



# NEHIA/HFMA

## 2023 Compliance & Internal Audit Conference

Wednesday, November 29 – Friday, December 1, 2023  
Mystic Marriott Hotel, Groton, CT

# Navigating HRSA 340B Audits: Best Practice for Healthcare Compliance

## Operational Considerations and Compliance Planning

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# Disclosure of Integrity and Independence Statement

- Kristin A. Chupka RPh., PharmD, BCACP, 340B ACE declares no relevant financial relationships or commercial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, honoraria.

# Objectives

- Describe best practices in setting up a 340B Yearly Compliance Plan
- List the crucial components to review during a Self Audit
- Identify operational activities that supplement a compliant 340B Program

# About Dartmouth Health

- Comprised of Multiple Entities
  - Mary Hitchcock Memorial Hospital (DSH)
    - Ryan White Part C Grantee
    - Ryan White Part D Grantee
    - Hemophilia Treatment Center Grantee
  - Southwestern Vermont Medical Center (RRC)
  - Cheshire Medical Center (RRC)
  - Alice Peck Day Memorial Hospital (CAH)
  - Mt. Ascutney Hospital and Health Center (CAH)
  - New London Hospital (CAH)



# Dartmouth Health's 340B Program

- Dubbed the 340B Center of Excellence
- Team consists of 11 FTEs
  - 1 Program Manager
  - 4 Senior 340B Analysts
  - 1 Staff Pharmacist
  - 5 340B Analysts
- 5 Third Party Administrators



# Main 340B Considerations

- Eligible Site
  - Main Entity or Child
- Eligible Patient
  - Documentation of Patient Relationship with the Eligible Site
- Pharmacy Types
  - Clinic/Infusion
  - Entity Owned
  - Contract
  - Inpatient
- Medicaid- Do you carve in or carve out?
- Orphan Drug Exclusion
- GPO Purchasing Prohibition

# Building a formal Compliance Tracking Plan

- What do you need to verify each month, quarter, year?
- What volume of claims will you review?
  - Percent?
  - By number?
- What does the statute guide for principles?
- What might be tracked for reporting to your leadership?
- Policy/Procedures



# DH FY2024 Compliance Plan

- Yearly
  - 340B HRSA Recertification Activities
  - Complete FY External Audit
  - Review and complete Management action plan on Previous FY External Audit
  - Schedule External Audit for next FY
- Quarterly
  - Steering Committee Meeting
  - Review Contract Agreements
  - Review Medicaid Chart for updates
  - Review EMR Location and Patient Type Data



# DH FY2024 Compliance Plan (cont'd)

- Monthly
  - Workgroup Committee Meetings
  - Validate Prescribers (start and end)
  - Audit 340B Mixed Use (Clinic/Outpatient Administered Medications)
  - Audit Contract/Entity Owned Pharmacy Claims
  - Review all claim data for Orphan Drug inclusions (RRC/CAH)
  - Review GPO Mixed Use (Inpatient Administered Medications - DSH)

# Tracking Mechanisms

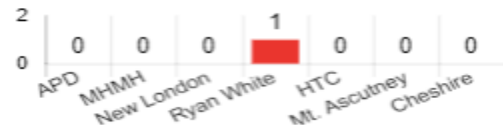
- Smartsheet

Ancestor	Level	W... H...	WBS ID	Task Name	Location	Don't Calculate in Percent Comple...	% Complete	Status
	0	0	0	FY 24 340b Compliance Tracker		<input type="checkbox"/>	22%	In Progress
FY 24 340b Compliance Tracker	1	0.1	1	340b Annual Compliance Activities		<input type="checkbox"/>	21%	In Progress
FY 24 340b Compliance Tracker	2	0.2	2	Quarterly Compliance Activities		<input type="checkbox"/>	21%	In Progress
FY 24 340b Compliance Tracker	3	0.3	3	Monthly Compliance Activities		<input type="checkbox"/>	15%	In Progress
FY 24 340b Compliance Tracker	4	0.4	4	As Needed - Develop Corrective Action Plan(s)		<input checked="" type="checkbox"/>	39%	In Progress
FY 24 340b Compliance Tracker	5	0.5	5	Other Operational Activites		<input checked="" type="checkbox"/>	9%	In Progress

# Tracking Mechanisms

- Dashboards

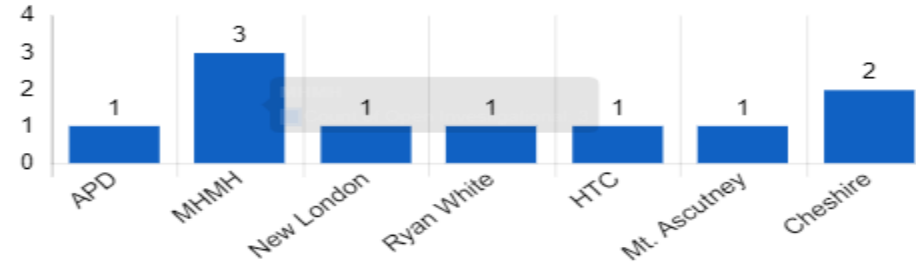
Count of Escalated Activities by Location



Count of Corrective Action Plans to Develop



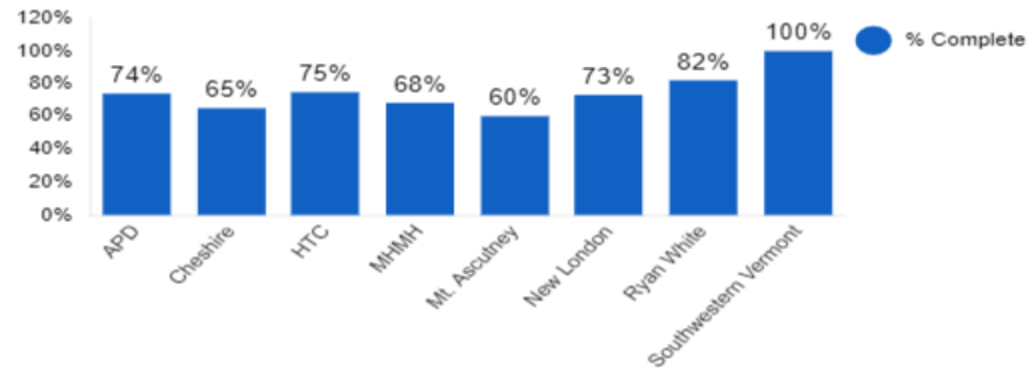
Open Investigational Activities by Location



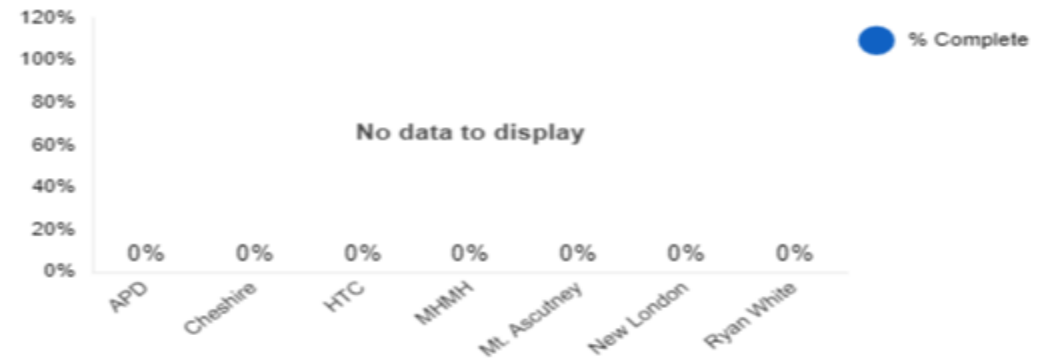
Open Activities by Quarter Reports

-  FY 24 Q1 Open Activities
-  FY 24 Q2 Open Activities
-  FY 24 Q3 Open Activities
-  FY 24 Q4 Open Activities

Quarterly % Completed-Q1



Quarterly % Completed-Q2



# Self Audits

- The **ONLY** way to understand your program
  - Extract Failures
  - Missed Opportunities
- HRSA only recommends 30 claims/month
  - Not realistic for claims insights
  - Non-Compliance findings may escape you
- Creative thinking to audit more with less
  - What can be reviewed en masse?
  - What needs to be reviewed in the EMR?



# Tracking Mechanisms

- Spreadsheets or other
  - Increased Accountability
  - Historical Records of Audit Counts
  - Could be requested by HRSA

100% TO AUDIT 1ST-15TH			
CONTRACT PHARMACY			
Audit built by			
Total claims			
Claims per person -2 SENIORS SPLIT 1 PERSON'S			
340B Teammate	Claims to Audit	Complete	Need Review
Amy			
Apryl			
Belma			
Dan	NA	NA	NA
Hannah			
Jeff			
Justin			
Kayla			
Merrill			
Shannon			
Suzy	NA	NA	NA
Actions Needed			
Historical			
Medicaid Chart			
Orphans			NA
CGP			
Nonmatched Provider			
Written After Term Date			
Medicaid Chart Verified by Jeff or Merrill			
Date Claims Reviewed by team			
Number of Reversals Sent & Date Sent			
Reversal Date/Confirmed By			
Additional Info			



# Tracking Mechanisms (cont'd)

- Spreadsheets or other
  - Increased Accountability
  - Historical Records of Audit Counts
  - Could be requested by HRSA

MHMH – TPA A - 100% TO AUDIT <b>1ST-15TH</b>			
CONTRACT PHARMACY			
Audit built by			Apryl
Total claims			1370
Claims per person			235/96
340B Teammate	Claims to Audit	Complete	Need Review
Amy	234	YES	3
Apryl	235	YES	0
Belma	235	YES	1
Dan	NA	NA	NA
Hannah	235	YES	3
Jeff	96	YES	1
Kayla	NA	NA	NA
Merrill	95	YES	0
Shannon	240	YES	0
Suzy	NA	NA	NA
Actions Needed			
Historical Audit?			NA
Medicaid Chart			0
Orphans			NA
CGP			0
Nonmatched Provider			0
Written After Term Date			0
Medicaid Chart Verified by Jeff or Merrill			6/30/23 jac
Date Claims Reviewed by team			6.28.23
Number of Reversals Sent & Date Sent			9 sent, 6.30.23
Reversal Date/Confirmed By			B.E on 6.30.23
Additional Info			



# Building an Operational Plan

- Drives Compliance Plan
- Confirms software program configurations align with compliance goals
- Closes gaps on Missed Opportunities
- Finds potential areas for future targeted compliance reviews



# DH Operational Plan

- Software
  - Update CMS Modifier Codes
  - True up any negative accumulations
  - Purchasing Invoice Gap Analysis
    - (did we load all invoices coming in by EDI?)
  - Upload Non-EDI Purchasing Invoices
  - Review Exceptions in 340B Software
  - Reverse Ineligible Claims findings from Audits
- Finance
  - Built by Monthly Finance Reporting
  - Quarterly Program Value Financials
  - Complete any Credit/Rebill Requests

# DH Operational Plan (cont'd)

- Programmatic Opportunities
  - Pending Claim Approvals
  - Referral Claim Approvals
  - 340B ESP Submissions
  - Manual Claim Uploads



# Thank you for your engagement

- Questions?

Kristin Chupka RPh, PharmD., BCACP, 340B ACE  
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SPEND MEND

HFMA-NEHIA Compliance and  
Internal Audit Conference

340B HOT TOPICS



Statement of Disclosure  
I have no conflicts of interest.

# OBJECTIVES

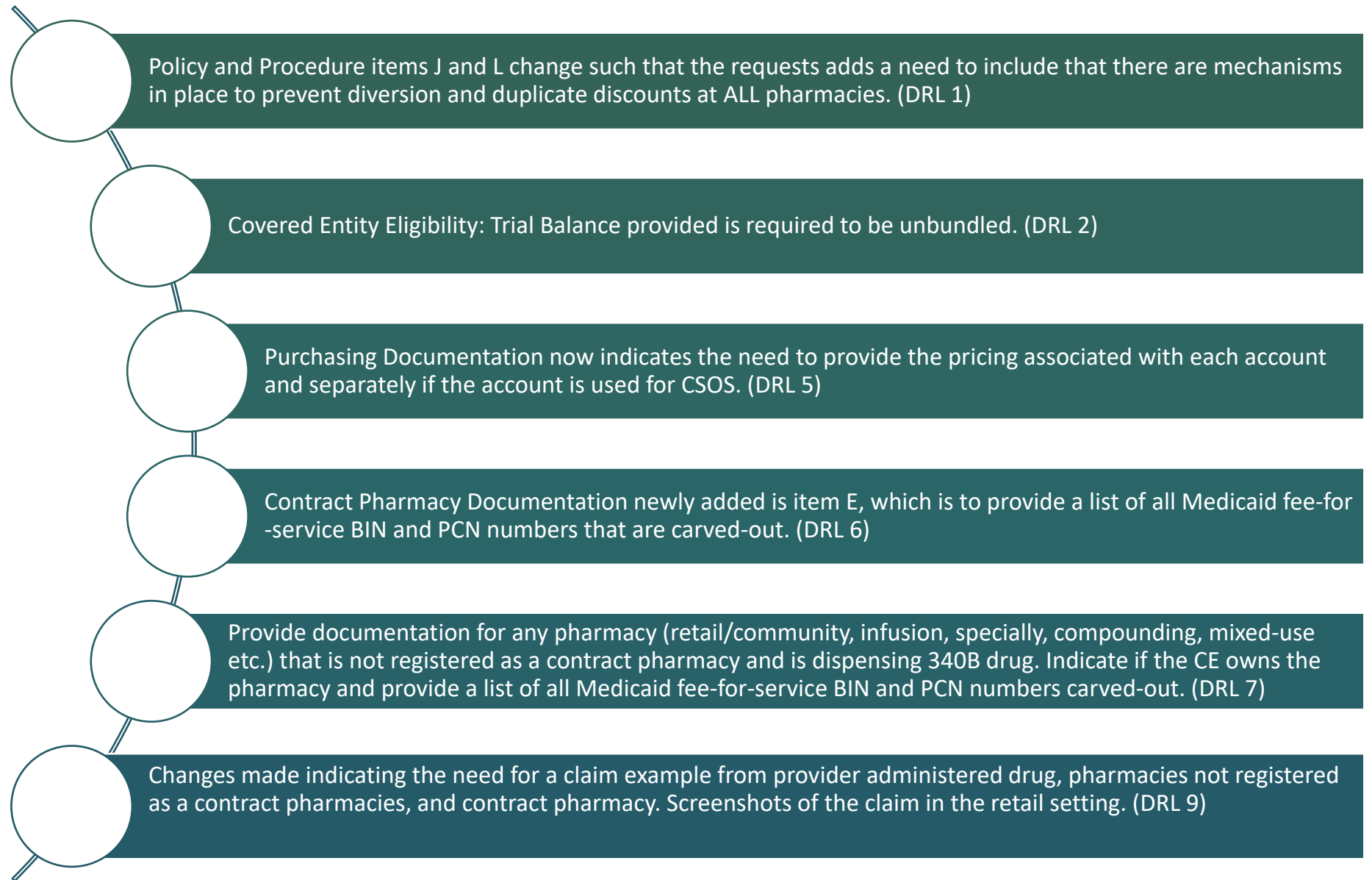
List the HRSA Data Request List (DRL) changes for FY24.

Describe Potential Risks of Using New 340B Location Immediate Eligibility.

Detail Current State of Drug Manufacturer Restrictions in 340B Contract Pharmacies.



# FY24 DRL AUDIT UPDATES





# HRSA AUDIT FOCUS

What has HRSA been focusing on during HRSA Audits in 2023 and FY2024?

- OPAIS database accuracy
- Duplicate Discount, especially out-of-state Medicaid Billing
- Updates from FY 2024 recent HRSA audit experience



# FAQ 4301 – TIMELINE OF CHANGES

- June 2020 – FAQ 4301 initially published
  - Apexus response to inquiries indicated that FAQ 4301 was reflective of HRSA’s interpretation of child site eligibility timing, independent of the COVID-19 PHE
- May 2023 – COVID-19 PHE expires May 11<sup>th</sup> & HRSA retires 340B-related flexibilities
  - May 8 – 340B Report reports that HRSA intends to retire FAQ 4301
    - Apexus responses to inquiries, at that time, was instruction to CEs to STOP 340B purchasing/qualification after May 11 for unregistered outpatient locations
  - May 12 – HRSA removes COVID-19 Resources page and Apexus removes FAQ 4301
    - HRSA indicates (via communication to 340B Health) that neither FAQ 4301 or the interim instructions from Apexus are in effect

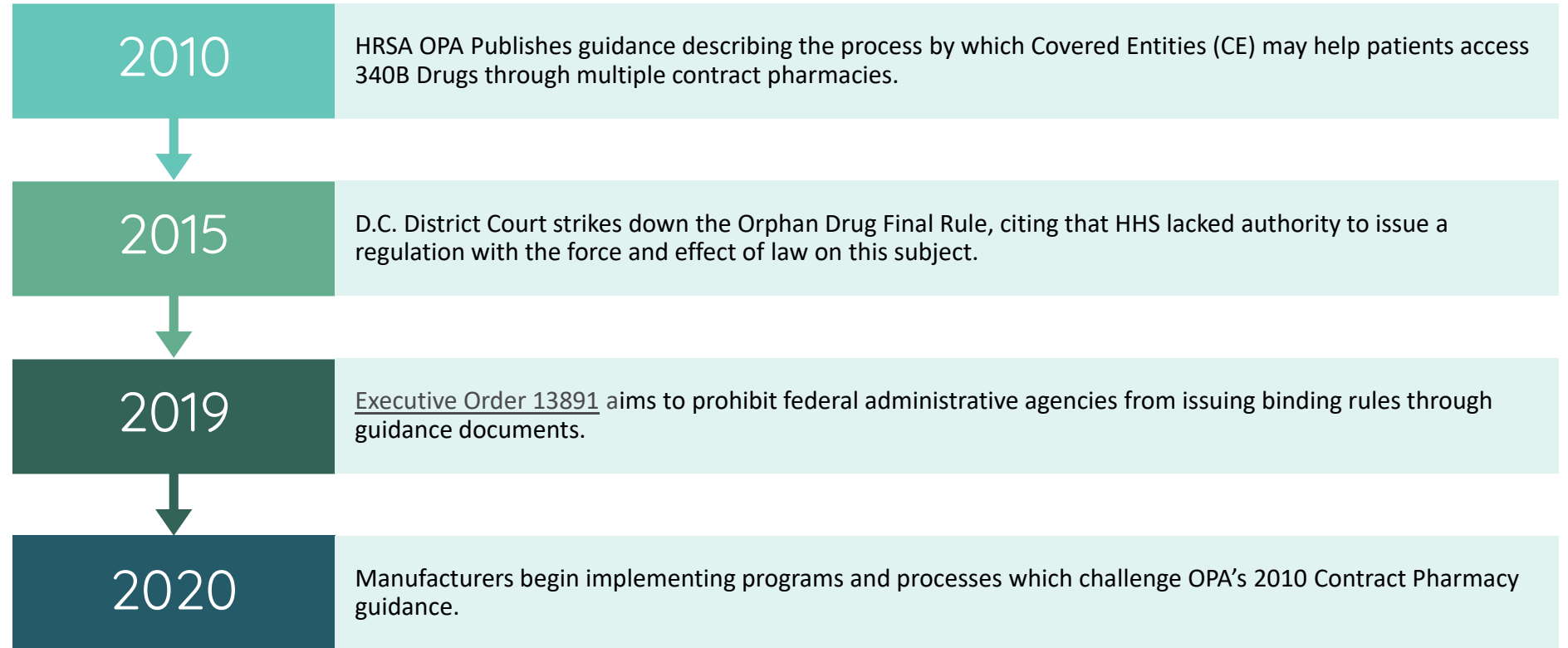
# 10/27/2023 HRSA NOTICE

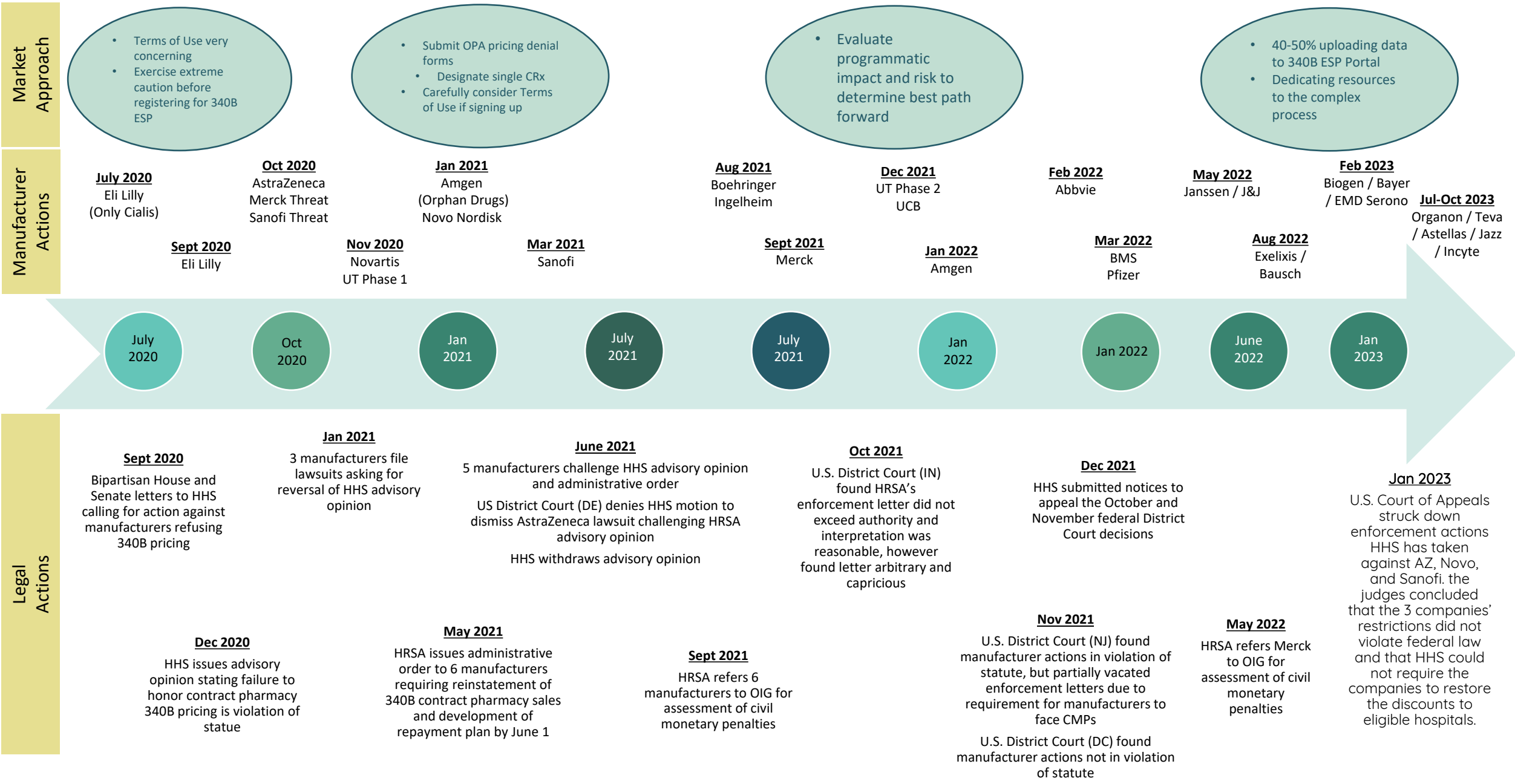
## Registration Requirements in the 340B Pricing Program

- Requiring eligible locations to be on a filed MCR.
- 90-day grace period.
- 90-days to send information in to be grandfathered-in if new location started prior to 10/27/2023.
- A lot of commentary on why they are doing this. Odd for a government Notice. . .



# BACKGROUND





# CURRENT

\*Updated as of 10/30/202

#	Manufacturer	Restriction Start Date	Allow Single Designation if No CE/(HS Owned Exception)	Claims Through 340B ESP for 340B Pricing at All CPs	Grantee Claim Submission to 340B ESP
1	Eli Lilly	9/1/2020	Yes: <a href="mailto:340B@lilly.com">340B@lilly.com</a>	Yes	Yes
2	AstraZeneca	10/1/2020	Yes: <a href="mailto:Membership@AstraZeneca.com">Membership@AstraZeneca.com</a>	No	No
3	Merck	10/1/2020	Yes: 340B ESP 40 miles (upload voluntary)	No	No
4	Sanofi	11/1/2021	Yes: 340B ESP	No	Yes
5	Novartis	11/16/2020	Yes: 340B ESP (HS Exception)	No	-
6	Novo Nordisk	1/1/2021	Yes: 340B ESP (HS Exception)	No	-
7	United Therapeutics	9/1/2020	Yes: 340B ESP	Yes	Yes
8	Boehringer Ingelheim	9/1/2021	Yes: 340B ESP (HS Exception)	No	No
9	Amgen	12/13/2021	Yes: 340B ESP (No HS Exception) – 40 miles <b>and</b> upload	No	-
10	UCB	12/13/2021	Yes: 340B ESP (HS Exception)	No	-
11	AbbVie	2/1/2022	Yes: 340B ESP (No HS Exception) – 40 miles <b>and</b> upload	No	-
12	BMS	3/1/2022	Yes: 340B ESP (HS Exception)	No	-
13	Pfizer	3/1/2022	Yes: 340B ESP (No HS Exception)	No	-
14	GlaxoSmithKline	4/1/2022	Yes: 340B ESP (HS Exception)	No	No
15	Gilead	5/2/2022	Yes: 340B ESP (HS Exception)	Yes	Yes
16	Johnson & Johnson	5/2/2022	Yes: 340B ESP (No HS Exception) – 40 miles <b>and</b> upload	No	-
17	Exelixis	8/1/2022	Yes: 340B ESP	Yes	-
18	Bausch Health	8/1/2022	Yes: 340B ESP (No HS Exception) – 40 miles <b>and</b> upload	No	No
19	Biogen	2/1/2023	Yes: 340B ESP (HS Exception)	No	-
20	Bayer	3/1/2023	Yes: 340B ESP (No HS Exception) – 40 miles	No	-
21	EMD Serono	3/1/2023	Yes: 340B ESP (HS Exception)	No	-
22	Organon	7/1/2023	Yes: 340B ESP (No HS Exception) <b>and</b> upload	No	-
23	Teva	7/5/2023	Yes: 340B ESP (No HS Exception) – 40 miles <b>and</b> upload	No	-
24	Astellas	9/1/2023	Yes: 340B ESP (HS Exception)	No	-
25	Jazz (Epidiolex)	10/9/2023	Yes: 340B ESP (No HS Exception)	No	-
26	Incyte (Opzelura)	10/16/2023	Yes: 340B ESP (No HS Exception) – 40 miles	No	-



# MANUFACTURER RESTRICTIONS UPDATES



Have there been further Manufacturer Restrictions since 10/1/2023?

# CURRENT

\*Updated as of  
10/30/2023

#	Manufacturer	Restriction Start Date	Allow Single Designation if No CE/(HS Owned Exception)	Claims Through 340B ESP for 340B Pricing at All CPs	Grantee Claim Submission to 340B ESP
1	Eli Lilly	9/1/2020	Yes: <a href="mailto:340B@lilly.com">340B@lilly.com</a>	Yes	Yes
2	AstraZeneca	10/1/2020	Yes: <a href="mailto:Membership@AstraZeneca.com">Membership@AstraZeneca.com</a>	No	No
3	Merck	10/1/2020	Yes: 340B ESP 40 miles (upload voluntary)	No	No
4	Sanofi	11/1/2021	Yes: 340B ESP	No	Yes
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6	Novo Nordisk	1/1/2021	Yes: 340B ESP (HS Exception)	No	-
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8	Boehringer Ingelheim	9/1/2021	Yes: 340B ESP (HS Exception)	No	No
9	Amgen	12/13/2021	Yes: 340B ESP (No HS Exception) – 40 miles <b>and</b> upload	No	-
10	UCB	12/13/2021	Yes: 340B ESP (HS Exception)	No	-
11	AbbVie	2/1/2022	Yes: 340B ESP (No HS Exception) – 40 miles <b>and</b> upload	No	-
12	BMS	3/1/2022	Yes: 340B ESP (No HS Exception)	No	No
13	Pfizer (27 drugs)	3/1/2022	Yes: 340B ESP (No HS Exception)	No	-
14	GlaxoSmithKline	4/1/2022	Yes: 340B ESP (HS Exception)	No	No
15	Gilead	5/2/2022	Yes: 340B ESP (HS Exception)	Yes	Yes
16	Johnson & Johnson	5/2/2022	Yes: 340B ESP (No HS Exception) – 40 miles <b>and</b> upload	No	-
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25	Jazz (Epidiolex)	10/9/2023	Yes: 340B ESP (No HS Exception)	No	-
26	Incyte (Opzelura)	10/16/2023	Yes: 340B ESP (No HS Exception) – 40 miles	No	-
27	Eisai (6 drugs)	11/01/2023	Yes: 340B ESP	No	-

# WHAT ARE OTHER ENTITIES DOING?

## Stay the Course

- Maximizing Exceptions
- Monitoring the Normalization of Data Submission
- Concerned About Future Risk

## Decided to Upload

- Recent Manufacturer Decisions “Broke the Camel’s Back” with Lost 340B Savings
- Cons Worth the Financial Benefit

## Alternate Strategies

- Emerging strategies to mitigate lost savings (e.g., alternate delivery models, CRx -> In-House Retail Rx conversion, HOD conversion, other qualification models)
- Varying operational complexity, financial impact, and untested through HRSA audits at this point

# Questions?

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*THANK YOU*