

340B Myths and Facts Regarding Other Arrangements

SUNRx and AuthorityRx



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- Aaron Lott and John Bretz have no relevant financial relationship(s) with ineligible companies to disclose.
and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

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Learning Objectives

At the completion of this activity, the participant will be able to:

1. Learn more about SUNRx and AuthorityRx.
2. Learn more about 340B Savings and the features of Referral Capture and Advanced Claims Capture.
3. Understand the Myths and Facts regarding “Other Arrangements.”



About SUNRx

Vision

SUNRx delivers pharmaceutical and technology-related solutions that improve the value of healthcare. We provide 340B savings 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.

Experience

- Early “pioneer’ in 340B, beginning in 2006
- Committed to the intent and success of 340B
- Recognized for our compliance approach
- Trusted 340B TPA with exclusive endorsements from 35+ State Hospital and Pharmacy Associations



About SUNRx

What We Offer

-  Advanced Claims Capture
-  Referral Capture
-  Specialty Pharmacy
-  Uninsured 340B Prescription Discount Card
-  Contract Pharmacy
-  Split Billing

Who We Serve

-  Hospitals
-  Health Centers
-  Pharmacies





About AuthorityRx

ARx

- Multiple HRSA audits supported annually (9 audits in last 18 months)
- The only company with extensive compliance expertise which owns multiple automated 340B cloud-based applications to include referral capture
- Over a decade of 340B program implementation and independent audit support

Who We Serve

Hospitals | Grantees | 340B TPA's | Pharmacies

What We Offer

- Advanced Claims Capture (ACC)
- Zero cost program check-up
- MFG Mandate Management (M3)
- No cost on-site HRSA audit support
- Increased savings
 - P&P language optimization (4 key areas)
 - Best in class reclassification turnaround
- Savings Transparency Reporting (STR)

CURRENT ENVIRONMENT - Drug Manufacturers impose limitations on 340B Access

HOW IT STARTED:

- 7/1/2020 – Lilly limits distribution of 340B pricing
- Limited response from entity community – Trial Balloon
- AstraZeneca, United Therapeutics, and Novartis quickly implement limitations

Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs

This notice provides information to 340B eligible covered entities seeking to purchase Cialis® (tadalafil) tablets indicated only for erectile dysfunction, specifically:

00002-4463-30: 10 mg 30 tablet bottle

00002-4464-30: 20 mg 30 tablet bottle

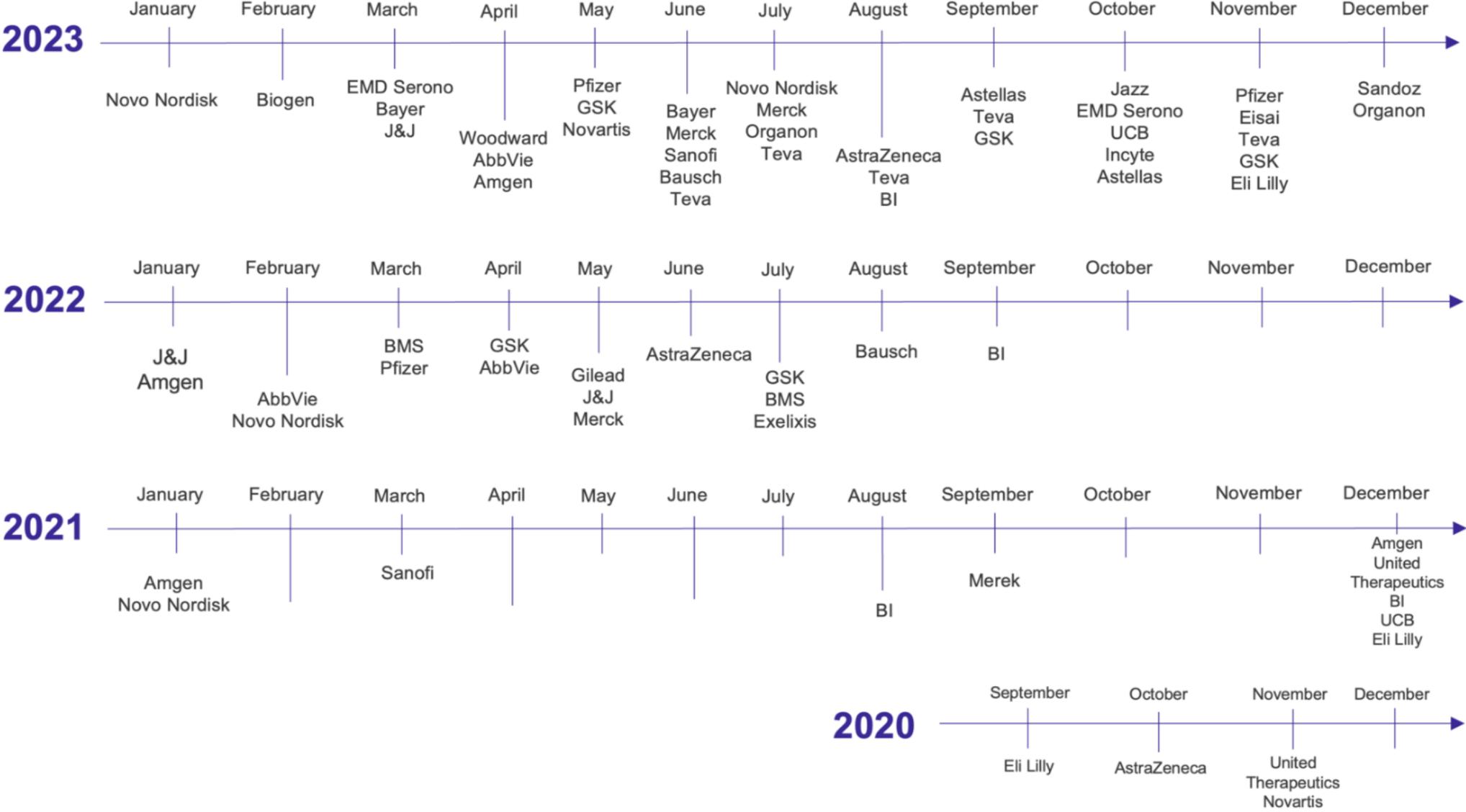
00002-4465-34: 2.5 mg 2x15 blister pack

These formulations of Cialis are approved exclusively for use in patients with erectile dysfunction. Since October 2018, generic versions of Cialis have been widely available, and currently more than a dozen generic manufacturers offer low-priced versions of these medicines.

Effective, July 1, 2020, Lilly is limiting distribution of 340B ceiling price product of these Cialis formulations directly to covered entities and their child sites only. Contract pharmacies will not be eligible to receive these formulations of Cialis at the 340B ceiling price. Any contract pharmacy orders placed with a wholesaler as of June 30 will be honored. Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

Lilly is committed to compliance with the 340B statute and to responsible distribution of its products. If you have any questions regarding how to acquire Cialis please contact Lilly at 340B@lilly.com.

Manufacturer Disruption



From	Subject	Received	Size	Category
340B ESP™ Hello Aaron, Astellas has just announced an update to their 340B Contract Pharmacy policy. Please log in to your 340B ESP™ account to learn more. Thank you, The 340B ESP™ Team For support, you can rep	Astellas Has Updated Their 340B Policy	Mon 4/1/2024 12:13 PM	119 KB	
▼ Last Week				
340B ESP™ Hello Aaron, Amgen has announced an update to their 340B Contract Pharmacy policy. Please log in to your 340B ESP™ account to learn more. Thank you, The 340B ESP™ Team For support, you can reply direc	Amgen Has Updated Their 340B Contract Ph...	Fri 3/29/2024 3:40 PM	119 KB	

AbbVie Has Updated Their 340B Contract Pharmacy Policy

 340B ESP™ <support@340besp.com>
To: Aaron Lott

  Reply  Reply All  Forward 

Mon 4/1/2024 6:07 PM

 If there are problems with how this message is displayed, click here to view it in a web browser.

External (support@340besp.com)

[Report This Email](#) [FAQ](#) [GoDaddy Advanced Email Security, Powered by INKY](#)

340B ESP

Hello Aaron,

AbbVie has just announced an update to their 340B Contract Pharmacy policy. Please log in to your 340B ESP™ account to learn more.

Thank you,
The 340B ESP™ Team

For support, you can reply directly to this email or call us during regular business hours at 1.888.398.5520.

Sumitomo Pharma America has announced a 340B Contract Pharmacy policy. Please log in to your 340B ESP™ account to learn more.

Thank you,
The 340B ESP™ Team

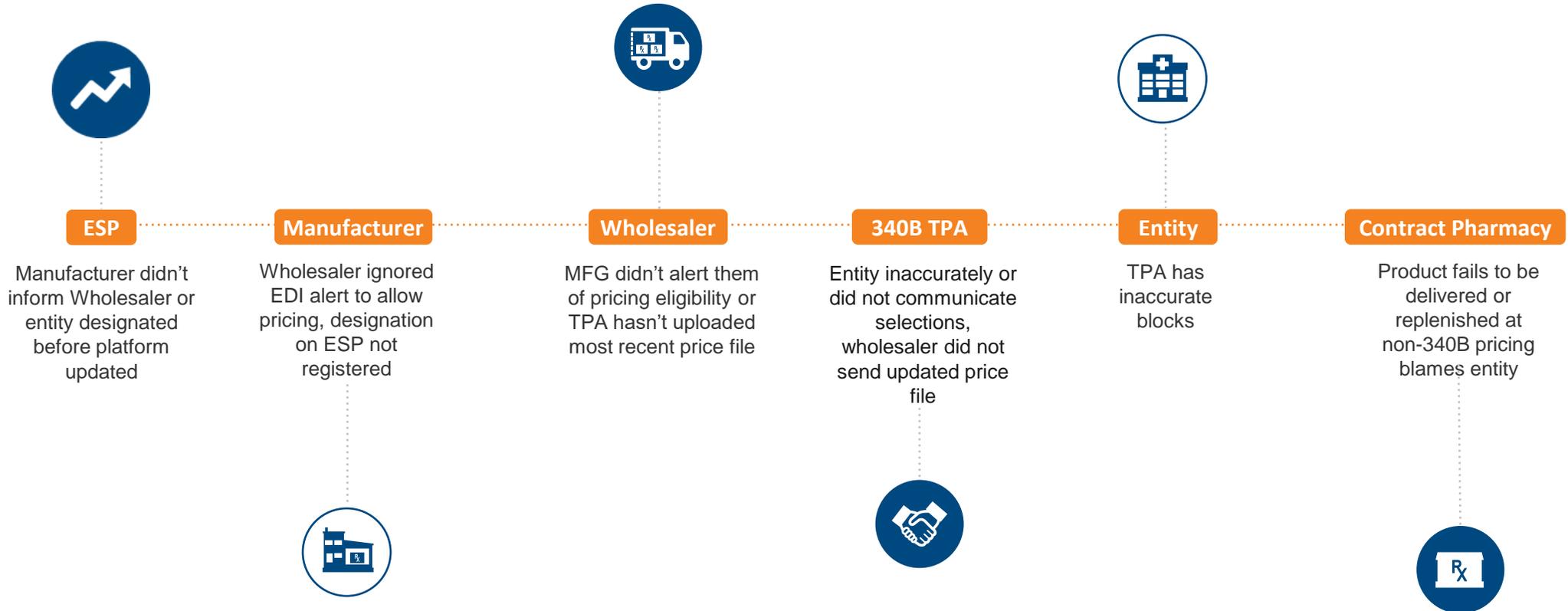
For support, you can reply directly to this email or call us during regular business hours at 1.888.398.5520.

Common Products by Manufacturer

BOEHRINGER	LILLY	NOVO NORDISK	ABBVIE	AMGEN
<ul style="list-style-type: none"> Jardiance: Avg savings \$1000 per Rx Spiriva: Avg savings \$1100 per Rx Tradjenta: Avg savings \$1300 per Rx Combivent: Avg \$500 	<ul style="list-style-type: none"> Trulicity: Avg savings \$1000 per Rx Humalog KP: Avg savings \$500 per Rx Humalog V: Avg savings \$300 per Rx Emgality: Avg \$120 	<ul style="list-style-type: none"> Levemir, Ozempic, Tresiba, Rybelsus- All avg savings per \$400 each Rx <div data-bbox="1067 731 1467 859" style="background-color: #f4a460; text-align: center; padding: 5px;">UCB</div> <ul style="list-style-type: none"> Cimzia: Avg savings per \$4000 Rx Keppra and Neupro: Avg savings \$400-\$1000 	<ul style="list-style-type: none"> Humira: Orphan for adolescent patients, ensure not blocked avg. savings \$3000 per Rx Creon: Avg savings \$1470 per Rx 	<ul style="list-style-type: none"> Enbrel: Avg savings \$5000 per Rx Otezla: Avg savings \$3000 per Rx Prolia: Avg savings \$600 per Rx Amiovig: Avg \$400



When Processes Fail: Let the Blame Game Begin



NAVIGATING MANUFACTURER MANDATES

Entities Getting Creative



Alternate distribution models

Ship the delivery of 340B products traditionally sent to contract pharmacy to entity; then entity essentially act as a wholesale distributor and deliver products to the contract pharmacy.

Challenge: Entities implementing these models have been receiving cease and desist letters from MFG's. (Lawsuits to follow?)



Build In house Pharmacy

Entities considering either building or acquiring licensed pharmacy.

Challenge: Resources, community politics, and ability to educate staff and shift location of dispense (redesign own health plan?)



Child Site to Grantee

Hospitals entities consider changing child site location(s) to grantee status if possible.

Challenge: Difficult to assess eligibility for entity type change and provider arrangements in order to see benefit.

Myths and Facts Regarding Other Arrangements



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Other Arrangements (e.g., Referral)

- Rural entities, especially hospitals and grantees, rely on other arrangements to compliantly qualify claims from providers who are not employed or do not see entity patients in eligible location(s)
- 1996 Federal Register Notice states:
“....either employed by the covered entity or provides health care under contractual or **other arrangements (e.g., referral for consultation)**;
- Defining any other arrangement in P&P’s and outlining how it is operationalized is a necessity for entities utilizing other arrangements



Common Myths and Misconceptions

- Myth 1: There is only one way to outline an “other arrangement”
- Myth 2: Incorporating any other arrangement is complicated
- Myth 3: Other arrangements are prone to non-compliance



Myth: Only One Way to Outline an Other Arrangement

Fact

- **There are different names for, and types of other arrangements** outlined by entities across the Nation
- “Shared patient”
- “Referral”
- “Best practice”
- “340B extended provider”
- “Collaborative care”

Reason for Myth

- Consultants
 - May not have 340B compliance background
 - Can lack 340B operational experience
- Vendors (referral and TPA’s)
 - Most TPA’s abstain from incorporating updated logic
 - Referral vendors one size fits all approach
- Referrals were one of the first other arrangements outlined
 - The language crafted and utilized in P&Ps by the entities who first outlined referral capture became the standard



Myth: Incorporating an Arrangement is Complicated

Fact

- **It can be simple** to operate a compliant program that incorporates any other arrangement to address your communities needs
- Majority of other arrangements outlined incorporate unnecessary operational constraints
- Poorly written language results in management processes that are cumbersome and overly complex

Reason for Myth

- Consultants
 - May not have 340B compliance background
 - Can lack operational experience
- Vendors (referral and TPA's)
 - TPA's dated capture logic
 - Referral vendors only built to process the earliest outlined arrangements
- Entities
 - Unnecessarily creating self-imposing constraints
 - Taxes resources
 - Reduces savings
 - Risks incidental non-compliance



Myth: Arrangements too Risky (Non-compliance)

Fact

- **Less prone to non-compliance** for those entities who craft appropriate language and operationalize the arrangement; as well as partner with compliance focused vendors
- Have clear and well written declaration in purpose statement, leaving no doubt how the program is operating
- HRSA has transactionally tested and passed claims that were a result several different types of other arrangements

Reason for Myth

- Consultants
 - May not have compliance background
 - May lack operational experience
- Vendors (referral and TPA's)
 - TPA's dated capture logic
 - Most referral vendors lack compliance expertise and real-world operational understanding
- Entities
 - The more self-imposed complexity; the higher risk of incorrect processes and capture



Where We are Today

- Multiple types of arrangements that encompass referrals continue to be drafted, put into practice and pass HRSA audits
- Other arrangements continue to be an excellent and compliant mechanism for addressing entity challenges
- Consultants
 - Can perpetuate myths due to their lack of 340B program understanding
- Vendors
 - “One size fits all” narratives regarding arrangements due to lack of platform flexibility and real-world program environment
- Entities
 - Beginning to realize there is a better way forward concerning arrangements and partnerships

340B Innovation

Compliantly increasing the footprint of 340B eligible claims

OPA Annual Conference & Trade Show
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BETTER PATIENT CARE. GREATER SAVINGS.

INNOVATION - 340B Referral Capture

- Allows a 340B Covered Entity to realize savings for prescriptions written outside of their contracted/employed prescriber network.
- For example, a patient sees a 340B eligible prescriber and is referred out to a specialist for care.
- If Covered Entity can show they maintained responsibility for the patient's care, related prescriptions written by specialists can be captured at 340B pricing — and savings are realized!



ADDITIONAL CLAIMS CAPTURE

Why capture referral prescriptions?



Referral prescriptions

- Many are for specialty medications such as Humira®, Embrel®, Harvoni®, Otezla®, Sovaldi®, Skyrisi®, and Cosentyx®.



Specialty medications

- Specialty medications have significantly higher reimbursement and 340B savings for Covered Entities.



Increase savings

- Just a few prescriptions can significantly add 340B savings to your program.

ADDITIONAL CLAIMS CAPTURE

Self-Service Referral Capture.

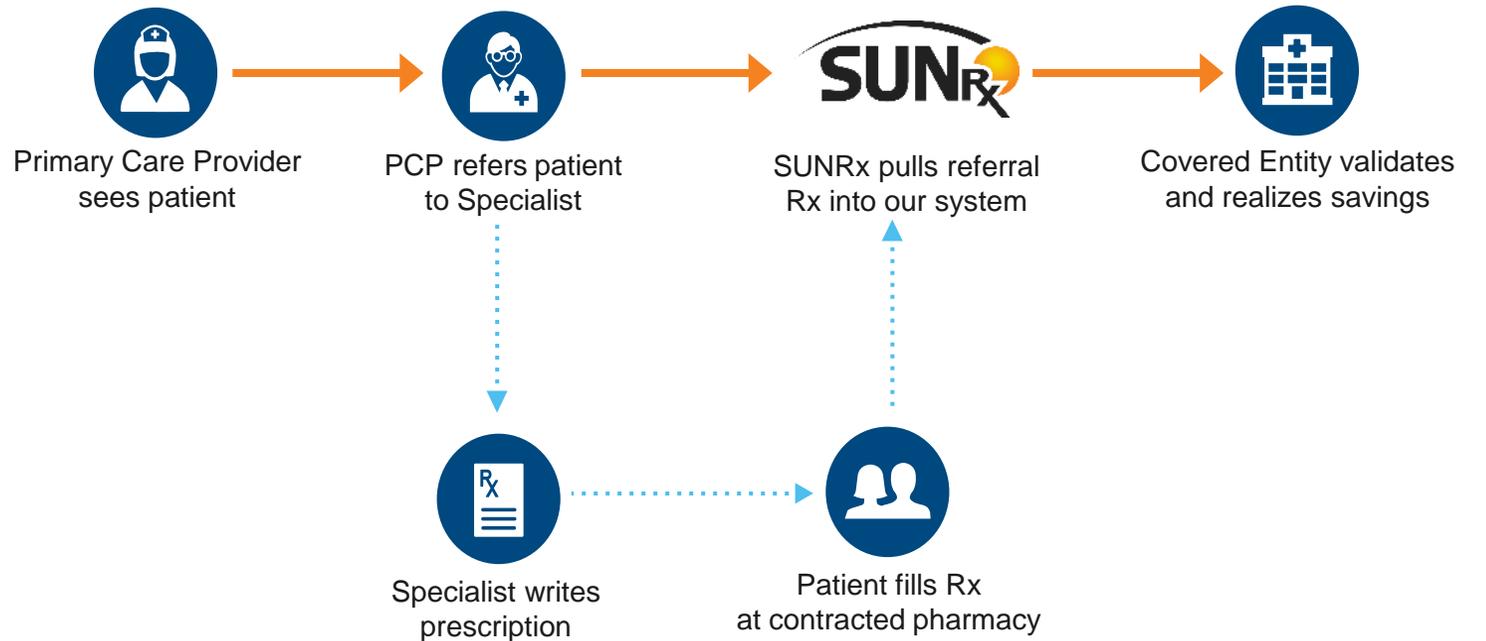
Allows clients to capture referral prescriptions and deliver savings to their Covered Entity

Process coordinates and follows client's policies and procedures

Partner who understands the referral process in 340B regulation

Account executives train and work closely with staff to help realize significant savings

How many referrals do your providers send annually?





ADDITIONAL CLAIMS CAPTURE

Advanced Claims Capture (ACC)

- Helps significantly increase 340B savings by identifying and resolving why claims are not 340B qualified.
- Process and application may resolve compliance challenges that can result in previously ineligible claims reclassified as 340B eligible.
- Reviews and proposes modifications to Covered Entity's 340B Policies and Procedures to ensure maximum identification and referral capture
- Once review is complete, SUNRx can automatically identify and capture significantly more 340B prescriptions, including referral prescriptions.



Statute Interpretation and Mandatory Language Creation

Entity Drafted Language
(Not Defined by Statute)



Compliant in HRSA Audits

Avg. Increase in Savings

All Referral Programs

- Complete patient definition
- Patient eligibility statement
- Provider eligibility statement
- Other arrangement
- Yes
- 5% to 15%

Advanced Claims Capture

- Complete patient definition
- Patient eligibility statement
- Provider eligibility statement
- Other arrangement
- Yes
- 18% to 50%+

Common Education Points

- Close the loop
- Visit 12/18/24 mo.
- Documentation
- “Primary” care
- Receives health care service or range of service(s)

....either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity;

Apexus statement:

“It is true that an eligible patient (meeting pt definition in FAQ 1642) does not have to be strictly provided “primary” care to be eligible. The patient definition states the patient receives “a health care service or range of services”.

Advanced Claims Capture.



TPA-Agnostic

- Does your administrator provide an ACC solution that is 340B agnostic?
- Are you required to change current 340B TPA?
- Provides ACC services for pharmacy chains utilizing their own 340B TPA (e.g. CVS) ?



Pricing Model: No capture, no cost.

- Are Fees based on a percentage of additional 340B claims captured?
- if there is no additional capture, is there still a cost to the entity?.



Identify missed claims

- Can your ACC solution help identify claims beyond current referrals or that their 340B staff may have missed?



ADVANCED CLAIMS CAPTURE

Optimal ACC Process

	Traditional Referral (TPA Review Queue)	Traditional Referral (Review/Fallout)	Advanced Claim Capture	Optimal solution
Avg# of Claims Available for Review/mo	21	120*	319	
Avg % Rate of Verification for claims/mo	42.9% (9 claims)	33.2% (40 Claims)	47.8%* (152 Claims)	
Avg \$/claim	\$192	\$268	\$315	
Avg Turnaround Time/days	Up to 21	Up to 45	3*	
Average % in Annual Savings	5%	15%	48%+	

(Figures from AuthorityRx Client Data)

A TRUSTED 340B PARTNER.

Referral Capture Checklist

-  **Compliance expertise** We support multiple HRSA audits annually.
-  **Truly automated process** Most referral vendors are not integrated and automated with 340B TPAs. ACC is a cloud-based platform that is truly automated, working with large national chain pharmacies.
-  **No Middleman** Some vendors contract out the work and do not own their platform. We own the ACC platform and do the work!
-  **SOC 2-Certified** Service and platform security, third-party auditor certification, and high visibility and transparency throughout the process.
-  **P&P Language** We revise language to maximize new savings and align P&P language with a robust claims application.
-  **Results** Move beyond TPA queue management – no more outlandish claims or anemic results due to suboptimal service.
-  **Value and Support** We offer a 90-day without cause termination, and do not commit clients to long-term agreements.

**Better Patient Care.
Greater Savings.**

A TRUSTED 340B PARTNER.

Advanced Claims Capture Takeaways



Unlock new savings

Program savings only continues to decline; clients are eager to identify new savings opportunities.



Application

It's critical that your service is integrated and automated, resulting in maximizing savings and eliminating additional work.



Implementation

ACC does not require EHR integration or entity resources — it's up and processing within a few weeks — not months. Clients with CVS pharmacies can take 14 days or less.



Speed to capture

Our average time for the entire reclassification cycle is usually 3 days or less; not up to 90 days like outdated legacy vendors.



TPA agnostic

No need to change 340B administrators! Most clients have multiple administrators we can work with.



Manufacturer mandates

Challenging MFG mandates make ACC an absolute necessity for entities, 340B TPAs, contract pharmacies, and patients.

THANK YOU!

Need More Information?

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