Executive Series

340B Overview & Market Update

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Agenda

- Terms and Definitions
- Overview

 - Background MFG and Lawsuits
- History and GrowthCurrent trends and updates
- 340B Economics
- Advanced Claims Capture Pitfalls and Risks
- StrategiesOutlook
- Q&A



340B terms & definitions

340B third-party administrators

- Macro Helix, PharmaForce, SUNRx, Verity
- Provides software platform to manage processes necessary for program operation and compliance
 - Connects wholesaler accounts and tracks drug accumulations
 - Coordinate's payment and invoices
- Most entities have multiple TPA's

Advanced Claims Capture

A service that includes different types of strategies to increase the savings. The strategies and tactics include the revision of P&P's, outlining "other arrangements" allowed by HRSA, sending of and/or obtaining documentation from outside providers who provide care to common patients, mining data with EHR, analyzing escribe data, and analysis of the health plan as it pertains to the cost, location and drug selection of employee prescriptions.

MFG claim submission vendors

- Second Sight ESP
- Kalderos

GPO exclusion

A statutory prohibition against obtaining covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement for certain covered entities. WAC and 340B only.

· Orphan drugs

A drug designated by the secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition. Manufactures aren't required to provide certain covered entities' orphan drugs under the 340B Program.

Duplicate discount

Manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug.

Pharmacy marketplace verticals

Large healthcare corporations that own and operate for-profit business lines that are essential to administer health benefits and services to the public

Integrated pharmacy

A comprehensive strategy that allows healthcare providers within a community to keep healthcare local while strengthening relationships with employers and patients. The strategy alleviates challenges from outside institutions faced by multiple community healthcare stakeholders by leveraging the inherent advantages of each stakeholder.



340B terms & definitions

Health and Human Services (HHS)

- Current Secretary Xavier Becerra
- Former Secretary Alex M. Azar II previous president for Eli Lilly and lobbyist
- Health Resources and Services Administration (HRSA)
 - An agency of HHS that provides healthcare to people who are geographically isolated, and/or economically or medically vulnerable

Office of Pharmacy Affairs (OPA)

Educate and inform 340B Drug Pricing Program stakeholders about the program

Apexus

- Part of Vizient
 - HRSA-designated Prime Vendor for the 340B Drug Pricing Program
- Created additional business models and consulting services
 - Acentrus assists entities with implementing specialty pharmacy solutions

Covered entity (Parent)

- A healthcare organization that meets certain criteria as outlined HRSA to participate in the 340B program
- May have departments or operations outside of the physical address of the parent entity called Child sites (i.e., clinics)

· Contract pharmacy

- A pharmacy that is traditionally not owned by the entity and fills prescriptions that are written by entity providers
- Pharmacy service agreement (PSA) outlines arrangement
- Dispense fee and payment schedule
- Replenishment model

· Outpatient mixed-use

- Service locations deemed eligible according the Medicare Cost Report to have 340B drugs dispensed and administered
 - Examples include Infusion clinic, outpatient surgery, ER, etc.

Medicaid carve-in carve-out

Entities are required to elect on the HRSA website that they will bill Medicaid fee-for-service for drugs purchased at 340B prices or they will not bill.



340B background overview

· The program

- In 1992, section 340B of the Public Health Service Act was created, which requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations.
- This federal program allows 340B-eligible entities to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve. Most entities use 340B savings to provide free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement medication management and community health programs.

Health Care Reform Bill (ACA) expands access

- Passed by Congress in March 2010
- · Expanded types of qualified entities (hospitals) and allowed for unlimited contract pharmacy
- Two types of eligible organizations within an entity
 - Parent and child site(s)
- · Two sides of the program
 - · Contract pharmacy and outpatient/mixed use



340B MFG overview

- MFG began denying 340B pricing (Summer 2020)
- MFG sent letter to HSS stating their opinion (Fall 2020)
- Letters from Congress signed by majority in the House and CE's urge HHS to address
- HHS general counsel provides controversial advisory opinion (Winter 2020)
- HRSA previously warned each of the manufacturers that their refusal to offer discounts through
 contract pharmacies "have resulted in overcharges and are in direct violation of the 340B statute."
 noting that they faced civil monetary penalties (May 2021)
- HRSA referred six drug manufacturers to the HHS OIG regarding their refusal to offer 340B discounts (Sept 2021)
- Judges for AstraZeneca, Novartis, and United Therapeutics in agreement that the statute doesn't speak to contract pharmacy relationships and HRSA's position legally flawed (Oct 2021)
- Federal judge gave government lawyers until 10/13 to weigh in on drug manufacturer Sanofi's request for emergency protection from being brought before a 340B ADR panel.



Polling Question

Have you designated a contract pharmacy for Eli Lilly, Astra Zeneca, Boehringer, and Novo Nordisk?

- A Yes
- B No

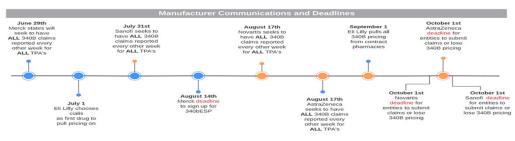
Do you submit claims data twice monthly to Second Sight ESP for Merck, Sanofi, and Novartis?

- A Yes
- B No



340B MFG overview

Manufacturer	Mandate	Notes
Eli Lilly	1 CP	Fill out form and send to 340B@lilly.com
AstraZeneca	1 CP	Fill out form and send to Membership@astrazeneca.com
Novo Nordisk	1 CP	340BInfo@novonordisk.com
United Therapeutics	1 CP til 5/13 then Claims submission	UTAssist.com 340b@unither.com
Merck	Submit claims ESP	twice monthly for all pharmacies
Sanofi	1CP or all if submit claims ESP	twice monthly for all pharmacies
Novartis	40 mile radius	recommends claims submission but not required





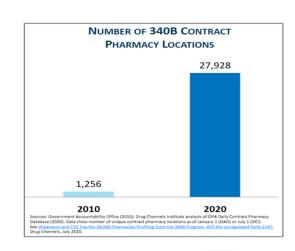


- Significant drop in savings and claims qualification
- Some CE's seeing over 30% or more reduction in savings
- CE's with one CP not impacted unless didn't designate and/or submit claims
- Are NDC's really being replenished?
 - MFG wholesaler communications
 - TPA entity communications
- Wal-Mart's conservative approach
 - · Opt out
 - · Replenishment issues
- Advanced claims capture is crucial for every CE
- Some CE's need to revisit outpatient pharmacy strategies to include specialty accreditation



History & growth

- Siloed pharmacy strategies; entities and consultants fail to fully connect and keep pace with marketplace opportunities
- 2010 ACA expands entity types and contract pharmacy
- · HRSA lacks rule making authority
 - Court ruling on orphan drugs 2014 and 2015
- · Program models
 - Antiquated; failure to adapt with specialty sector
 - Significantly strained contract pharmacy and entity relationships
- Entity challenged with integrating technology platforms and keeping pace with IT demands
- Low number of knowledgeable consultants in 340B space
- Entities lack quality analytics and willingness to be forward-thinking
- · PhRMA increases efforts to rollback program





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History & growth

- Brand and specialty drugs (open access)
 - Biologics account for about 77% of Medicare Part B FFS prescription drug
 - Currently, 30%-40% of all pharmacy revenues are specialty pharmaceuticals
 - 47%-50% of U.S. drug spend | 17%-20% growth in three years
 - >300 gene and cell therapies in drug pipeline
- Pharmacy benefit managers
 - Currently over \$250 billion in revenue
 - · Projected to exceed \$500 billion in revenue
 - Half of projected revenue to come from specialty





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They Are Vilified

HOW A HOSPITAL SYSTEM GREW TO GAIN MARKET POWER AND DROVE UP CALIFORNIA HEALTH CARE COSTS

Sutter Health is in the midst of a lawsuit for business practices that drove

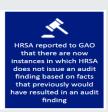
https://www.cbsnews.com/news/california-sutter-health-hospital-chain-high-prices-lawsuit-60-minutes-2020-12-13/



Current trends & updates







- Change in HRSA's approach to audits due to the absence of binding and enforceable regulations. The agency will no longer issue findings based solely on perceived non-compliance with guidance.
- · Findings involving guidance will no longer be issued.
- Findings HRSA issued in the past will no longer result in a finding in the future unless the action(s) are in clear violation of the statute itself.
- 340B providers will need to be innovative to offset the significant financial loss they will continue to incur due to MFG mandates.

 The matter won't be resolved shortly.



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Of Counsel/Senior Advisor
Baker Donelson





Current trends & updates

Pre-RSV	Real-Time Sampling					
	Three business days before the Remote Site Visit, the covered entity will receive the Agenda.					
	 We encourage you to complete the DRL before the due date provided in the Welcome Email. It is imperative the DRL be completed before the Remote Site Visit. 					
Day 1	The Remote Site Visit will be conducted via the Adobe Connect platform. The covered entity will use the platform's screen-sharing capabilities to display relevant information to the auditor similar to an in-person audit.					
	The Remote Site Visit will be scheduled for 1 day with a maximum duration of 8 hours unless additional time is requested by the covered entity.					
Day 2, 3 & 4	If necessary, the covered entity will be granted 3 business days, post-Remote Site Visit, to upload documentation requested/discussed during the Remote Site Visit.					

HRSA audits

- Currently administered remotely called a remote site visit (RSV)
- Asked to see 2021 independent audit
- Bizzell provided transaction claims 2 days prior to audit
- 4 pg. Connect platform tip document



Current trends & updates

- Environment evolves due to specialty drugs and high-dollar brands
- Contract pharmacy models forced to change
- Referral claims capture uptake in adoption; viewed as critical not optional

Why Specialty? As the specialty pharmaceutical industry continues to grow, there are significant 340B savings opportunities and a specialty pharmacy program will help maximize and maintain those savings.

\$212B

REVENUE

In 2020 Specialty pharmacies dispensed \$212 billion in specialty products.

47%

SPENDING

By 2022, specialty drugs will reach 47% of the pharmacy industry's drugs spend.



FOOTPRINT

Retail and health system pharmacies are rapidly expanding to include specialty pharmacy services.

{Internet} http://drugchannelsinstitute.com/files/2017-PharmacyPBM-DCI-Overview.pdf https://www.drugchannels.net/2016/04/our-2020-outlook-for-specialty-pharmacy.html

340B Rx economics

- Models
 - Changed in response to higher cost brands and specialty drugs
 - Most dispense fees now percentage savings
 - TPAs pivoting in fees as well
 - All scripts vs. brand only
 - Dispense fee
 - Flat or single amount per claim
 - · Percentage of savings
 - Combination of flat and percentage
 - Tiered flat depending on amount of savings
 - Bill on dispense vs. bill on replenishment
 - · TPA dependent

- · All scripts (dated)
 - Usually flat fees (\$20 to \$35)
 - Brand name and generics
 - Entities subsidize pharmacies spread on generics offsets savings from high-cost brands
 - Contract pharmacies would rather take the rebate and purchase on own account
- · Brand only
 - Usually percentage of savings (25% to 50%)
 - Contract pharmacy sees revenue benefit from filling on 340B instead of taking rebate
 - Lowers numbers eligible claims by about 90%



340B Rx economics

Projected Brand Only 40%

Current Dispense Fee	Current Revenue	Current Profitability	Projected Dispense Fee	Projected Revenue	Projected Profitability
\$535,806.00	\$618,579.39	\$391,636.68	\$326,088.94	\$489,133.42	\$346,953.33

Projected Flat All scripts \$20 and 20%

Current Dispense Fee	Current Revenue	Current Profitability	Projected Dispense Fee	Projected Revenue	Projected Profitability
\$535,806.00	\$618,579.39	\$391,636.68	\$826,217.00	\$328,168.00	\$101,225.00

Projected Tiered \$25/\$75/\$125

Current Dispense Fee	Current Revenue	Current Profitability	Projected Dispense Fee	Projected Revenue	Projected Profitability
\$535,806.00	\$618,579.39	\$391,636.68	\$837,775.00	\$316,610.39	\$89,667.68

^{**} Current numbers are based off existing \$18 all scripts



340B Rx economics

	Pay on Dispense	Pay on Replenishment		
When is revenue passed to CE?	On a predefined invoice and accounting period. All claims that qualify/disqualify during the invoice period will be reconciled.	Once the NDC for the product has been replenished/received by the pharmacy, the qualified claim will be included in the invoice cycle.		
Pros	340B qualified claims are included on the invoice period regardless of replenishment.	No rewinds or reconciliations Maximize <u>pharmacy</u> cash flow.		
Cons	Processing of slow-mover rewinds and reconciliation. Constant revenue changing hands due to manual claim disqualification.	340B profitability subject to ordering practices and inventory capacity of pharmacy.		

What are your pharmacies on?

 The pay on replenishment model is being used by entities to eliminate the need for ongoing financial reconciliation due to revenue being passed that are ultimately returned to the chain pharmacy for any number of reasons.



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340B Rx economics

- · Pay on dispense
 - Pay on dispense occurs when a contract pharmacy passes revenue, less the contracted dispensing fee, to the covered entity based on a predefined invoice and accounting period.
 - For example, any claims dispensed between March 1 and March 30 would be invoiced on April 15, regardless of whether the pharmacy has taken receipt of replenishment product.
 - The pay on dispense model is a more traditional model for covered entity payment that does have its challenges, including ongoing financial reconciliation due to slow moving and nonreplenishable inventory.
- Pay on replenishment
 - Pay on replenishment occurs when a pharmacy chain passes revenue, less the contracted dispensing fee, only once replenishment product has been ordered and received by the contract pharmacy.
 - For example, if Product X is dispensed three (3) times, each for a quantity of thirty (30) units from a bottle with an NDC-11 which indicates a one-hundred (100) count pack size, between March 1 and March 30, those three (3) prescriptions would not be payable on the April 15 invoice because the pharmacy has not received replenishment of Product X. If the pharmacy dispenses one (1) additional script thirty (30) units of Product X on April 4, TPA would invoice pharmacy chain for one-hundred percent (100.0%) of the revenue less the dispensing fee for the first three (3) prescriptions and invoice the pharmacy chain for one third (1/3) of the revenue from the fourth prescription.

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Polling Question

Have you had a 340B independent audit recently?

- A Yes
- B No

If not, what is holding you back?

- A Yes
- B No

Have you had a HRSA audit?

- A Yes
- B No



340B Rx economics

Advanced Claims Capture

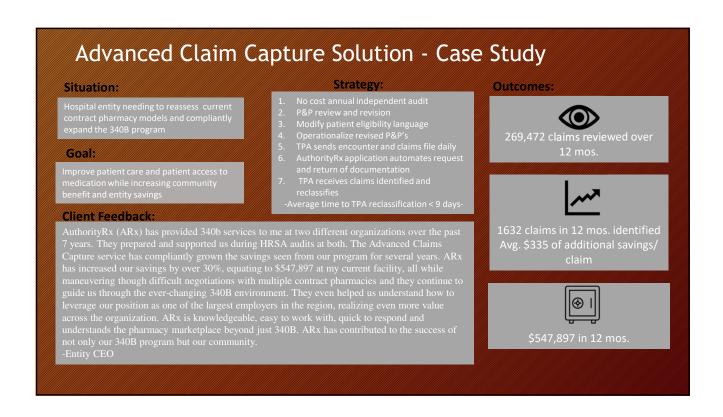
- · New client assessment
- SPECIALIST \$243,138.65
- MENTAL HEALTH \$227,882.29
- UNKNOWN \$803,256.80

\$900,000 per month in opportunity
Projected to capture over
\$127,000/mo
\$1.52M annually

- Not one "right way" to capture outside provider scripts
 - Many types of "other arrangement" (referral only 1 example)
- HRSA audit supported in 2020/2021
 - No need for return of notes
 - 2 claims chosen that did not have notes, but P&P's had appropriate language, zero findings
- Apexus 2021 states eligible patient does not have to be strictly provided "primary" care to be eligible, only needs receive "a health care service or range of services"
- Entities can and should define patient eligibility purely on the statute, the notice for section 602, and a few aspects of interpretative guidance.

Revise patient eligibility and qualifying language within your P&P's then operationalize







htti hiitiidhii hiiliida ka		Generates N	lew Savings				
Program	20	20		Program	2021		
Revenue	Aug	Sep	YTD	Revenue	Aug	Sep	YTD
Received Amount	\$124,962.54	\$120,498.45	\$245,460.99	Received Amount	\$187,286.47	\$154,205.79	\$341,492.2
Total Revenue	\$124,962.54	\$120,498.45	\$245,460.99	Total Revenue	\$187,286.47	\$154,205.79	\$341,492.2
Program				Program Expenses			
Expenses	412.551.12	440.405.40	405.045.00	340B Ingredient Cost	\$25,592.95	\$20,789.24	\$46,382.1
340B Ingredient Cost	\$12,561.42	\$12,485.48	\$25,046.90	True Up Ingredient Cost	\$0.00	\$0.00	\$0.0
True Up Ingredient Cost	\$0.00	\$0.00	\$0.00	U&C /Network Ingredient Cost			
U&C /Network Ingredient Cost				Dispensing Fees			
Dispensing Fees				Sales Tax			
Sales Tax				SUNRx Admin Fees			
SUNRx Admin Fees				Switch Fee			
Switch Fee				General Credit			
340B Direct Connection Fee				340B Direct Connection Fee			
Totals				Percentage Price Model Charge			
Program Profit/(Loss)	\$74,923,54	\$70.056.96	\$144,980,50	Totals			
Paid Amount	\$87,484,96	\$82,542,44	\$170.027.40	Program Profit/(Loss)	\$107,885.34	\$99,640.99	\$207,526.3
T did Tilliodit	Ç077101130	402/3 12.11	Q170,027110	Paid Amount	\$133,478.29	\$120,430.23	\$253,908.5
Replenishment Value							
n Time Period	\$11,307.35	\$12,860.41	\$24,167.76	Replenishment Value	\$21.096.12	\$23,748.13	\$44.844.2

	with addressing other program			2021				
Program Revenue	Aug	Sep	Oct	YTD	Program Revenue	Aug	Sep	YTE
Received Amount	\$84,386.52	\$92,780.34	\$62,142.07	\$239,308.93	Received Amount	\$201,034.09	\$219,480.58	\$420,514.6
Total Revenue	\$84,386.52	\$92,780.34	\$62,142.07	\$239,308.93	Total Revenue	\$201,034.09	\$219,480.58	\$420,514.6
Program Expenses					Program Expenses			
340B Ingredient Cost	\$17,440.95	\$24,862,71	\$9,408,73	\$51,712.39	340B Ingredient Cost	\$41,349.98	\$43,879.03	\$85,229.0
True Up Ingredient Cost	\$0.00	\$0.00	\$0.00	\$0.00	True Up Ingredient Cost	\$0.00	\$0.00	\$0.0
U&C /Network Ingredient Cost					U&C /Network Ingredient Cost			
Dispensing Fees					Dispensing Fees			
Sales Tax					Sales Tax			
SUNRx Admin Fees					SUNRx Admin Fees			
Switch Fee					Switch Fee			
General Credit					340B Direct Connection Fee			
340B Direct Connection Fee					Percentage Price Model Credit			
Totals					Totals			
Program Profit/(Loss)	\$15,759.09	\$10,592.62	\$10,870.04	\$37,221.75	Program Profit/(Loss)	\$109,258.78	\$83,616.35	\$192,875.
Paid Amount	\$33,200.04	\$35,455.33	\$20,278.77	\$88,934.14	Paid Amount	\$150,608.76	\$127,495.38	\$278,104.

Polling Question

Do you capture outside provider scripts currently?

- A Yes
- B No

If not, what is holding you back?

- A Yes
- B No

If so, does your process match your P&Ps?

- A Yes
- B No



Common pitfalls & risks

- Pitfalls
 - Not compliantly capturing outside provider scripts
 - Choosing a company to provide advanced claims capture services that lack expertise in 340B implementations and compliance
 - Need better understanding of program and pharmacy marketplace
 - 340B
 - Specialty (seeing benefit as CP)
 - Employer health plan advantages
 - Ignore dated CP arraignments
 - Neglecting inherent advantages
 - Limit negative effect of verticals/cp

- Risks
 - Significant reductions in savings
 - Inability to grow savings
 - Ineffective or limited pharmacy network
 - Program noncompliance
 - Strained contract pharmacy relationships
 - Inability to drive scripts to operations that make the most sense
 - · Out-of-control employee drug spend
 - Nonexpansion of strategic initiatives



Strategies for optimization

- Implement Advanced Claims Capture
 - Conserve and grow savings
 - Improve patient care
- Pharmacy marketplace education
 - Make connections between health plan, PBM, specialty pharmacy, infusion therapy and 340B
 - Plan design the hospital medical and pharmacy benefit to narrow network in entity favor and optimize eligible employee 340B scripts
- · Push back against verticals where possible
 - Hospital-owned pharmacy
 - Save all or most dispense fee dollars
 - No longer a need to pay for 340B TPA
 - Decrease employee drug spend (340B and GPO)

- · Meds to beds
 - Improve STAR rating
 - Increase medication adherence
 - Partner with entity friendly CP
- Understand history of entity's journey
 - Past strategies and tactics (outcomes)
 - Current challenges and goals
- 340B
 - Full program assessment
 - Prioritize program realignment
 - Pharmacy network (eval chains and SP)
 - Dispense fee and models
 - Mine escribe and pharmacy switch data
 - Understand MFG impact
 - Compliance
 - Education



Outlook

- 340B program and pharmacy marketplace continues to become increasingly complex
- · Now more than ever to capitalize on opportunities, consultants and entities must be nimble and decisive
- · Unprecedented pressures have forced entities toward an end point they should have already been seekina
- Increase in entities' need for consultants with knowledge that addresses entire pharmacy marketplace strategies and tactics
- Advanced Claims Capture now becomes a core addition to entity programs
- Things we didn't discuss
 - Program auditing and compliance environment risks real or perceived
 - Keeping open access specialty in community and 340b network and why independent CP's care

 - How hospitals are being denied access to some drugs (Limited Distribution Drugs) needed to administer in their outpatient mixed use setting (i.e., infusion)
 - Challenge for entities to manage multiple 340B TPAs (340B Complete, Wellpartner) and now submit claims to ESP



Word to the Wise

- Do not settle for a one or two-dimensional solution or consultant to guide your approach to pharmacy. Your resource needs to have broad pharmacy marketplace expertise to bring real optics and value

 - Specialty pharmacy
 - Health plan vertical structures and health plan design
 - Community employer and pharmacy relations
 - Ambulatory pharmacy
- Do not select an advanced claims capture solution that only addresses one of your 340B TPA's
- Beware of companies touting increases of 340B annual savings by 150% and 400%
- · Avoid companies that do not have significant expertise in auditing/compliance
- · Understand and verify the impact MFG's are having on your program, and understand what can be done
- · A few TPA's and consultants offering what they call referral capture, most offerings are extremely anemic in opportunity regarding savings and support is almost nonexistent





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AuthorityRx is committed to keep entity costs low, entity value high, and work to pay for the services we provide. We are not a negative or even neutral cost to clients, we more than pay for our services by conserving and growing 340B savings compliantly and by adding value to all aspects of pharmacy in relation to our client's organization and community.

