2022 NCOIL Summer Meeting

Joint State-Federal Relations & International Insurance Issues Committee

The 340B Program
The Parties & The Disputes

Thursday, July 14, 2022

Miranda C. Motter
AHIP SVP, State Affairs and Policy
mmotter@ahip.org

Today's Agenda

- **The 340B Program**
  - Purpose
  - Participants
  - How it works
- **The Disputes**

The 340B Program – Purpose & Participants

- **Purpose:** Created by Congress in 1992 to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services

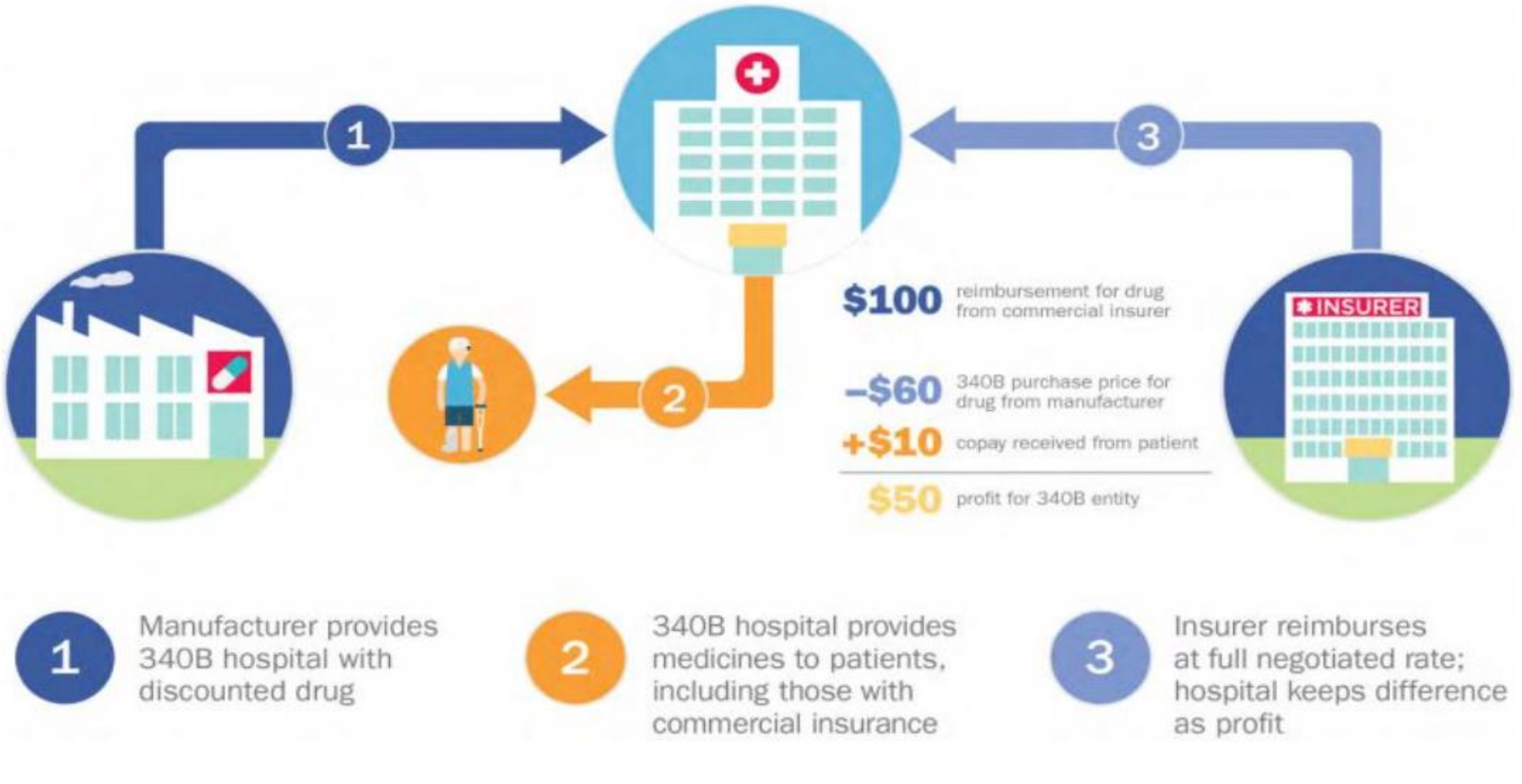
- **The Program Participants:** 4 main categories of participants
  - The Health Resource and Services Administration (HRSA)
  - Drug Manufacturers participating in the Medicaid Drug Rebate Program
  - Covered Entities/Contracted Pharmacies (serve as an extension of the 340B provider)– health centers, hospitals, and specialized facilities
    - Covered entities may elect to dispense 340B drugs to patients through contract pharmacy services
  - Eligible Patients
    - Established relationship with the covered entity
    - Have received health care services from a health care professional employed/contracted by the covered entity, or
    - Have a health care service/range of services consistent with the services for which grant funding or FQHC look alike status has been provided to that entity.

The 340B Program – How It Works

- **How it Works:**
  - Drug manufacturers provide discounts amounting to 20-50% on outpatient drugs purchased by covered entities (discount is in exchange for coverage of their drugs under Medicaid)
  - Covered entities/contracted pharmacies must comply with all 340B program requirements, including dispensing drugs purchased with 340B discounts only to “eligible patients”
  - "Duplicate discounts“ are prohibited; that is manufacturers are not required to provide a 340B discount and a Medicaid drug rebate for the same drug.
  - HRSA FAQ

340B FUNDS FLOW

Flow of Funds



https://catalyst.phrma.org/how-340b-discounts-work

This is NOT a Health Plan Issue

- This is a dispute between:
  - Drug manufacturers - who are resisting 340B program requirements by refusing to provide 340B discounts or seeking to impose conditions or restrictions limiting their participation in the program

    AND

  - Covered entities - who are seeking to protect their 340B funding and discounts.

The Disputes: Drug Manufacturers

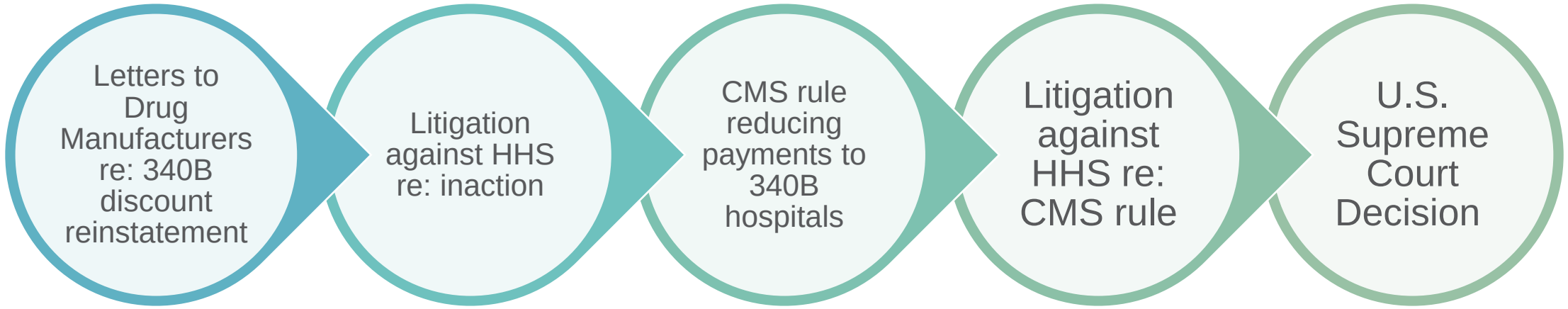
PhRMA: 340B Reform

The Disputes: Drug Manufacturers

- **PhRMA**: 340B Reform
- In 2020, drug manufacturers posted notices with HHS that it was limiting distribution of drug discounts to pharmacies that offer medications on behalf of providers participating in the program.
  - Other drug manufacturers followed suit. Drugmakers cut back participation in federal drug discount program | Health | stltoday.com
  - 17 drug companies have imposed limits on 340B discounts on outpatient prescription drugs sold to safety-net hospitals and dispensed to eligible patients through community and specialty pharmacies under contract with the hospital.
  - 10 of the drug companies have conditioned hospitals' access to 340B discounts at contract pharmacies.
- In December 2020, **HHS** issued:
  - a Statement and Advisory Opinion concluding drug manufacturers are required to deliver discounts under the 340B Program on covered outpatient drugs when contract pharmacies are acting as agents of 340B covered entities.
  - the Final Rule setting forth the administrative dispute resolution (ADR) process for certain disputes regarding the 340B Drug Pricing Program.
- Drug manufacturers and PhRMA filed several lawsuits that have challenged HRSA's advisory opinion, ADR, or both.
- Between 2021-2022, **HRSA** has sent letters to drug manufacturers that announced they would no longer supply 340B drugs that are dispensed through contract pharmacies at or below the 340B ceiling prices. Program Integrity | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)
- In September 2021, **HRSA** publicly referred six matters involving drug manufacturers to the United States Department of Health and Human Services (HHS) Office of Inspector General (OIG) for possible imposition of civil monetary penalties (CMPs) https://www.hrsa.gov/opa/program-integrity/index.html

The Disputes: Drug Manufacturers

American Hospital Association (AHA): 340B advocacy
340BHealth: https://www.340bhealth.org/about/



The Disputes: Covered Entities

- **American Hospital Association** (AHA): 340B advocacy
  - 340BHealth: https://www.340bhealth.org/about/
- **AHA and other 340B providers sent letters** to drug companies in early January 2021, asking them to reinstate sending the discounted products to their pharmacies and reimburse facilities for damages
- **340B providers have filed lawsuits** against HHS to force the government to take action against drug manufacturers that were refusing to provide 340B discounts at contracted pharmacies dispensing medications on behalf of covered entities.
  - In February, a district court in Oakland, CA dismissed a lawsuit by hospital groups to require HHS to sanction 6 drug companies that either stopped providing 340B discounts or placed restrictions on 340B pricing in the contact pharmacy setting. Decision was based on procedural grounds, declaring lawsuit was premature until HHS had adjusted the matter under the ADR process.
  - In March, a federal district court in Indianapolis granted Eli Lilly a preliminary injunction preventing HRSA from implementing the ADR process with Eli Lilly. The injunction put on hold the petitions filed through the ADR system by community health centers that hoped to use the ADR process to resolve disputes over 340B pricing restrictions a contract pharmacies.

- **CMS issued a rule** that would reduce reimbursement to 340B hospitals for Part B drugs to ASP minus 22.5% effective January 1, 2018. This was intended to better align Medicare payments with the resource expenditures by hospitals.
  - AHA, AAMC, AEH, the Eastern Maine Healthcare System, Henry Ford Health System, and Park Ridge Health filed suit against HHS in the U.S. District Court for the District of Columbia. They argued that the rule exceeded HHS' authority and the cuts were illegal because CMS did not survey hospitals to determine their average drug acquisition costs.
  - In June, the U.S. Supreme Court held that "HHS's 2018 and 2019 reimbursement rates for 340B hospitals were contrary to the statute and unlawful." Noting that "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support," the Supreme Court observed that "this case has immense economic consequences, about $1.6 billion annually." Despite those serious practical impacts, the Supreme Court concluded that "[u]nder the text and structure of the statute," the case is "straightforward" as a matter of law: "Because HHS did not conduct a survey of hospitals' acquisition costs, HHS acted unlawfully by reducing the reimbursement rates for 340B hospitals." https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf

In Short…

- This is **not** a health plan issue, but a dispute between:
  - Drug manufacturers - who are resisting 340B program requirements by refusing to provide 340B discounts or seeking to impose conditions or restrictions limiting their participation in the program; and
  - Covered entities - who are seeking to protect their 340B funding and discounts.

- Caution against state proposals that would leave the ultimate purchaser of health care (employers/patients) holding the bag.
  - Do not require employers and patients to cover inflated prices
  - Do not relieve drug manufacturers from having to pay the 340B discount
  - Do not relieve 340B covered entities from abiding by 340b program requirements

Questions?

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