

A black and white photograph of classical building columns, likely from a government or institutional building, serving as a background for the title slide.

340B Uncharted: Navigating Pharma Restrictions, Evolving Interpretations and the Rebate Model Shift

Presented by Michelle Pinzon & Jeff Davis

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AGENDA:

1. Introduction to 340B
2. Contract Pharmacy Developments
3. 340B Rebate Models
4. HRSA Enforcement Activity
5. HHS Updates
6. Congressional Updates

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INTRODUCTION TO 340B

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History & Goals of the Program

- Section 340B of the Public Health Service Act created the 340B Pricing Program in 1992.
- This federal program requires drug manufacturers that participate in Medicaid Drug Rebate Program and Medicare Part B to offer discounts on covered outpatient drugs to eligible healthcare organizations (“covered entities”) (“CE”s)
- These CEs use 340B savings to stretch scarce resources, reaching more patients and providing more comprehensive services

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Oversight & Regulation

- HRSA: The Health Resources and Services Administration
 - Oversees the program
 - Ensures drug manufacturer and CE compliance with the program
- Two key areas in which HRSA ensures compliance:
 - **Duplicate Discounts**: Pharmaceutical manufacturers do not need to give both a 340B discount AND a Medicaid rebate for the same drug.
 - **Diversion**: CEs must not sell the drug to anyone other than the patient (but contract pharmacies can be used to dispense the drug to the patient).

Eligibility

- Categories of healthcare organizations eligible to be a CE listed in the 340B statute
- CE categories include recipients of federal grants (“grantees”) and hospitals
- 6 recognized hospital types:
 - Children’s Hospital
 - Disproportionate Share Hospital
 - Critical Access Hospital
 - Free-Standing Cancer Hospital
 - Rural Referral Center
 - Sole Community Hospital

CONTRACT PHARMACY DEVELOPMENTS

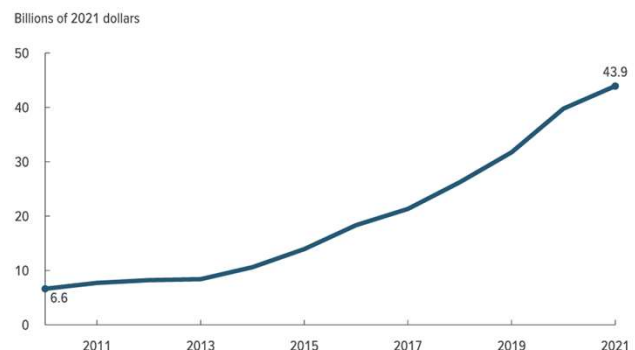
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Background

- Contract Pharmacies – retail, specialty, and mail order pharmacies that CEs contract with to dispense 340B acquired drugs, their use was initially limited.
- However, in 2010, HRSA allowed covered entities to work with an unlimited number.
 - As a result, drug manufacturers argued that the unlimited use of contract pharmacies has contributed to exponential growth program and compliance issues.
- In response, manufacturers imposed stricter restrictions.

Spending in the 340B Program, 2010 to 2021



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Restrictions & HHS Response

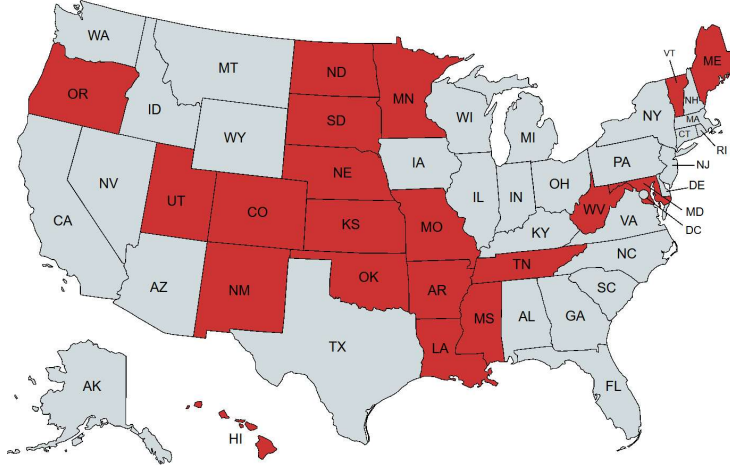
- Nearly 40 pharmaceutical manufacturers have implemented restrictions on the number and types of contract pharmacies that CEs can use to obtain 340B pricing.
- Some manufacturers have required CEs to provide data on 340B claims to obtain 340B pricing. These data requests have unfavorable terms like licensing of data, indemnification, and limitations on liability of the third-party data vendors hired by Pharma.
- Many manufacturers have limited CEs to one contract pharmacy location and only if they do not have their own entity owned in-house pharmacy.
- HHS issued an advisory opinion in 2020 asserting that the 340B statute requires manufacturers to supply drugs to an unlimited number of contract pharmacies.
- This triggered legal action from drug manufacturers who contested the HHS opinion, claiming it overreach HRSA's authority.

Court Rulings Favor Pharma

- Third Circuit, in *Sanofi* (2023), ruled against the HHS.
 - Determined that 340B does not compel manufacturers to deliver drugs to an unlimited number of contract pharmacies
- D.C. Circuit in *United Therapeutics and Novartis* (2024).
 - 340B statute does not inherently restrict manufacturers from setting conditions on the distribution of covered drugs to covered entities, including contract pharmacies
- Seventh Circuit, in *Eli Lilly* is still pending
 - Outcome of this case might influence whether the issue is escalated to the Supreme Court

State Contract Pharmacy Legislation

20 states* have passed laws prohibiting manufacturer contract pharmacy restrictions



* Rhode Island has passed a law that is awaiting signature. Oklahoma's law applies only to community health centers.

Stakeholder Reactions

- States are passing legislation banning contract pharmacy restrictions, and manufacturers are challenging state laws in court
 - Some states are requiring CE reporting requirements to ban contract pharmacy restrictions
- Covered entities are considering distribution options and ways to continue using the contract pharmacy model
 - Some manufacturer policies prohibit use of alternative distribution mechanisms
- Manufacturers are monitoring drug purchases and inquiring into purchasing aberrations
- In some cases, manufacturers are attempting to conduct their own audits of hospitals, seemingly related to their contract pharmacy use
- Five manufacturers have proposed 340B rebate models

340B REBATE MODELS

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340B Rebate Model Proposals

Johnson & Johnson (J&J)

Rebates for DSH hospitals for Stelara and Zarelto; HRSA did not approve and notified of potential enforcement actions; J&J paused and filed a lawsuit

Eli Lilly

“Cash replenishment model” for all CEs and all Lilly products via Kalderos; HRSA did not approve; Lilly filed a lawsuit (Kalderos has also filed a lawsuit)

Sanofi

“Credit model” for certain hospitals (DSH, CAH, RR, and SCH) and health centers for 25 products; patient definition component; HRSA did not approve and notified of potential enforcement actions; Sanofi filed a lawsuit

Bristol Myers Squibb (BMS)

Rebate model for Eloquis for all CEs; HRSA did not approve; BMS filed a lawsuit

Novartis

“Cash-rebate model” for all Novartis products for DSH hospitals; HRSA did not approve; Novartis filed a lawsuit

340B Rebate Proposals

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Drug manufacturers have historically provided 340B pricing through upfront discounts. Five manufacturers have proposed rebate models, under which CEs would purchase drugs at Wholesale Acquisition Cost (WAC), submit rebate requests with claims data after dispensing, and receive refunds if validated as 340B-eligible.

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Court Decision

- On May 15, 2025, a D.C. District Court judge issued a decision in four of the five cases ruling primarily for the government:
 - “In sum, the Court finds that HRSA did not act contrary to law by requiring the plaintiffs to obtain approval before implementing their proposed rebate models.”
 - “To the extent that the intervenors-defendants seek a declaration that rebates are categorically prohibited under the 340B statute, however, that portion of their cross motion will be denied.”
 - “The agency adequately distinguished the plaintiffs’ proposed rebate models from previously approved models, and it has not yet made a final decision on whether to accept the Lilly, BMS, and Novartis rebate proposals. With respect to Sanofi’s credit rebate proposal, however, the agency has made a final decision, and it has done so without providing adequate justification for its decision. Accordingly, the Court will remand that decision to the agency for further consideration of Sanofi’s proposal.”

Expected HRSA Guidance on 340B Rebates

NOTICE

Large-scale implementation of rebate models to effectuate the 340B ceiling price would be a significant change for the 340B Program and its stakeholders. Because the implications are not straightforward, the Department of Health and Human Services continues to carefully evaluate its options alongside ongoing efforts to address 340B program integrity matters and keeping in mind the approaching effective date of certain Inflation Reduction Act requirements. The Department expects to be in a position to provide guidance for stakeholders in thirty days.

Dated: May 2, 2025

Respectfully submitted,

Rebate Guidance Under Review

The screenshot shows the Reginfo.gov website header with the seal of the Executive Office of the President, the text "OFFICE of INFORMATION and REGULATORY AFFAIRS", "OFFICE of MANAGEMENT and BUDGET", "EXECUTIVE OFFICE of the PRESIDENT", and "Reginfo.gov". It also includes the U.S. General Services Administration (GSA) logo and a search bar with radio buttons for "Agenda", "Reg Review" (selected), and "ICR". A navigation bar contains links for "Home", "Unified Agenda", "Regulatory Review", "Information Collection Review", "FAQs / Resources", and "Contact Us".

Pending EO 12866 Regulatory Review

RIN: 0906-ZA14	Received Date: 06/01/2025
Title: 340B Rebate Guidance	Stage: Notice
Agency/Subagency: HHS / HRSA	Economically Significant: No
Legal Deadline: None	Affordable Care Act [Pub. L. 111-148 & 111-152]: No
International Impacts: No	Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]: No
Pandemic Response: No	

[View EO 12866 Meetings](#) [Request EO Meeting](#)

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Effects on Hospitals

- Hospitals would face substantial harm if these proposed rebates were to be implemented –
 - “UMMC (UMass Memorial Medical Center) would need to spend nearly \$400,000 on staffing and legal fees just to comply with J&J’s rebate requirements and would need to pay an additional \$24 million a year to purchase *Stelara* and *Xarelto* at full price upfront.”
 - GenesisHealthCare System, in Zanesville, Ohio, “would need to spend more than \$200,000 a year to comply with the J&J rebate requirements and an additional \$300,000 a year to purchase the two J&J drugs at full price, with that upfront cost rising to more than \$62 million per year if the rebates expanded to all 340B drugs.”
- Invariably, this would threaten hospitals 340B initiatives like free care to low-income individuals, patient or prescription drug assistance programs, mental health counseling, mobile care clinics, social support, etc.

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Effects on Hospitals (cont'd.)

- Administrative Burden –

- Rebate models require data, e.g., patient encounter, prescription, and drug purchasing data, which require new systems that are currently not set up.
- States require 340B providers to use specific modifiers on their Medicaid claims to indicate that a drug was purchased through the 340B program.
- If the 340B discount isn't realized until after the claim is submitted to Medicaid, it becomes difficult to accurately use these modifiers. The hospital wouldn't know for certain at the time of billing whether a drug ultimately qualifies for 340B rebate. Medicaid could reject or delay claims with incorrect modifiers, impacting cash flow.

- Financial Burden –

- If hospitals do not submit data, it would result in the hospitals not getting the rebate
- 340B providers would need to purchase drugs at full price upfront, tying up significant capital while waiting for rebates, which could strain their finances. They would be required to float hundreds of thousands with no guarantee a manufacturer will approve a rebate request and issue a refund.

HRSA Enforcement Actions



Covered Entity Diversion Audit Findings

Audit results

Audits of covered entities – results by fiscal year

- [FY 2025 Audit Results](#) (updated 5/6/25)
- [FY 2024 Audit Results](#) (updated 5/6/25)
- [FY 2023 Audit Results](#) (updated 5/6/25)
- [FY 2022 Audit Results](#) (updated 3/26/25)
- [FY 2021 Audit Results](#) (updated 10/28/24)
- [FY 2020 Audit Results](#) (updated 1/31/23)
- [FY 2019 Audit Results](#) (updated 8/30/24)
- [FY 2018 Audit Results](#) (updated 11/28/23)
- [FY 2017 Audit Results](#) (updated 11/28/23)
- [FY 2016 Audit Results](#) (updated 12/1/23)
- [FY 2015 Audit Results](#) (updated 2/25/20)
- [FY 2014 Audit Results](#) (updated 2/20/19)
- [FY 2013 Audit Results](#) (updated 5/30/18)
- [FY 2012 Audit Results](#) (updated 7/14/17)

New Findings

- Diversion - 340B drug dispensed at contract pharmacy for prescription written at ineligible site.
- Diversion - 340B drug dispensed for prescription written at ineligible site.

Manufacturer Audit Findings

Audits of manufacturers – results by fiscal year

- [FY 2025 Mfr Audit Results](#) (updated 5/20/25)
- [FY 2024 Mfr Audit Results](#) (updated 5/20/25)
- [FY 2023 Mfr Audit Results](#) (updated 3/28/25)
- [FY 2022 Mfr Audit Results](#) (updated 9/12/23)
- [FY 2021 Mfr Audit Results](#) (updated 8/29/22)
- [FY 2020 Mfr Audit Results](#) (updated 9/22/21)
- [FY 2019 Mfr Audit Results](#) (updated 3/19/21)
- [FY 2018 Mfr Audit Results](#) (updated 5/23/19)
- [FY 2017 Mfr Audit Results](#) (updated 9/11/18)
- [FY 2016 Mfr Audit Results](#) (updated 9/11/18)
- [FY 2015 Mfr Audit Results](#) (updated 9/11/18)

New Findings

- 23 findings requiring repayment to CEs since FY 2018
- HRSA began collecting pricing data from manufacturers in 2019

Alternative Dispute Resolution (ADR) Process

- On May 15, 2025, HSRA issued its first decision in the ADR Process
- The ADR Panel ruled in favor of the manufacturer, finding there was no overcharge

“There is no overcharge violation in Petition ID 240723-0024, consistent with the rulings of the U.S. District Court for the District of Delaware and U.S. Court of Appeals for the Third Circuit with respect to AstraZeneca’s contract pharmacy policy.”

<https://www.hrsa.gov/opa/340b-administrative-dispute-resolution/340b-adr-decision-summaries>

HHS UPDATES



HHS Updates

- White House budget proposal indicates HHS plans to move administration of 340B from HRSA to CMS
- April 15, 2025, Executive Order
 - Directs CMS to survey hospital drug acquisition costs and consider reducing Medicare Part B payments to hospitals based on survey data
 - Directs HHS to ensure grants to FQHCs are conditioned on making insulin and injectable epinephrine available at or below the 340B price to certain low-income individuals
 - June 24, 2025, HHS issued updated award terms
- May 12, 2025, Executive Order directs HHS to facilitate direct-to-consumer purchasing programs for manufacturers to sell drugs to patients at the “most favored nation” (MFN) price and propose rulemaking to impose MFN pricing if necessary
- CMS continues to implement Inflation Reduction Act (IRA) Medicare negotiation program
- Litigation continues challenging HRSA’s policy on hospital child site registrations

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CONGRESSIONAL UPDATES

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Senate 340B Bipartisan Working Group

Jerry Moran
(R-KS)

Shelley
Moore Capito
(R-WV)

Markwayne
Mullin
(R-OK)

Tammy
Baldwin
(D-WI)

Tim Kaine
(D-VA)

John
Hickenlooper
(D-CO)

Senate HELP Committee Majority Staff Report

CONGRESS MUST ACT TO BRING NEEDED REFORMS TO THE 340B DRUG PRICING PROGRAM

MAJORITY STAFF REPORT



APRIL 2025

1. Requiring covered entities to provide detailed annual reporting on how 340B revenue is used to ensure direct savings for patients, providing a more transparent link between program savings and patient benefit
2. Addressing potential logistical challenges caused by increased administrative complexity, leading to burdens that may impede patient benefit from the program
3. Investigating the types of financial benefits contract pharmacies and TPAs receive for administering the 340B Program to ensure that increasing fees do not disadvantage covered entities and patients
4. Requiring transparency and data reporting for entities supporting participants in the 340B Program (i.e., contract pharmacies and TPAs)
5. Providing clear guidelines to ensure that manufacturer discounts actually benefit 340B-eligible patients, including examining legislative changes to the definition of eligible patient and contract pharmacies' use of the inventory replenishment model.

THANK YOU!



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Questions

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