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AETC Program National Centers and HIV Curriculum

- **National Coordinating Resource Center** – serves as the central web –based repository for AETC Program training and capacity building resources; its website includes a free virtual library with training and technical assistance materials, a program directory, and a calendar of trainings and other events. Learn more: <https://aidsetc.org/>
- **National Clinician Consultation Center** – provides free, peer-to-peer, expert advice for health professionals on HIV prevention, care, and treatment and related topics. Learn more: <https://nccc/ucsf.edu>
- **National HIV Curriculum** – provides ongoing, up –to-date HIV training and information for health professionals through a free, web –based curriculum; also provides free CME credits, CNE contact hours, CE contact hours, and maintenance of certification credits. Learn more: www.hiv.uw.edu

Fundamentals of 340B Purchasing

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340B Policy and Compliance Director
Apexus



June 21, 2023

Learning Objectives

- Explain how 340B price are offered on covered outpatient drugs
- Review different price points loaded to 340B accounts
- Determine how to verify pricing accuracy and utilize Prime Vendor resources to support compliance purchasing
- Discuss pricing challenges and special situations

Covered Outpatient Drugs and 340B Pricing

340B Pricing Cornerstones

- Manufacturers participating in the Medicaid Drug Rebate Program (MDRP) must offer 340B prices on covered outpatient drugs (CODs) to participating covered entities
 - Must offer the 340B ceiling price (or below) to covered entities if the drug is made available to any other purchaser at any price
 - Calculation based on formula set by law



True or False?

- There is a public resource available to search active drugs of MDRP-participating manufacturers



← Data.Medicaid.gov Keeping America Healthy About Us Newsroom Data & Research

Open Data Datasets NADAC NCCI API Search

[Back to Drug Products in the Medicaid Drug Rebate Program](#)

Drug Products in the Medicaid Drug Rebate Program

Property	Operator	Value	
NDC	Is	12345678901	Delete filter

[+ Add filter](#) [Apply filters](#)

1 - 8 of 8 rows [Download filtered data \(CSV\)](#) [Copy link to filtered data](#) [Display settings](#)

Year	Quarter	Labeler Name	NDC	Labeler Code	Pro
2022	1	Manufacturer A	12345678901	12345	
2021	1	Manufacturer A	12345678901	12345	



MDRP website
 → Program Data
 → Drug Product Data

*Direct link available in
 HRSA FAQ #2583*



U.S. Department of Health and Human Services > HRSA > OPA

HRSA Office of Pharmacy Affairs

Health Resources & Services Administration 340B OPAIS

Home Search Reports/Files

12345 - Manufacturer A (Active)

Comment

Labeler Code	12345
Manufacturer Name	Manufacturer A
Manufacturer Sub Name	

Authorizing Official	Primary Contact	PPA Official	Addendum Official
Manufacturer A Leroy Anderson CEO (414) 123-4567	Manufacturer A Melanie Chen Director, Gov't Pricing (414) 123-7654	Allison Frost (973) 123-1212	

PPA Signed Date	1/7/1996
Addendum Signed Date	1/22/2017
HRSA PPA Co-Signed Date	12/6/1995
HRSA Addendum Co-Signed Date	1/29/2017
OPA Termination Date	
CMS Termination Date	
Termination Reason	
Termination Comment	

Street Address

1200 Innovation Way
Parsippany, NJ
07054

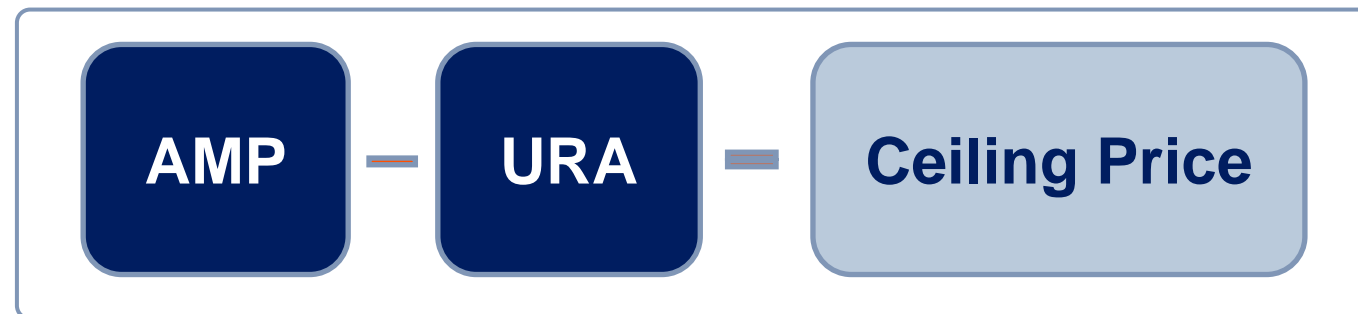
340B OPAIS website
 → Search
 → Manufacturers



Delivering 340B Pricing

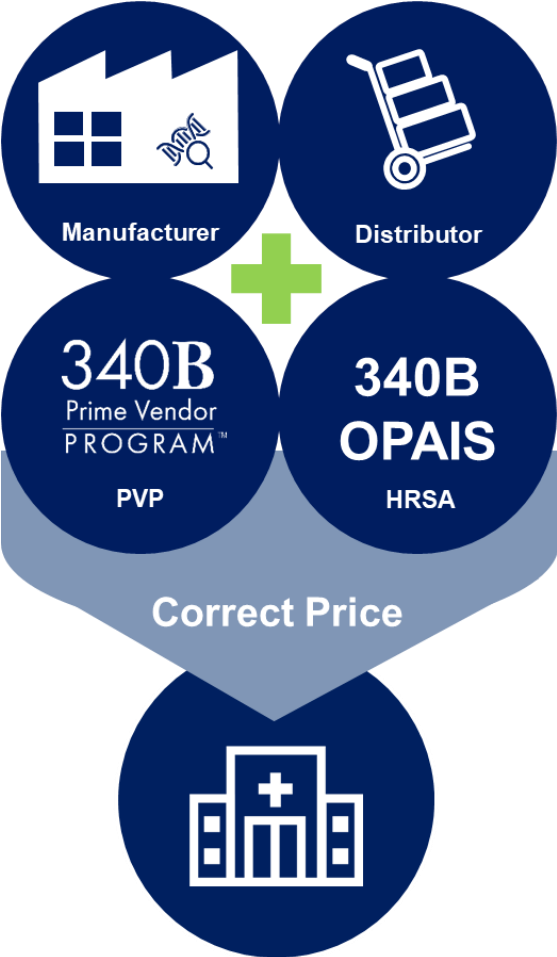
340B Ceiling Price Calculation

- Pricing components based on complex pricing formulas and reporting required by CMS
- HRSA publishes the 340B ceiling price quarterly in 340B OPAIS based on pricing data provided by the manufacturer



AMP = average manufacturer price
URA = unit rebate amount

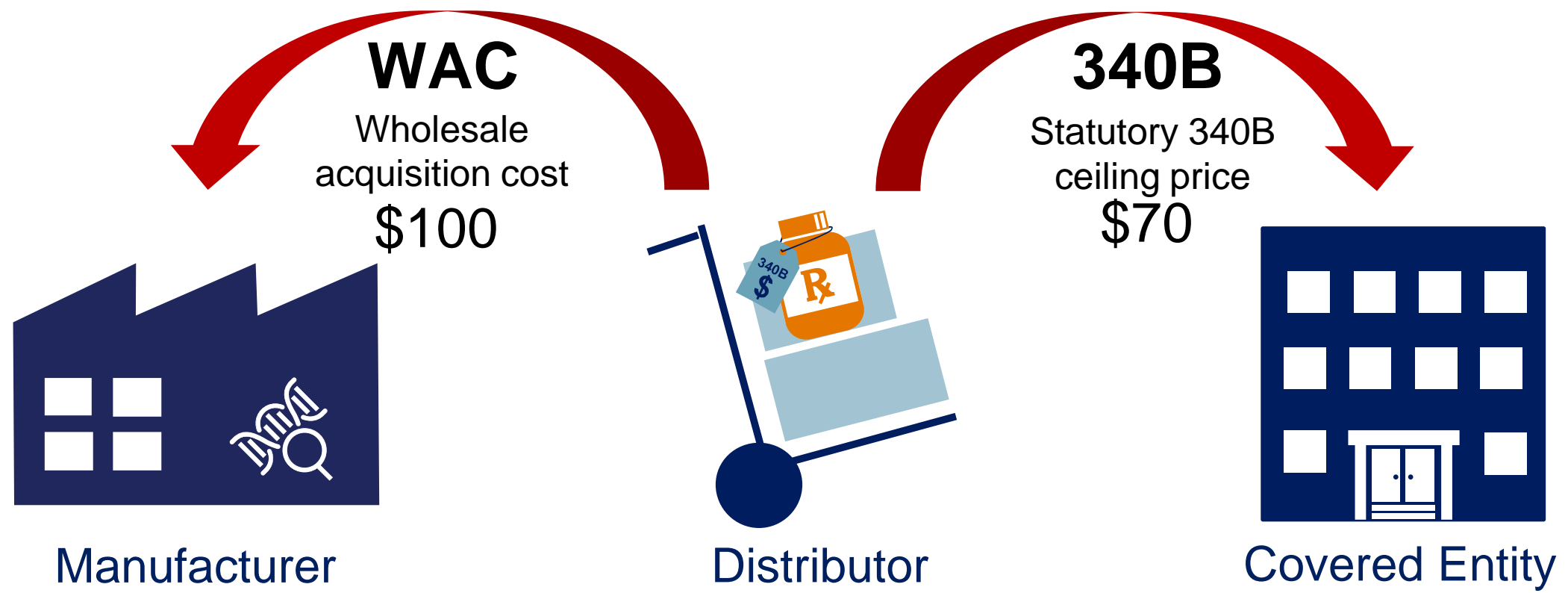
Working Together to Ensure Accurate Pricing



Distributor Roles and Responsibilities

- Open 340B accounts only for eligible entities
 - Various identifier (DEA, HIN, 340B ID)
 - Contract pharmacies present unique challenges
- Deliver correct price to 340B entities
- Integrate with 340B vendor software
- Provide support for limited distribution products
- Process chargebacks with manufacturer correctly

Chargeback Example



Manufacturer Roles and Responsibilities

- Offer covered outpatient drugs to 340B covered entities at a price no higher than the calculated ceiling price
- Calculate the 340B ceiling price and report pricing components to CMS
 - A 340B ceiling price that calculates to an amount $< \$0.01$ will be published in 340B OPAIS as \$0.01 and the manufacturer must charge \$0.01 per unit
 - Maintain records for at least 3 years
- Send quarterly price files to wholesaler for appropriate account loads
- Load and reconcile pricing data in 340B OPAIS quarterly



Manufacturer Roles and Responsibilities (continued)

- Verify covered entity eligibility based on chargebacks
- Estimate 340B ceiling price on the date the drug is first available for sale using WAC until AMP is available
- Offer repayment if entities are overcharged for 340B drugs
 - Manufacturers that “knowingly and intentionally” overcharge more than ceiling price may be subject to a civil monetary penalty (CMP) for each instance of overcharging plus repayment amount



True or False?

- 340B purchasing accounts are restricted to CODs with 340B pricing



Examples of COD pricing

- 340B ceiling price: manufacturer-calculated price for 340B CODs according to the statutory formula
- PVP sub-340B: contracted pricing available to PVP participants below the ceiling price negotiated by the Prime Vendor with the manufacturer on behalf of 340B CEs

Examples of non-COD pricing

- PVP value-added: contracted pricing available to PVP participants on non-CODs such as certain vaccines, blood glucose monitoring supplies, prescription vials and labels, etc.
- No contract pricing: price loaded at a non-contracted price, such as wholesale acquisition cost (WAC)

Verifying Pricing Accuracy

Case Study – 340B Price Validation

A pharmacy buyer goes to purchase a 340B drug and the list price is noticeably higher than the prior order

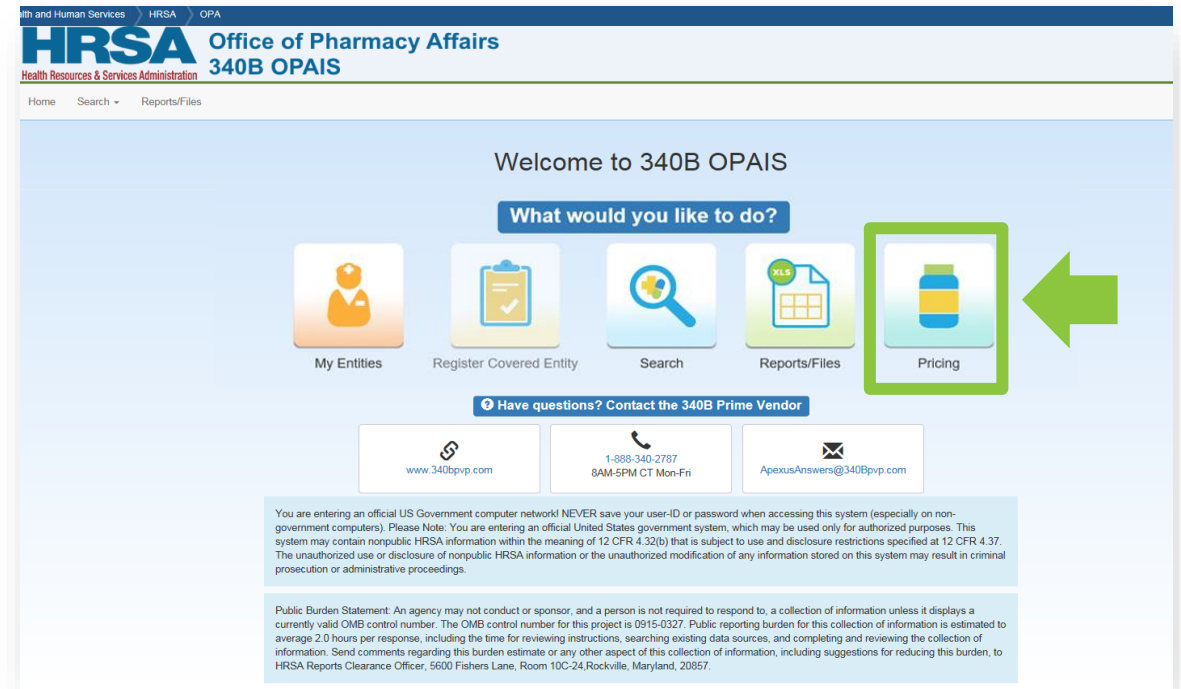


Invoice #4338		Date: 3/23/2023
Unit cost	Order quantity	Total
\$7.22	1 bottle	\$7.22

What could be reasons for price discrepancy?

Steps to Resolve an Inaccurate 340B Price

1. Check the labeler code on 340B OPAIS and/or MDRP website to help determine if the drug is a COD in MDRP and subsequently should have a 340B price
2. Validate the correct price using the 340B OPAIS pricing system (AO/PC)



Steps to Resolve an Inaccurate 340B Price

- 3. For Prime Vendor participants, verify the selling price accuracy by visiting the PVP secure website
- 4. Work with the distributor and/or manufacturer directly to resolve the pricing issue

340B PVP Catalog

Search for PVP Contracts, Products and Pricing

Refine Search:

CONTRACTED MANUFACTURERS + NON-CONTRACTED MANUFACTURERS + PRODUCTS +

NDC / Item #	Contract #	Manufacturer Name	Generic Name/ UNSPSC Category	Description	340B Account (Best Price)
+			omeprazole	OMEPRAZOLE DR 20 MG CAPSULE	\$17.19 PVP Contracted
+			omeprazole	OMEPRAZOLE DR 20 MG CAPSULE	\$12.16 PVP Contracted
+			omeprazole	OMEPRAZOLE DR 20 MG CAPSULE	\$15.26 PVP Contracted
+			omeprazole	OMEPRAZOLE DR 20 MG CAPSULE	\$26.99 340B Selling ←



Steps to Resolve an Inaccurate 340B Price

5. If necessary, contact OPA for further investigation

Contact OPA

Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W05A
Rockville, MD 20857

Notify OPA

<https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa.pdf>



340B Tools

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, please attach additional documentation as necessary to provide additional details (examples: screen shot of wholesaler catalog showing that 340B pricing is not available or lack of product availability; reports of eligible dispensations from third party vendor software that cannot be replenished; note: do not include PHI in documentation submitted to HRSA). HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Entity Background Information
Entity Name: _____ 340B ID: _____

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Please list the product(s) affected in the table below:

11-digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug Yes No
- The issue reported is limited to a contract pharmacy purchase Yes No
- If shortage-related, is this a recurrent/intermittent availability issue? Yes No
- If shortage-related, is this due to (please specify) local regional national global

Reason for lack of 340B access (check all that apply):

- Unavailable for purchase by covered entity
- Unavailable for purchase by covered entity through contract pharmacy
- Drug subject to limited distribution or specialty pharmacy plan
- Other (please describe): _____
- Unknown

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340B Prime Vendor Program | 888.340.BPVP (2787) | apexusanswers@340bpvp.com | www.340bpvp.com

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True or False?

- 340B OPAIS is the source of truth for ceiling price information



Case Study – Invoice Price Discrepancy

A pharmacy buyer tells you that the 340B invoice price of atorvastatin has changed since the last time you purchased it. You notice it's a new quarter and suspect the 340B price may have changed, so you navigate to 340B OPAIS to check the current price:

- Drug: Atorvastatin 40 mg 1,000 count bottle
- NDC: 12345-6789-01
- 340B invoice price from distributor: \$98
- 340B OPAIS lists ceiling price as \$0.10 and the package adjusted price as \$100

Case details:

- 340B invoice price from distributor: \$98
- 340B OPAIS lists ceiling price as \$0.10 and the package adjusted price as \$100

What is the difference between the ceiling price and the package adjusted price on 340B OPAIS?

Ceiling price (\$0.10) is calculated at the billing unit level

Package adjusted price (\$100) is calculated at the selling unit level and should reflect the same package size as the invoice

- Package size: 1,000 tablets
- Case package size: 1 bottle

What could be reasons that the invoice price (\$98) is different from the 340B OPAIS package adjusted price (\$100)?

- Wholesale distribution fees/discounts
- PVP-contracted pricing
- Individual manufacturer contracts on 340B account

PVP Contract Details

340B Prime Vendor PROGRAM
 MY HOMEPAGE | [CATALOG AND PRICING](#) | PURCHASING DECISION RESOURCES | MY PURCHASING ANALYTICS

340BFQHC PARTICIPANT

COVERED ENTITIES | MANUFACTURERS | DISTRIBUTION | 340B UNIVERSITY | HRSA FAQs | RESOURCE CENTER | ABOUT 340B & PVP | APEXUS ANSWERS

12345678901 – Atorvastatin 40mg Tablet

Manufacturer: Manufacturer A
 UNSPSC Category: N/A
 Contract: N/A
 Distribution Method: N/A
 Contract /Product Attributes ?

PRODUCT INFORMATION

ATORVASTATIN CALCIUM

Generic Name: atorvastatin calcium
 Trade Name: ATORVASTATIN CALCIUM
 NDC: 12345678901
 Item #: 12345678901

SPECIFICATIONS

Strength: 40 MG
 Dosage form: TABLET
 Package Quantity: 1 x1000EA
 Rx / OTC Indicator: F
 Rx / OTC Description: Prescription Required

CONTRACT DOCUMENTS

Your Best Price 340B Account **\$98.00^{EA}**
 340B Selling Price

Price Type	Effective Date	Current	Previous
WAC	07/25/2022	\$128.62	N/A
340B Selling	07/01/2022	\$98.00	\$98.00
PVP Contracted		N/A	N/A
AGP		N/A	N/A

DISTRIBUTION FEE IS: -2%

Change Or Manage Your Distributor
[Manage >](#)



Supporting Account Load Integrity

- PVP team reviews distributor price files to ensure accurate PVP contract price loads
- PVP provides a current list of participating covered entities to manufactures to assist with correct contract pricing access



Manufacturer Refund Process

- Manufacturer must contact covered entities and notify HRSA in writing on intention to issue refund
- HRSA may post the letter on its website:
<http://www.hrsa.gov/opa/manufacturernotices/index.html>
- Timeframe for new drug refunds: within 120 days of the determination by the manufacturer that an overcharge occurred
- For overcharges on other drugs, HRSA expects repayment procedures to follow similar processes that align with standard business practice and be documented in the manufacturer's policies and procedures
- The manufacturer may issue refunds to the covered entities directly, or use a service such as the Manufacturer Refund Service (through the PVP)



Takeaways

- Manufacturers and distributors have important roles in supporting program integrity
- There are resources available to verify the 340B ceiling price and manufacturers participating in MDRP
- It is important to understand the different types of pricing loaded to 340B accounts
- PVP secure website resources are available to participants to support compliant purchasing

Questions

June 21, 2023

