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Lead

340B Drug Pricing Program

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Association of
American Medical Colleges

340B Program: Background

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Overview: 340B Drug Pricing Program

Valuable program for hospitals

- *76% of AAMC member teaching hospitals participate in the 340B Program*

No cost to taxpayers

Allows hospitals to use savings derived from the Program to expand services to vulnerable populations

Represents a small percentage of U.S. drug sales

Critics of the Program include drug companies and some insurers

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What is the 340B Drug Pricing Program?

Enacted in 1992, Section 340B of Public Health Service Act

"to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"

Drug manufacturers must participate in the 340B Program in order to have their drugs covered under Medicaid and Medicare Part B and are required to sell covered outpatient drugs to certain safety-net providers (known as "covered entities") at a reduced or same price as given to Medicaid

Drugs can only go to eligible patients

Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs administers 340B Program

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How does it work?

Drug companies sell covered outpatient drugs at a discount to covered entities participating in the 340B Program

Discount based on formula in statute that is used to calculate Medicaid rebates

- Manufacturer cannot charge more than the 340B ceiling price
- 340B ceiling price = AMP minus unit rebate amount (set in statute)

Savings accrued when

- Insurer pays for 340B discounted drug at same rate it pays for non-340B drug; patient does not have to be low income to receive 340B drugs
- Hospitals use savings to provide items and services, including Rx, to low-income, under-served patients

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Covered Entities – Who can participate?

Hospitals

1. owned or operated by state or local government
2. a public or private non-profit corporation which is formally granted governmental powers by state or local government, or
3. a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare

Non-hospital sites

- Federally-qualified health centers (FQHCs), AIDS / Ryan White Clinics, tuberculosis clinics, black lung clinics, Title X family planning clinics, STD clinics, hemophilia treatment centers, Urban Indian clinics, Native Hawaiian health centers

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Hospital Categories

Most hospitals qualify by having sufficient Medicare disproportionate share (DSH) hospital adjustment percentage

Type of Hospital	DSH adjustment percentage
Disproportionate Share Hospitals (1992) Children's Hospitals* (2005) Free-standing Cancer Hospitals* (2010)	>11.75%
Rural Referral Centers (2010) Sole Community Hospitals (2010)	>8%
Critical Access Hospitals (2010)	No DSH adjustment percentage required

*Although free-standing children's hospitals and free-standing cancer hospitals do not receive DSH adjustment payments, they must have a payer mix that would give them a DSH percentage of greater than 11.75 percent.

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Non-hospital site: Ryan White HIV/AIDS Program (Ryan White Clinics)

Safety-net providers who receive Federal funding from HRSA to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured

Federal funding is used for technical assistance, clinical training, and the development of innovative models of care

340B savings must be used for services within the clinic

- Provide prescription drugs to needy patients at no or reduced cost
- Assist patients with their insurance premiums
- Provide medical services at little or no cost to needy patients

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Group purchasing organization prohibition

DSH hospitals, children's hospitals and free-standing cancer hospitals that participate in the 340B Program may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangements"

DSH hospital with an in-house pharmacy may *not* use a GPO to purchase drugs for our non-340B eligible patients that receive services at sites registered as part of the 340B

Prime Vendor Program

- Prime Vendor negotiates pricing discounts with participating manufacturers
- Voluntary program for covered entities and manufacturers
- No fee to enroll for eligible covered entities

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340B Program and Medicaid

Prevention of “duplicate discounts”

- Manufacturers do not have to pay a 340B discount and a Medicaid rebate on the same drug
- Complicated reporting requirements imposed on hospitals to prevent this from happening in the fee-for-service world
- No federal requirements as to how to prevent this for Medicaid managed care

CMS issued guidance on best practices for avoiding duplicate discounts (Jan. 8. 2020)

Not all 340B hospitals use 340B for Medicaid patients; may opt out

Federal legislative proposals would increase rebates to Medicaid which could decrease 340B use for Medicaid patients

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340B Eligible Patient

340B law prohibits the resale or transfer of discounted outpatient drugs to anyone other than a patient of the covered entity (e.g., diversion)

Definition of *eligible patient*:

- The patient is an outpatient of the covered entity (e.g., hospital)
- The covered entity maintains records of the patient's healthcare.
- The patient receives healthcare from healthcare professionals employed or contracted by the covered entity (i.e., responsibility of care remains with covered entity).
- The patient receives healthcare services beyond simply the dispensation of a drug.

An individual is not considered a patient of the covered entity if the only health care service received by the individual from the entity is the dispensing of a drug for subsequent self-administration or administration in the home setting

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340B Program: Fact v. Fiction

Drives high drug prices

- *No cost to taxpayers*
- *HRSA estimates 340B sales ~5% of total U.S. drug market*
- *Drug price increases drive costs, drugmakers collectively increased prices on 929 drugs in January 2021*

Hospital eligibility should be tied to hospitals' level of charity care; to help low-income individuals; should only be used for uninsured; pass discounts on to patients

- *Not a requirement. Savings used to expand services, including Rx, to vulnerable populations*

Lack of oversight

- *Hospitals invest in oversight activities to ensure compliance*
- *HRSA audits; sophisticated tracking systems for 340B drugs*

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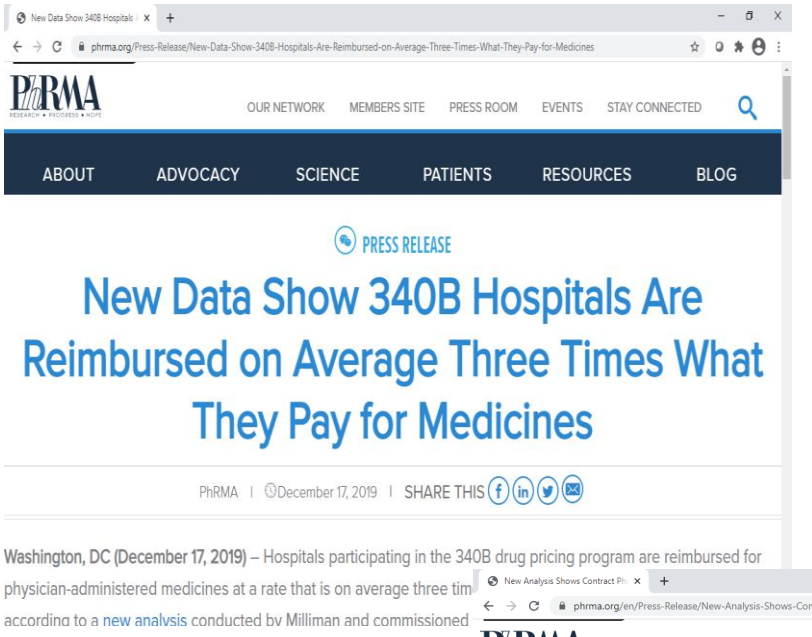
Drug manufacturers oppose 340B



Contract Pharmacies' Troubling Role in the 340B Drug Discount Program

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How are Pharma Companies doing?

Bristol Myers Squibb™

2020 full-year revenue of $42.5 Billion.
Eliquis sales rose 12% to $2.3 billion Q4 2020.

Eczema drug, ***Dupixent***, sales increased 54% in 2020 Q4, $1.2 billion.

SANOFI

MERCK

Keytruda sales accounted for just under $4 billion in 2020 Q4.

Humira, the world's best-selling drug, sales rose 4.8% to $5.2 billion in Q4 2020.

abbvie

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Compliance & Legal Issues

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Compliance

Annual recertification required

CE can be audited by HRSA or manufacturers:

- Eligibility (GPO prohibition)
- Duplicate Discounts (Medicaid/340B)
- Diversion (not eligible outpatient)
- FY2017-FY2020:~ 200 audits of CEs each year

HRSA audits of manufacturers

- ~ 5 audits per year, FY2017-FY2020

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ADR Final Rule

Alternative Dispute Resolution: Issued January 13, 2021

To resolve complaints:

- By CEs that they've been overcharged for drugs by manufacturers
- By manufacturers that after audit CE has violated prohibitions on diversion or duplicate discounts

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Community (Contract) Pharmacies

- ~1/3 of CEs contract with community pharmacies
  - CAHs: 74.1% have community pharmacies
  - DSH Hospitals: 66% have contract pharmacies
  - Free-standing cancer hospitals: 66%
  - Sole Community Hospitals: 66%
  - Rural Referral Centers: 64%
  - Children's Hospitals: 40%

Names of contract pharmacies must be registered with HRSA; signed agreement between CE and community pharmacy

GAO Report, Federal Oversight of 340B Contract Pharmacies Needs Improvement, June 2018

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Contract Pharmacies: Advisory Opinion

HHS Office of General Counsel, December 2020:

> For these reasons, the Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.

Let's call them "community pharmacies"

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340B Litigation

- ✓ 340B Drug Ceiling Prices and CMPs—a win!
- ✓ 340B Drug Pricing: writ of cert. to Supreme Court filed February 2021
- ✓ 340B Contract Pharmacy Litigation filed by drug companies in California, Delaware, New Jersey against HHS
  - ✓ Motions to intervene

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Legislative Update

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Lay of the Land

- Divisive and Political Issue
  - Hospital associations, providers, patient groups, other covered entities (Ryan White Clinics, FQHCs, etc.)
  - Drug manufacturers, PhRMA, Community Oncology Alliance

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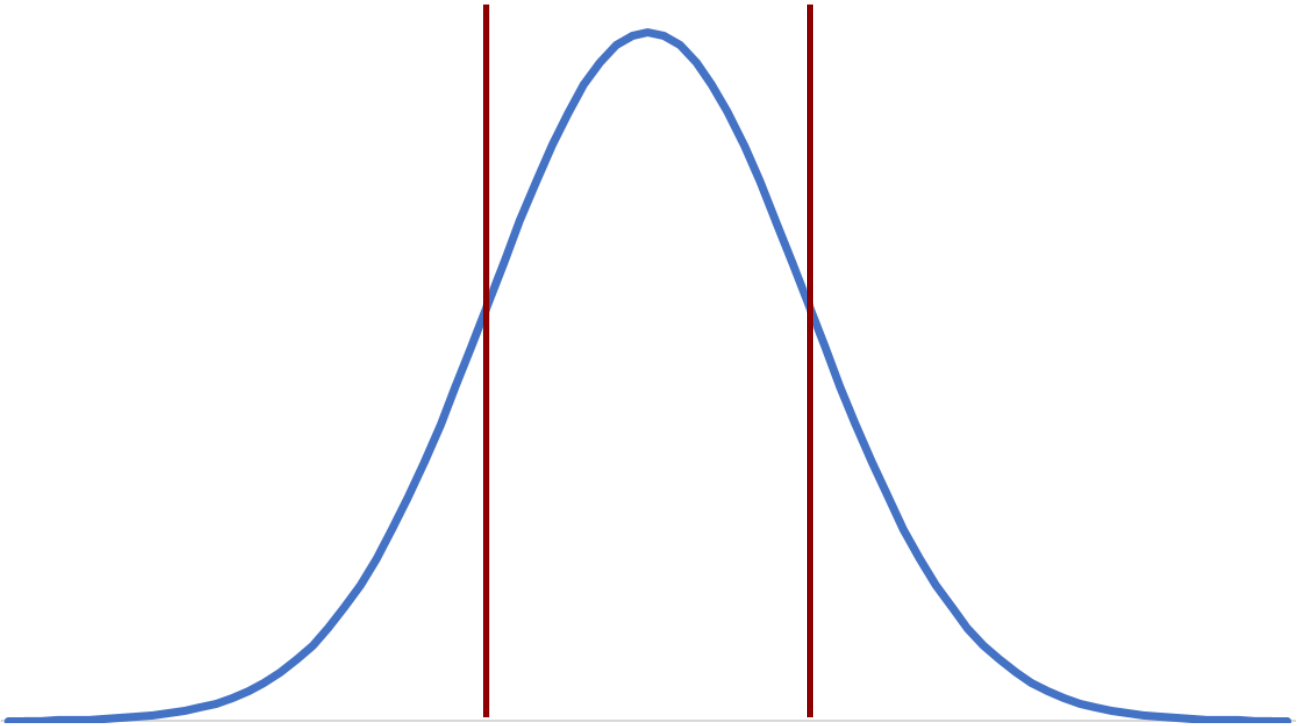
Legislative History



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Legislative History

Where We Were (2017-2019ish)

- House, Senate, Administration Make-Up
- House Energy and Commerce Investigation
- House, Senate Hearings
- House, Senate Bills to Reduce Scope of the Program, including:
  - Reduce eligibility (charity care, DSH%, etc.)
  - Increase burdensome reporting
  - Moratorium on new DSH hospitals
  - User Fees

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Legislative History

Where We Were (continued)

- AAMC Response
  - Oppose legislative/regulatory efforts to reduce the program
  - Build bipartisan champions in House, Senate
  - Encourage 340B hospitals to share their story
  - Endorse AHA 340B Hospital Commitment to Good Stewardship Principles

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Legislative History

Where We Were (continued)

- So what happened???
  - No major 340B legislation passed
  - Hospitals became more comfortable talking about their 340B programs
  - New bipartisan 340B champions

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Legislative Update

- Where We Are Now
- House, Senate, Administration Make-Up
- 340B/COVID-19 Legislation to Maintain Eligibility Throughout the PHE (DSH threshold)
  - AAMC-supported bills last congress:
    - H.R. 7838, Reps. Doris Matsui (D-Calif.) and Chris Stewart (R-Utah)
    - S. 4160, Sens. Thune (R-S.D.), Stabenow (D-Mich.), Portman (R-Ohio), Baldwin (D-Wisc.), Capito (R-W.Va.), Cardin (D-Md.)
  - Not yet re-introduced this congress

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Legislative Update

Other Major Issues

- Community Pharmacies and Rebates
  - “Kalderos Issue” – unilateral change from up-front discount to post-sales rebate
- Hill Response – Bipartisan Letters to HHS
  - Sept. 2020: House (250), Senate (28) letters
  - Sept. 2020: House E&C Leaders Letter
  - Nov. 2020: House letter (200)
  - Jan. 2021: Senate HELP Committee Chair Patty Murray (D-Wash.) and Sen. Baldwin (D-Wisc.)
  - Feb. 2021: House letter (226)

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Legislative Update

Where We're Going

- No news is good news
- Maintain 340B eligibility during PHE
- Remain vigilant
- Drug pricing legislation
- Continue to highlight the benefits of the 340B program
- AAMC outreach – Hill/Committee staff, other hospital associations, 340B Working Group
- https://www.aamc.org/news-insights/340b

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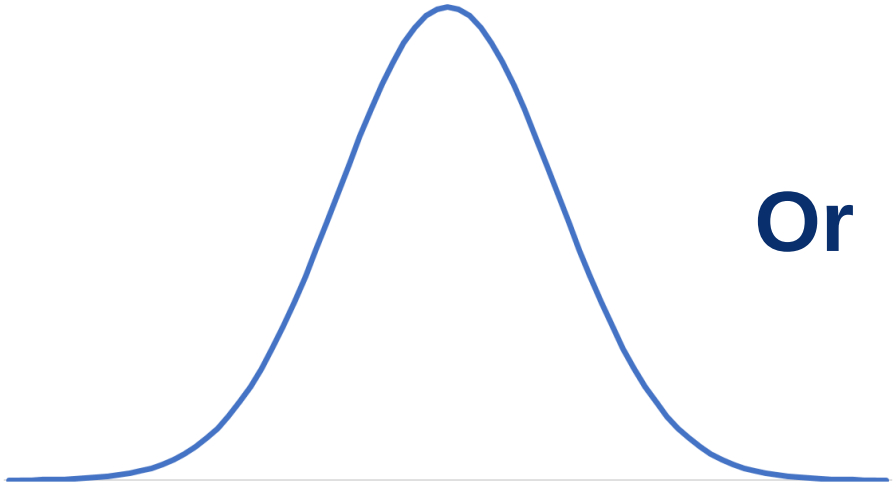
Where We're Going



Or

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HEALTH CARE

‘Repeal and replace’ is dead. Republicans can’t figure out what comes next.

Nowhere has the post-repeal Republican vacuum been more evident than in two days of Senate confirmation hearings this week for the likely next Health secretary, Xavier Becerra. Republicans seldom mentioned the landmark health care law, let alone critiqued it, across five-plus hours of testimony. They spent almost as much time quizzing Becerra, a longtime House member who is now California attorney general, about an obscure federal drug discount program called 340B that pharmaceutical companies and hospitals are feuding over than they did about the health care wars of the past decade.

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