

Webinar Agenda for May 18th Discussion of 340B ESP

1:30-3:00 PM Eastern

- Housekeeping-5 minutes
- Status of Contract Pharmacy Lawsuits and Speaker Introductions-10 minutes
- Opening Remarks from Speakers and Dialogue-20 minutes
- Questions Raised by Attendees in Advance -30 minutes
- More Q & A From Attendees-20 minutes
- Wrap up and how to contact speakers-5 minutes

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Housekeeping

- To use Q&A during the webinar:
 - Tap “Ask a Question”
 - Enter your question into the Q&A box
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 - If the host replies via Q&A, you will see a reply in the Q&A window
 - The host can also answer your question live
- Zoom technical questions can also be entered into the Q&A box so that you will receive assistance
- Recording of this webinar will be available behind the paywall

340B Report Team



Ted Slafsky, Publisher & CEO
ted.slafsky@340breport.com



Tom Mirga, Editor in Chief and Lead Writer
tom.mirga@340breport.com



Diane Slafsky, Vice President
diane.slafsky@340breport.com



Reshma Eggleston, Director of Subscription Services
reshma.eggleston@340breport.com



Lee-Anne Gabrielli, Senior Advisor
lee-anne.gabrielli@340breport.com



Inci Devin, Data and Research Analyst
inci.devin@340breport.com

www.340breport.com

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- Questions? Contact Lee-Anne Gabrielli at lee-anne.gabrielli@340breport.com

Types of Contract Pharmacy Restrictions

Restrictions on 340B Discounts by CE Type

- Hospitals - AbbVie, Amgen, BMS for non-IMiDs, Boehringer Ingelheim, GSK, J&J, Novartis, Novo Nordisk, Pfizer, UCB,
- Hospitals and FQHCs – Merck (all hospitals and FQHCs) and Sanofi (DSH and FQHCs)
- All CEs – AstraZeneca, BMS for IMiDs, Gilead, Lilly, United Therapeutics

Conditioning Access to 340B Discounts on Submitting Contract Pharmacy Claims to 340B ESP™

- AbbVie, Amgen, Gilead, GSK, J&J, Lilly, Merck, Pfizer, Sanofi, United Therapeutics

No ESP Exception

- AstraZeneca, Boehringer Ingelheim, Novo Nordisk and UCB

Types of Contract Pharmacy Restrictions (cont'd)

Geographic Restrictions on Contract Pharmacies

- Novartis

Conditioning Access to 340B Discounts on Submitting Claims Directly to Manufacturer

- BMS for IMiDs

Most Manufacturers Allow CE to Designate One Third Party Contract Pharmacy, Use In-House Pharmacies or Wholly-Owned/Affiliated Contract Pharmacies

- Exceptions:
 - United Therapeutics does not allow any contract pharmacy
 - J&J allows wholly-owned contract pharmacy only if owned by CE, nonprofit and located in CE
 - AstraZeneca does not have exception for wholly owned pharmacies

Contract Pharmacies: Manufacturer Lawsuits – District Court Actions and Appeals (2021-2022)

	Complaint Filed	District Court Decision	Appeal Filed
Eli Lilly S. District of Indiana	Jan. 12 – Complaint filed May 27 – Amended complaint filed	March 16 – Courts issues order prohibiting enforcement of ADR against Lilly Oct. 29 – Decision on merits issued	Nov. 10 – Lilly filed appeal in Seventh Circuit Dec. 28 – HHS cross-appealed
AstraZeneca Delaware	Jan. 12 – Complaint filed July 9 – Amended complaint filed	Feb. 16 – Decision on merits issued	April 12 – HHS filed appeal in Third Circuit
Sanofi New Jersey	Jan. 12 – Complaint filed May 25 – Amended complaint filed	Nov. 5 – Decision on merits issued (consolidated with Novo Nordisk)	Nov. 19 – Sanofi filed appeal in Third Circuit Dec. 28 – HHS cross-appealed
Novo Nordisk New Jersey	Jan. 12 – Complaint filed May 25 – Amended complaint filed	Nov. 5 – Decision on merits issued (consolidated with Sanofi)	Nov. 19 – NNI filed appeal in Third Circuit Dec. 28 – HHS cross-appealed
PhRMA Maryland	Jan. 22 – Complaint filed	N/A	N/A
Novartis District of Columbia	May 31 – Complaint filed	Nov. 5 – Decision on merits issued (consolidated with United Therapeutics)	Dec. 28 – HHS filed appeal in DC Circuit
United Therapeutics District of Columbia	June 23 – Complaint filed	Nov. 5 – Decision on merits issued (consolidated with Novartis)	Dec. 28 – HHS filed appeal in DC Circuit
Boehringer Ingelheim District of Columbia	Oct. 25 – Complaint filed Nov. 9 – Court granted request for administrative stay	N/A	N/A

Today's Panelists



AARON VANDERVELDE
Founder and Business
Development Lead,
340B ESP™



TED SLAFSKY
Publisher and Chief
Executive Officer of
340B Report



SUE VEER
President and CEO,
Carolina Health Centers



**ASHLEY
MAINS ESPINOSA**
Vice President of
Clinical Operations,
DocStation, and
Co-founder, The 340B
Collaborative



TOM MIRGA
Editor in Chief
and Lead Writer of
340B Report



JASON ATLAS
Vice President,
340B Enterprise
Strategy & Solutions,
AmerisourceBergen



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INTELLIGENCE THAT WORKS

340B ESP Overview

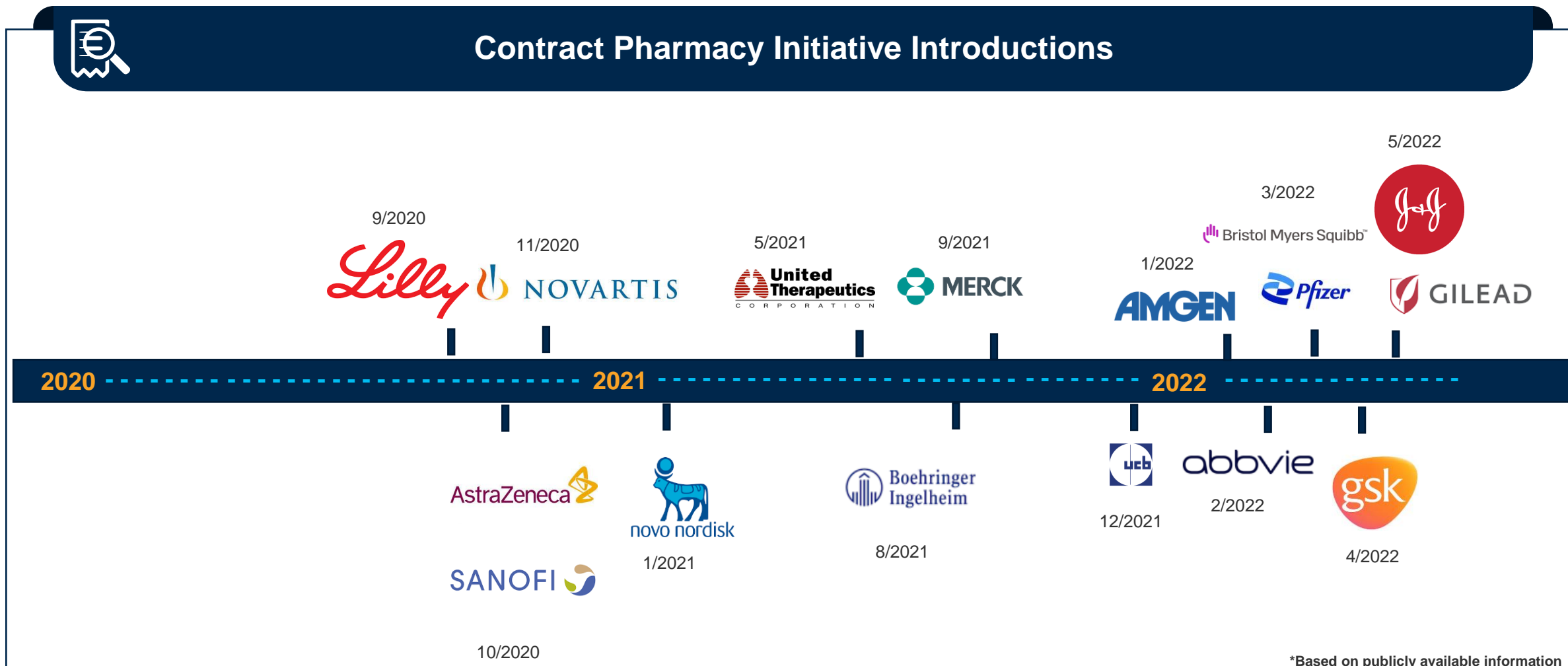
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Timeline of Pharmaceutical Manufacturer CP Initiatives



Contract Pharmacy Initiative Introductions



*Based on publicly available information

340B ESP: Utilization Metrics



340B ESP: Contract Pharmacy Purchasing Process

Summary

- In general, there are 3 phases of maintaining 340B eligibility for products incorporated in 340B ESP: **Eligibility Determination**, **Wholesaler/Contract Administration** and **340B CP Purchasing**
- Eligibility determination encompasses those steps necessary to establish and communicate pharmacy eligibility
- Contract Administration includes those steps taken by wholesalers to administer PHS contracts
- 340B CP Purchasing encompass those steps taken by covered entities and their third-party vendors to identify and place orders for 340B eligible prescriptions

Eligibility Determination

Submit Claims Data

- Covered entity submits 340B claims for one or multiple contract pharmacies

Request Exemption

- 1 contract pharmacy exemption
- Wholly owned contract pharmacy exemption

Validate Pharmacy Eligibility

- Review exemption requests
- Apply manufacturer specific aspects of contract pharmacy initiatives

Create and Send Eligibility File

- Convert eligible contract pharmacies to wholesaler files
- Apply wholesaler specific criteria to file formats

Wholesaler/Contract Administration

Create and Send 832 Files

- Generate 832 files and send to various 340B contract pharmacy administrators and other parties

Load Eligibility Files

- Load eligibility files into contracting system and associate with relevant 340B contracts on a manufacturer-by-manufacturer basis

Validate Eligibility Files

- Evaluate eligibility files for valid provider identifiers and eligibility dates

340B CP Purchasing

Incorporate 832 Files

- Ingest 832 files from relevant wholesalers
- Update pricing and pharmacy eligibility in 340B claims identification processes

Identify Eligible 340B Claims

- Process prescription claims to identify 340B eligible prescriptions
- Account for pharmaceutical manufacturer requirements related to lookback periods

Place Replenishment Orders

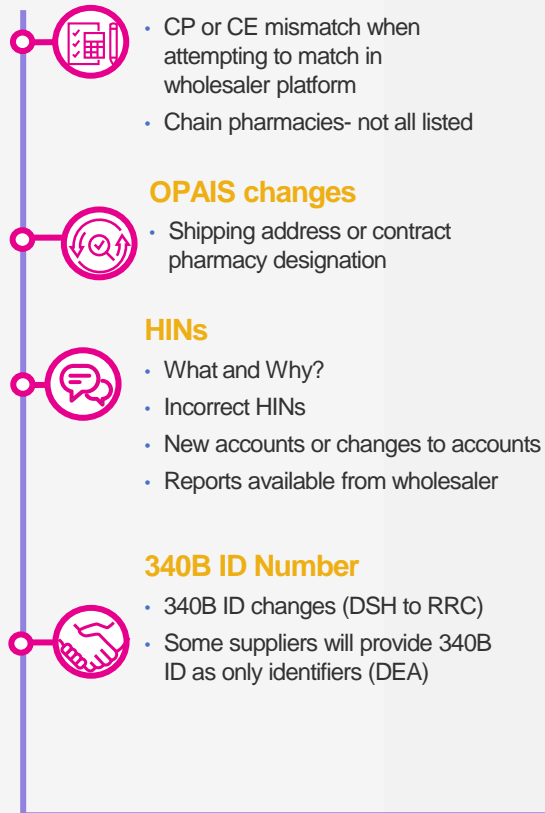
- Based on identified 340B eligible claims, place replenishment orders with wholesalers
- Manage downstream processes as per current set up

Wholesaler, Customer and Vendor challenges

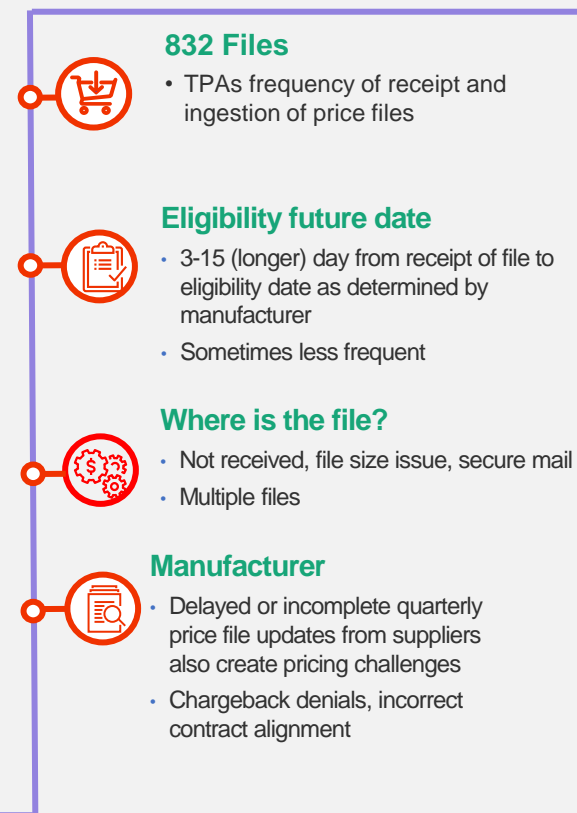
Where problems arise

- In general, there are two common themes for delays in 340B pricing restoration: **Eligibility defects** and **Delays/Inaccuracies**

Eligibility Defects



Delays/Inaccuracies



Resolution pathway



How to Contact Today's Speakers

- Jason Atlas, Vice President, 340B Enterprise Strategy & Solutions @AmerisourceBergen
 - JAtlas@amerisourcebergen.com
- Ashley Mains Espinosa, VP, Clinical Operations, Pharmacy Advisor @DocStation & Co-founder, The 340B Collaborative
 - ashley@docstation.co
- Aaron Vandervelde, Founder and Business Development Lead, Managing Director @340B ESP, Berkeley Research Group, LLC
 - avandervelde@340besp.com
- Sue Veer, President and CEO @Carolina Health Centers, Inc.
 - sveer@carolinahealthcenters.org
- Ted Slafsky, President and CEO, 340B Report, LLC
 - ted.slafsky@340breport.com
- Tom Mirga, Editor in Chief and Lead Writer, 340B Report, LLC
 - tom.mirga@340breport.com

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