



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

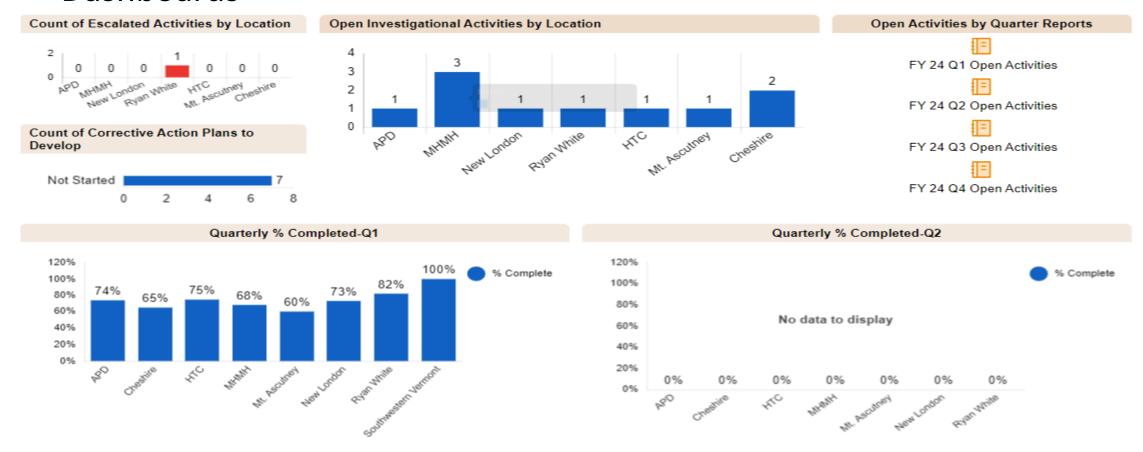
Ancestor	Level	W H	WBS ID	Task Name	Location	Don't Calculate in Percent Comple	% Complete	Status
J×	0	0	0	FY 24 340b Compliance Tracker			22%	In Progress
FY 24 340b Compliance Tracker	1	0.1	1	+ 340b Annual Compliance Activities			21%	In Progress
FY 24 340b Compliance Tracker	2	0.2	2	Quarterly Compliance Activities			21%	In Progress
FY 24 340b Compliance Tracker	3	0.3	3	■ Monthly Compliance Activities			15%	In Progress
FY 24 340b Compliance Tracker	4	0.4	4	 As Needed - Develop Corrective Action Plan(s) 		2	39%	In Progress
FY 24 340b Compliance Tracker	5	0.5	5	● Other Operational Activites		✓	9%	In Progress





Tracking Mechanisms

• Dashboards







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

	400455				
	100% TO AUDI				
	CONTRACT P	HARMACY			
Audit built by					
otal claims					
claims per person					
340B Teammate	Claims to Audit	Complete	Need Review		
Amy					
Apryl					
Belma					
Dan	NA	NA	NA		
lannah					
eff					
ustin					
(ayla					
Merrill					
Shannon					
Guzy	NA	NA	NA		
	Actions N	leeded			
Historical					
Medicaid Chart					
Orphans	NA				
CGP					
Ionmatched Provider					
Written After Tern					
Medicaid Chart Ve	rified by Jeff or I	Merrill			
Date Claims Revie					
Number of Revers					
Reversal Date/Con					
	Addition	al 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 1ST-15TH					
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 Prov	0				
Written After Tern	0				
Medicaid Chart Ve	6/30/23 jac				
Date Claims Revie	6.28.23				
Number of Revers	9 sent, 6.30.23				
Reversal Date/Cor	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?

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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.

HRSA AUDIT UPDATES AND
HRSA DATA REQUEST LIST
(DRL) CHANGES FOR FISCAL
YEAR 2024

FY24 DRL AUDIT UPDATES

Policy and Procedure items J and L change such that the requests adds a need to include that there are mechanisms in place to prevent diversion and duplicate discounts at ALL pharmacies. (DRL 1)

Covered Entity Eligibility: Trial Balance provided is required to be unbundled. (DRL 2)

Purchasing Documentation now indicates the need to provide the pricing associated with each account and separately if the account is used for CSOS. (DRL 5)

Contract Pharmacy Documentation newly added is item E, which is to provide a list of all Medicaid fee-for -service BIN and PCN numbers that are carved-out. (DRL 6)

Provide documentation for any pharmacy (retail/community, infusion, specially, compounding, mixed-use etc.) that is not registered as a contract pharmacy and is dispensing 340B drug. Indicate if the CE owns the pharmacy and provide a list of all Medicaid fee-for-service BIN and PCN numbers carved-out. (DRL 7)

Changes made indicating the need for a claim example from provider administered drug, pharmacies not registered as a contract pharmacies, and contract pharmacy. Screenshots of the claim in the retail setting. (DRL 9)

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

NEW 340B LOCATION IMMEDIATE ELIGIBILITY

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 11th & 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

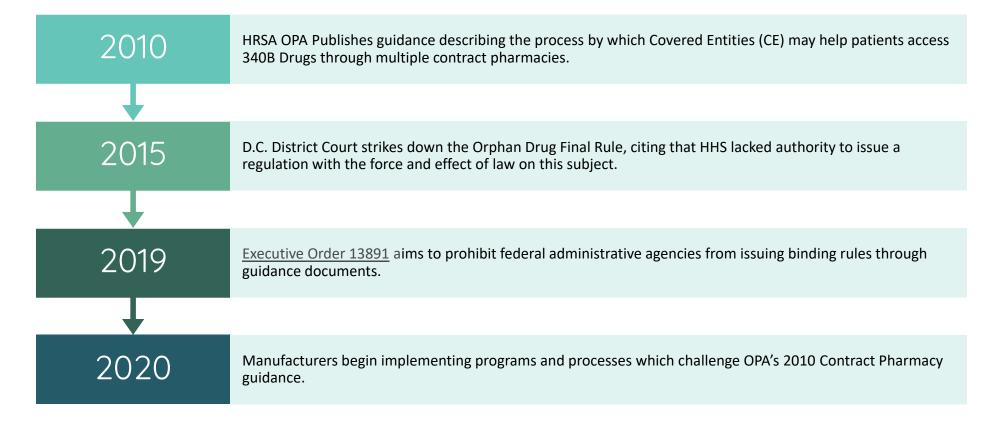
Registration Requirements in the 340B Pricing Program

- 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. . .

DRUG
MANUFACTURE
CONTRACT
PHARMACY
RESTRICTIONS

BACKGROUND







- Terms of Use very concerning Exercise extreme
- caution before registering for 340B ESP

July 2020

Eli Lilly Merck Threat (Only Cialis) Sanofi Threat

> Sept 2020 Eli Lilly

Oct 2020 AstraZeneca

Nov 2020 Novartis UT Phase 1

Submit OPA pricing denial

• Designate single CRx

Carefully consider Terms of Use if signing up

Jan 2021

Amgen (Orphan Drugs) Novo Nordisk

Mar 2021 Sanofi

Evaluate programmatic impact and risk to determine best path forward

Aug 2021

Boehringer Ingelheim

Dec 2021 UT Phase 2 UCB

Jan 2022

Amgen

Feb 2022 Abbvie

May 2022 Janssen / J&J Feb 2023

40-50% uploading data

to 340B ESP Portal

Dedicating resources

to the complex

process

Aug 2022

Exelixis /

Bausch

Biogen / Bayer / EMD Serono Jul-Oct 2023

Organon / Teva / Astellas / Jazz / Incyte

July 2020

manufacturers refusing

340B pricing

Oct 2020

Jan 2021

July 2021

July 2021

Sept 2021

Merck

Jan 2022 Jan 2022

Mar 2022

BMS

Pfizer

June 2022

Jan 2021

Sept 2020 Bipartisan House and Senate letters to HHS opinion calling for action against

3 manufacturers file lawsuits asking for reversal of HHS advisory

June 2021

5 manufacturers challenge HHS advisory opinion and administrative order

US District Court (DE) denies HHS motion to dismiss AstraZeneca lawsuit challenging HRSA advisory opinion

HHS withdraws advisory opinion

Oct 2021

U.S. District Court (IN) found HRSA's enforcement letter did not exceed authority and interpretation was reasonable, however found letter arbitrary and capricious

Dec 2021

HHS submitted notices to appeal the October and November federal District Court decisions

Nov 2021

U.S. District Court (NJ) found manufacturer actions in violation of statute, but partially vacated enforcement letters due to requirement for manufacturers to face CMPs

U.S. District Court (DC) found manufacturer actions not in violation of statute

May 2022

HRSA refers Merck to OIG for assessment of civil monetary penalties

Jan 2023

U.S. Court of Appeals struck down enforcement actions HHS has taken against AZ, Novo, and Sanofi. the judges concluded that the 3 companies restrictions did not violate federal law and that HHS could not require the companies to restore the discounts to eligible hospitals.

Dec 2020

HHS issues advisory opinion stating failure to honor contract pharmacy 340B pricing is violation of statue

May 2021

HRSA issues administrative order to 6 manufacturers requiring reinstatement of 340B contract pharmacy sales and development of repayment plan by June 1

Sept 2021

HRSA refers 6 manufacturers to OIG for assessment of civil monetary penalties

SPEND MEND

CURRENT

#	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: 340B@lilly.com	Yes	Yes
2	AstraZeneca	10/1/2020	Yes: Membership@AstraZeneca.com	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 <i>and</i> 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 <i>and</i> 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 <i>and</i> 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 <i>and</i> 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) <i>and</i> upload	No	-
23	Teva	7/5/2023	Yes: 340B ESP (No HS Exception) – 40 miles <i>and</i> 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	-

SPENDMEND

MANUFACTURER RESTRICTIONS UPDATES



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

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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	-
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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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