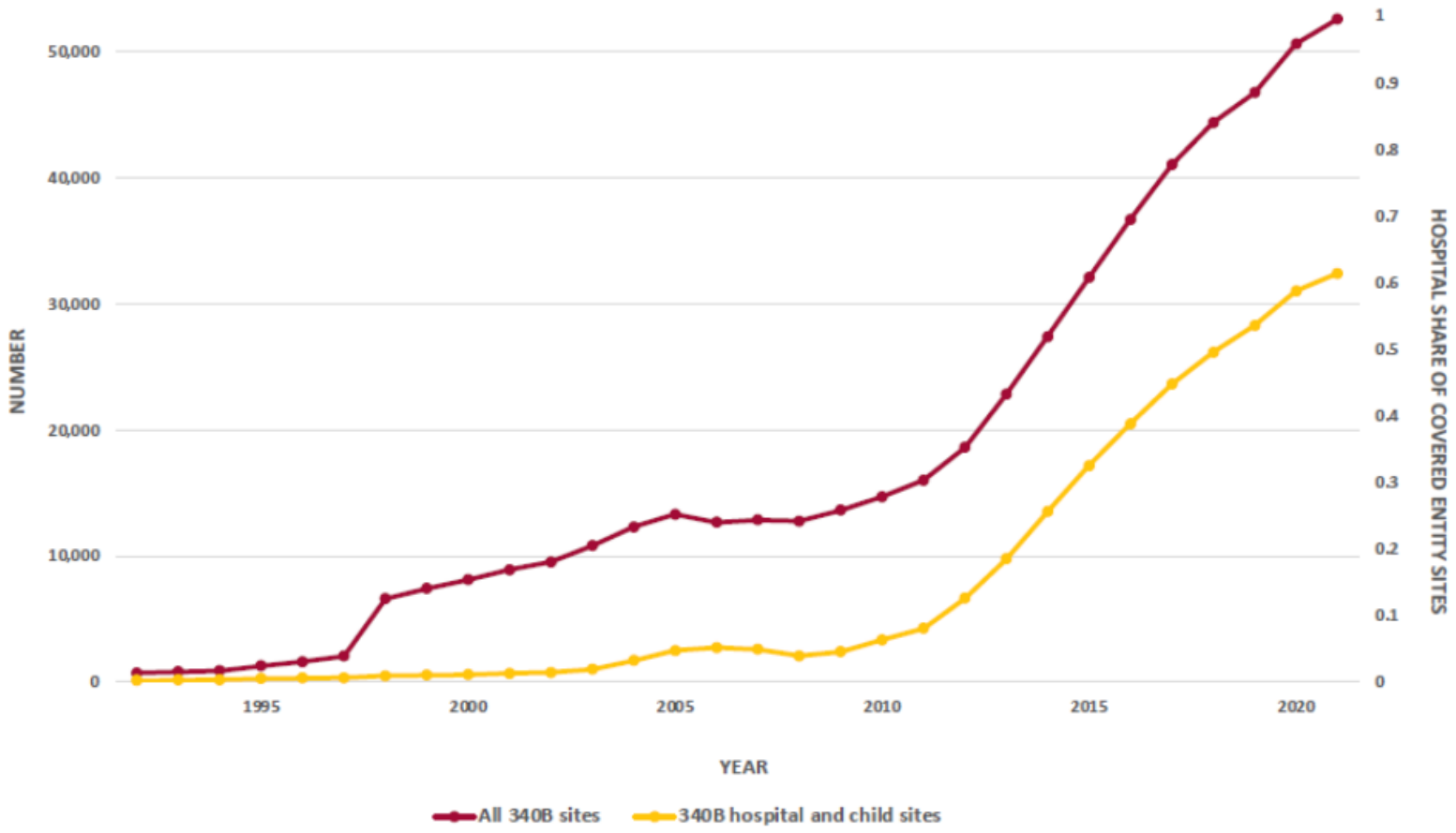
https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/

Contracted Pharmacy Growth



Number of 340B Covered Entities Sites, 1992 -2021

Figure 3: Number of 340B Covered Entity Sites, 1992–2021



Current Market Conditions

Aaron Lott
President, AuthorityRx

ARE MANUFACTERS ALLOWED TO DO THIS IN THE REGULATION?

WHAT IS HAPPENING ON THE LEGAL FRONT?

LITIGATION WITH MIXED RESULTS:

- LITIGATION IN PROCESS IN VARIOUS FEDERAL COURTS
- SOME OUTCOMES SEEM TO BE IN FAVOR OF MANUFACTURERS WHILE OTHERS ARE IN SUPORT OF HRSA
- MOST, IF NOT ALL. CASES ARE EXPECTING APPEALS
- LITIGATION WILL CONTINUE AND TAKE TIME

REGULATORY UPDATE

- A COMPANY NAMED KALDEROS IS WANTING TO CHANGE THE 340B DISCOUNT FROM AN “UPFRONT” DISCOUNT TO THE CE TO A RETROSPECTIVE 340B “REBATE”.
- THIS CONCEPT IS UNDER REVIEW FOR COMPLIANCE WITH THE 340B GUIDELINES
- DO NOT KNOW OF A MFG THAT HAS ADOPTED THIS PROCESS

ADDITIONAL MANUFACTURERS

- MANUFACTURERS ARE TAKING SIMILAR STANCES WHEN IT COMES TO CONTRACT PHARMACY AND MORE ARE PREDICTED TO BE ADOPTING LIKE POSITONS IN THE FUTURE
- END RESULT MAY BE FOR HRSA TO ISSUE A NEW GUIDELINE ON CONTRACT PHARMACY OR FOR CONGRESS TO RE-ASSESS THE 340B PROGRAM AND ISSUE CHANGES

WHAT ARE THE COMMON THEMES OF THE MANDATES

Limiting Contract Pharmacy Relationships and Data Transparency

- LIMITING 340B PRICING TO COVERED ENTITY'S OWN IN-HOUSE DISPENSING PHARMACY
- IF NO IN-HOUSE DISPENSING PHARMACY LIMITING TO ONE CONTRACT PHARMACY OR A CONTRACT PHARMACIES WITHIN A SPECIFIC RADIUS OF THE COVERED ENTITY
- REQUESTING SUBMISSION OF EITHER ALL CONTRACT PHARMACY CLAIMS OR SPECIFIC DRUG CLAIMS TO A THIRD PARTY SUCH AS SECOND SITE/ESP
- NOTE: LIMITATIONS ARE VARIED BY MANUFACTURER AND ARE SPECIFIC TO CERTAIN TYPES OF ENTITIES

WHAT DOES THIS MEAN FOR THE COVERED ENTITIES?

May limit ability to capture 340B savings	➢ LIMITS ABILITY TO CAPTURE ALL SCRIPTS FOR ALL PATIENTS
May increase dispensing options from an in-house pharmacy	➢ ABILITY TO PURCHASE WIDER FORMULARY OF DRUGS ➢ NEED TO CONTRACT WITH ADDITIONAL PAYORS
May require the need for additional reporting	➢ NEED TO CREATE METHOD OF REPORTING DATA TO MFG SPECIFICATIONS (DISPENSING SYSTEM, TPA, ETC.)
Requires action of selecting a contract pharmacy	➢ NEED TO ANALYZE SELECTION OF CONTRACT PHARMACY BY MFG

Common Stakeholder Disconnects and Challenges

ESP

- Timing of HIN upload
- Delayed notification to MFG
- Confusing Platform
- Lack of accountability chain

Manufacturer

- Notification to wholesaler delayed or not sent
- Does not inform entity when wholesaler has been notified
- Changing details of mandate

HIBCC

- HIN purpose is confusing
- Registration process unclear
- Lag time in registration to HIN issued
- Expensive to license database

Common Stakeholder Disconnects and Challenges

Wholesaler

- Lack of HIN knowledge
- Loading of pricing delayed or not performed
- Overlook EDI sent from MFG
- Disregard importance of urgency

340B TPA

- Inaccurate blocking and unblocking of products at specific pharmacies
- Do not understand mandates
- Reports to identify which pharmacy to designate confusing or unusable

340B Entity

- Unsure when HIN is needed
- Believe submission is HIPPA violation- It is not
- Do not understand mandates
- Lack time and resources to validate selections and manage ongoing mandates

The Blame Game

Results in Lost Savings and Frustration

ESP

Manufacturer didn't inform Wholesaler

Manufacturer

Wholesaler ignored EDI alert to allow pricing

Wholesaler

MFG didn't alert them of pricing eligibility

340B TPA

Entity inaccurately or did not communicate selections

340B Entity

340B TPA for inaccurate unblocks, wholesalers for not loading price

Contract Pharmacy

Product fails to be delivered or replenished at non-340B pricing

AARON LOTT, PHARMD
PRESIDENT, AUTHORITYRX LLC
ALOTT@AUTHORITYRX.COM
(913) 210-8901

Common Products by MFG

Astra Zeneca

- Farxiga- Avg savings per RX $500
- Brilinta- Avg savings per RX $300
- Symbicort- Avg savings per RX $200
- Breztri- Avg $200

Lilly

- Trulicity- Avg savings per RX $1000
- Humolog KP- Avg savings per RX $500
- Humolog V- Avg savings per RX $300
- Emgality- Avg $120

AbbVie

- Humira-Orphan for adolescent patients, ensure not blocked (avg. savings per RX $3,000
- Creon-Avg savings per RX $1470

Boehringer

- Jardiance- Avg savings per RX $1000
- Spiriva- Avg savings per RX $1100
- Tradjenta- Avg savings per RX $1300
- Combivent- Avg $500

Novo NorDisk

- Levemir, Ozempic, Tresiba, Rybelsus- All avg savings per RX $400 each

UCB

- Cimzia- Avg savings per RX $4000
- Keppra and Neupro-Avg savings $400-$1000

Novartis

- Kisqali- Avg savings per RX $4900
- Entresto- Avg savings per RX $600

Merck

- Januvia- Avg savings per RX $500
- Janumet- Avg savings per RX $400
- Dulera- Avg savings per RX $200
- Steglatro- Avg $150

Amgen

- Enbrel- Avg savings per RX $5000
- Otezla- Avg savings per RX $3000
- Prolia- Avg savings per RX $600
- Amiovig- Avg $400

Bristol Myers Squibb

- Eliquis- Avg savings per RX $200
- Revlimid- Avg savings per RX $400
- Yervoy- Avg savings per RX $400
- Thalomid- Avg savings per RX $400

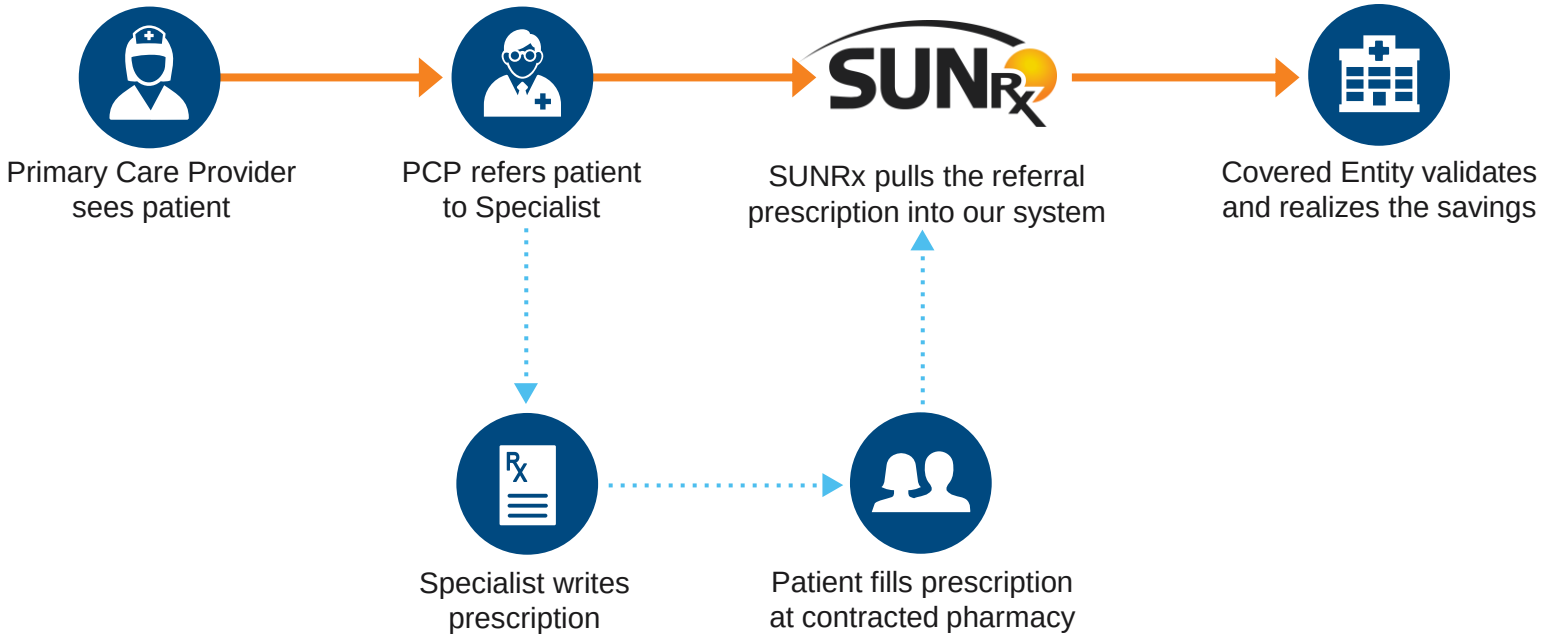
Sanofi

- Lantus- Avg savings per RX $400
- Toujeo- Avg savings per RX $600
- Soliqua- Avg savings per RX $300
- Multaq- Avg $150

Innovations in 340B

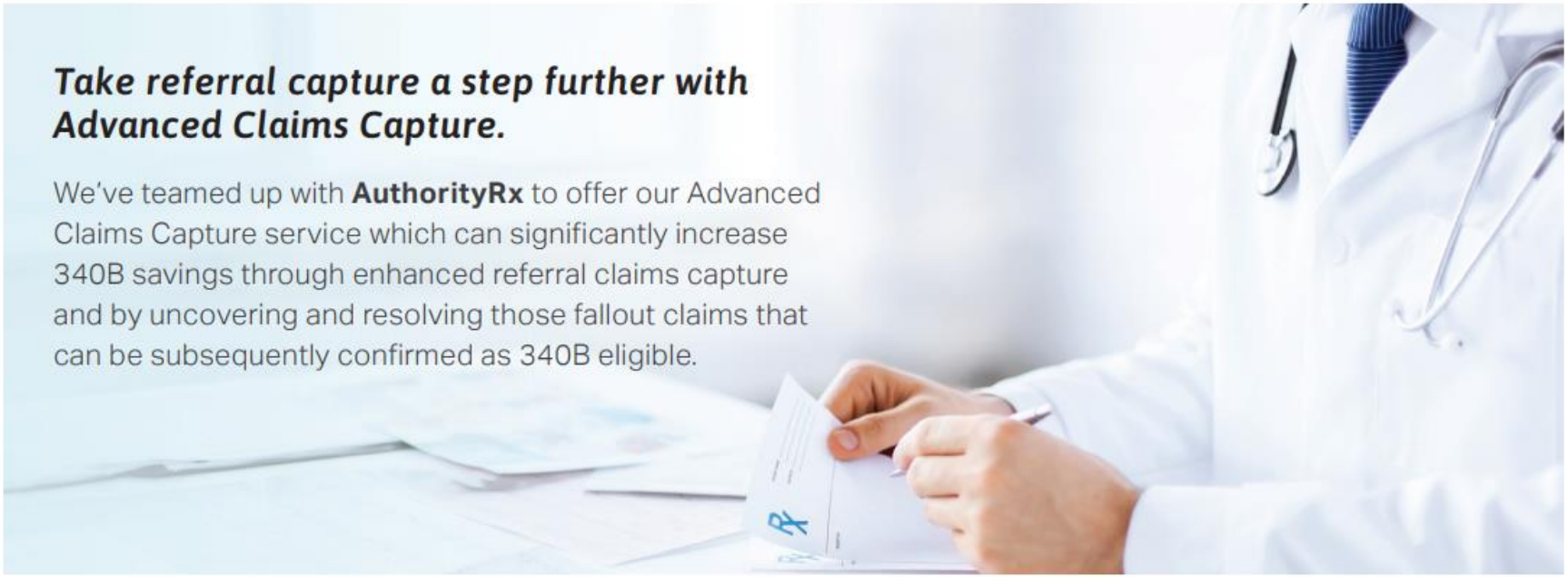
Referral Claims Capture

HOW MANY REFERRALS DO YOUR PROVIDERS SEND ANNUALLY?



Optimization of Claims Capture

Advanced Claims Capture



Advanced Claims Capture

Advanced Claims Capture → Compliantly Realize Additional Savings

No-cost annual 340B audit included.

Reviews & resolves claims from fallout report.

Experience & expert program recommendations.

Speedy Implementation time.

Optimizing 340B Savings

340B. Simplified.®
Powering Compliance & Savings

Considerations for C-Suite

QUESTIONS USUALLY ASKED

ARE MORE RESOURCES NEEDED?

WHEN SHOULD I LOOK FOR OUTSIDE HELP?

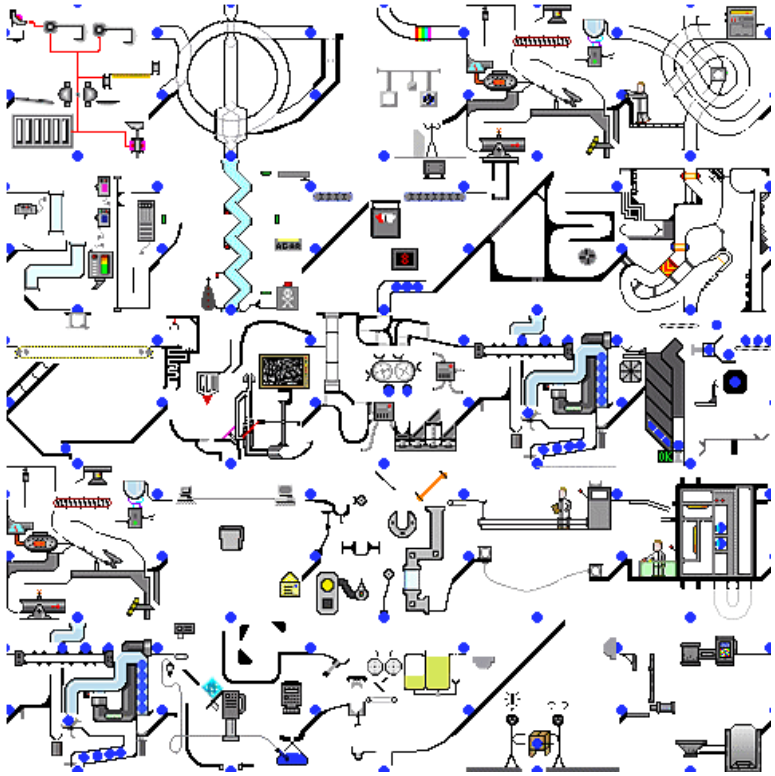
WHAT SHOULD WE BE MONITORING?

WHAT MIGHT I BE MISSING?

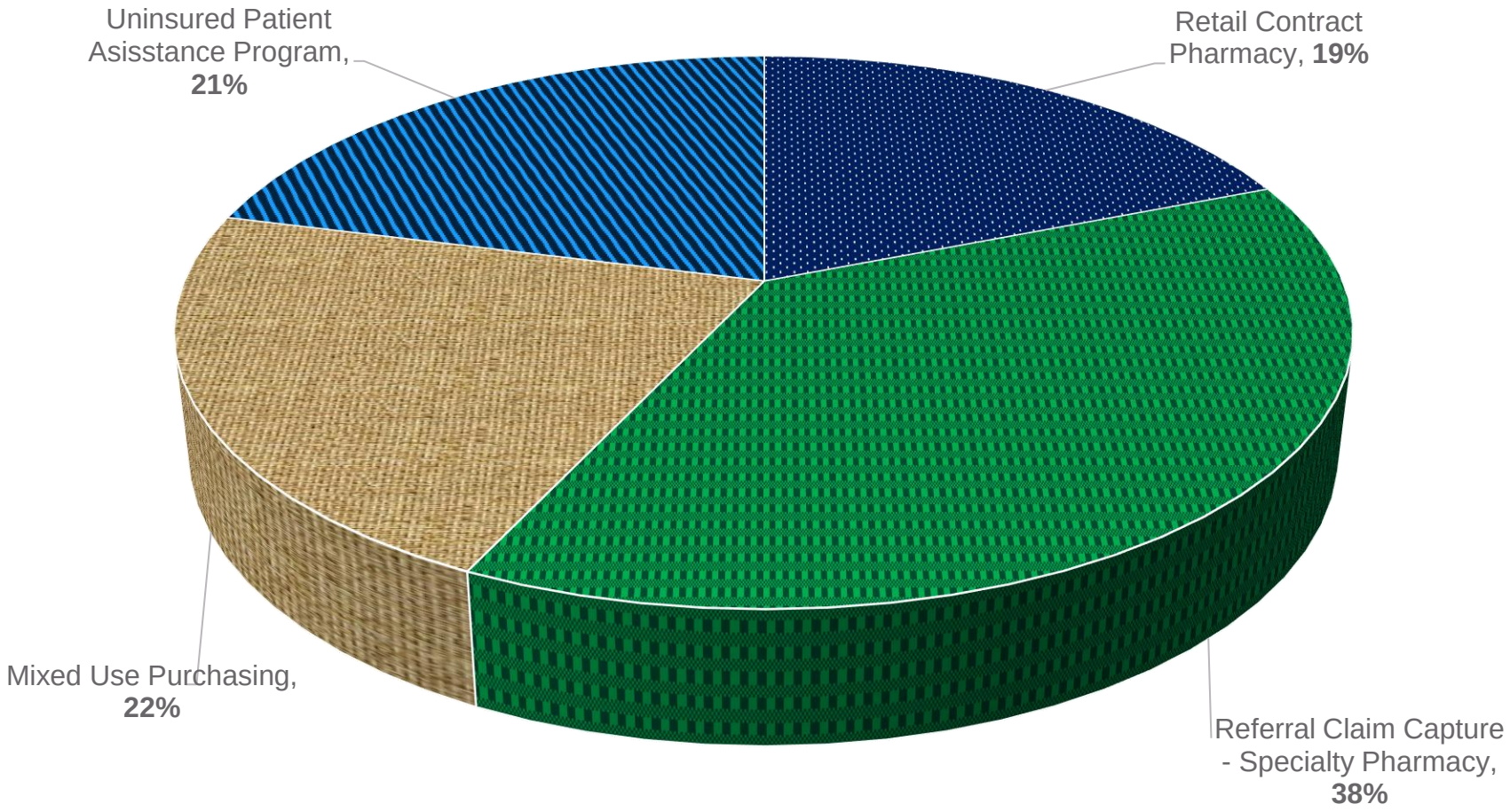
340B Program Optimized?

When your 340B program is fully optimized,

1. You're maximizing your buying power,
2. Capturing referrals claims from Specialists,
3. Your uninsured patients can afford their medications and
4. You're getting the results you deserve



340B Saving Options



340B COMPLIANCE

Adding Specialty

Chronic Diseases

- Dermatology
- Rheumatology
- Gastroenterology

Autoimmune

- Eligibility / Prior Authorizations

Oncology or Infusions

- Limited distribution
- Specialty handling
- Side-effects

Self-pay / Uninsured Patients Solution

340B Card

In 2021, patients Saved approximately **$89.5M**

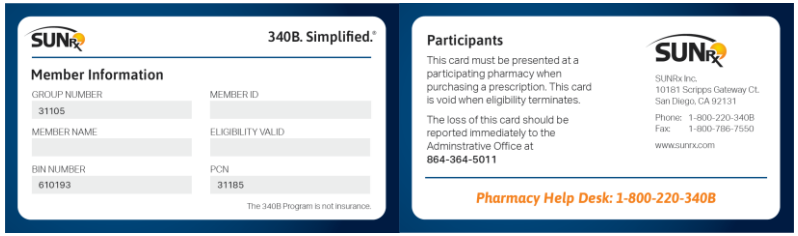
- Minimizes Risk of Increased Charity
- Minimizes Risk of Medicare Readmissions
- Load 340B eligibility at the PBM (low-income patients, providers, 340B pricing)

The Lowest Price Every Time

FACT
For nearly 50% of prescriptions 340B is NOT the lowest available price

THE LOWEST PRICE
SUNRx scans all available prices, and processes the script using the lowest price

Sample Cards



Takeaways

Funded by	Pharmaceutical Manufacturers
Critical Program	Requires a lot of work
Uninsured patients	Are part of the benefit of 340B
Referrals	Can add significant 340B Savings
Is 340B Worth it?	It depends. Do the Analysis

Thank You!

For additional information, please contact:

Chris Combs
Regional Manager, SUNRx

Email: ccombs@sunrx.com

Mobile: 858.269.7114

SUNRx.com