The 340B Program: Current Environment in States

Connecticut 340B Drug Pricing Workgroup

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NATIONAL ACADEMY
FOR STATE HEALTH POLICY

nashp.org

340B: Why It Matters to States

- As the program has grown so dramatically it accounts for a much larger share of the total drug purchasing
- As states act to lower pharmacy costs, they are addressing questions from covered entities who are protective of the financial value of 340B discounts
- As states look to increase access to treatment for low income and uninsured people, there is concern that drugs purchased with 340B discounts are not being used to benefit those patients
- States want to understand the connection between the growth of 340B and health system consolidation
- Growth of 340B has reduced Medicaid rebates and hampered state efforts to reduce drugs spending via pharmacy carve out

340B Discount Program

- Program is now over 30 years old – Enacted by Congress as part of the Veterans Health Care Act of 1992 (Public Law 102-585)
- Program provides mandatory discounts from drug manufacturers to "covered entities"
  - In order for manufacturers to participate in the Medicaid Drug Rebate Program, they must participate in 340B
- Intended to help providers serve low-income people: "to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"
- Federal administration of the program resides within the Office of Pharmacy Affairs of the Health Resources & Services Administration (HRSA).

Scope of the Original Program

- **Discounts:**
  - Minimum discounts – 23.1% of average manufacturer price but inflationary discounts result in price reductions up to 50%
  - Penny pricing – When the price of a drug increases faster than inflation, covered entities can sometimes acquire them for $0.01 per unit. Humira is an example
- **Original covered entities:**
  - Disproportionate Share Hospitals
  - Safety net providers such as Federally Qualified Health Centers (FQHCs), Ryan White Centers and Title X family planning clinics
- A covered entity without an in-house pharmacy was allowed to contract with ***a single outside pharmacy*** to provide drugs to patients

Changes to the Program

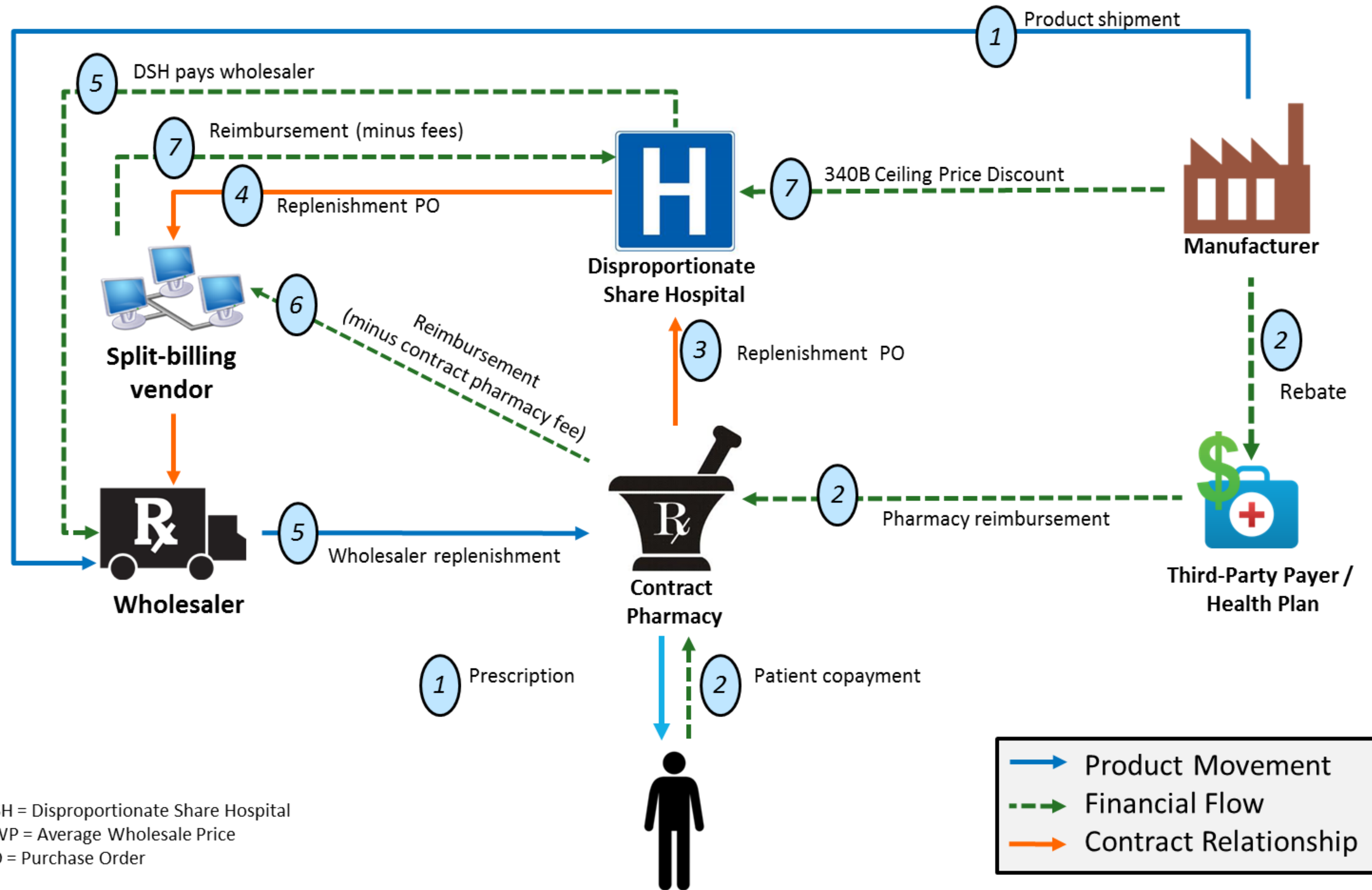
- Congress changed the law in 2006 and in 2010 (as part of the ACA), which in both instances resulted in expansion of the entities participating in the program
- Expansion of covered entities to include more hospitals
  - Critical access hospitals, sole community hospitals, stand alone cancer hospitals
  - Coverage of “child sites” – clinics and other facilities that exist outside of the four walls of a hospital but included in a hospital’s cost report
- Huge expansion in the availability of contract pharmacies
  - Any covered entity can use an unlimited number of contract pharmacies

Result of the Changes

- Dramatic increase in number of covered entities
  - The number of covered entities has ballooned from 8,100 in 2010 to approximately 50,000 in 2020
  - Prior to 2004 hospitals accounted for 10% of CEs, now account for over 60%
  - DSH Hospitals account for 78% of 340B sales

- Skyrocket in number of contract pharmacies
  - 1,300 in 2010 to over 30,000 in 2021
  - CVS, Walmart and Walgreens make up 58% of the contract pharmacy locations (even though the covered entities they contract with are required to be not for profit)

Flow of Funds & Products with Contract Pharmacies



DSH = Disproportionate Share Hospital
AWP = Average Wholesale Price
PO = Purchase Order

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Impact of Growth - $$

340B Drug Pricing Program, Purchases by Covered Entities

Source: Drug Channels Institute estimates based on data from Health Resources and Services Administration (for purchases at discounted 340B prices) and IQVIA (for purchases at list prices). Dollar figures in billions. Purchases exclude sales made directly to healthcare institutions by manufacturers and some sales by specialty distributors. Data for purchases at discounted prices show value of purchases at or below the discounted 340B ceiling prices.

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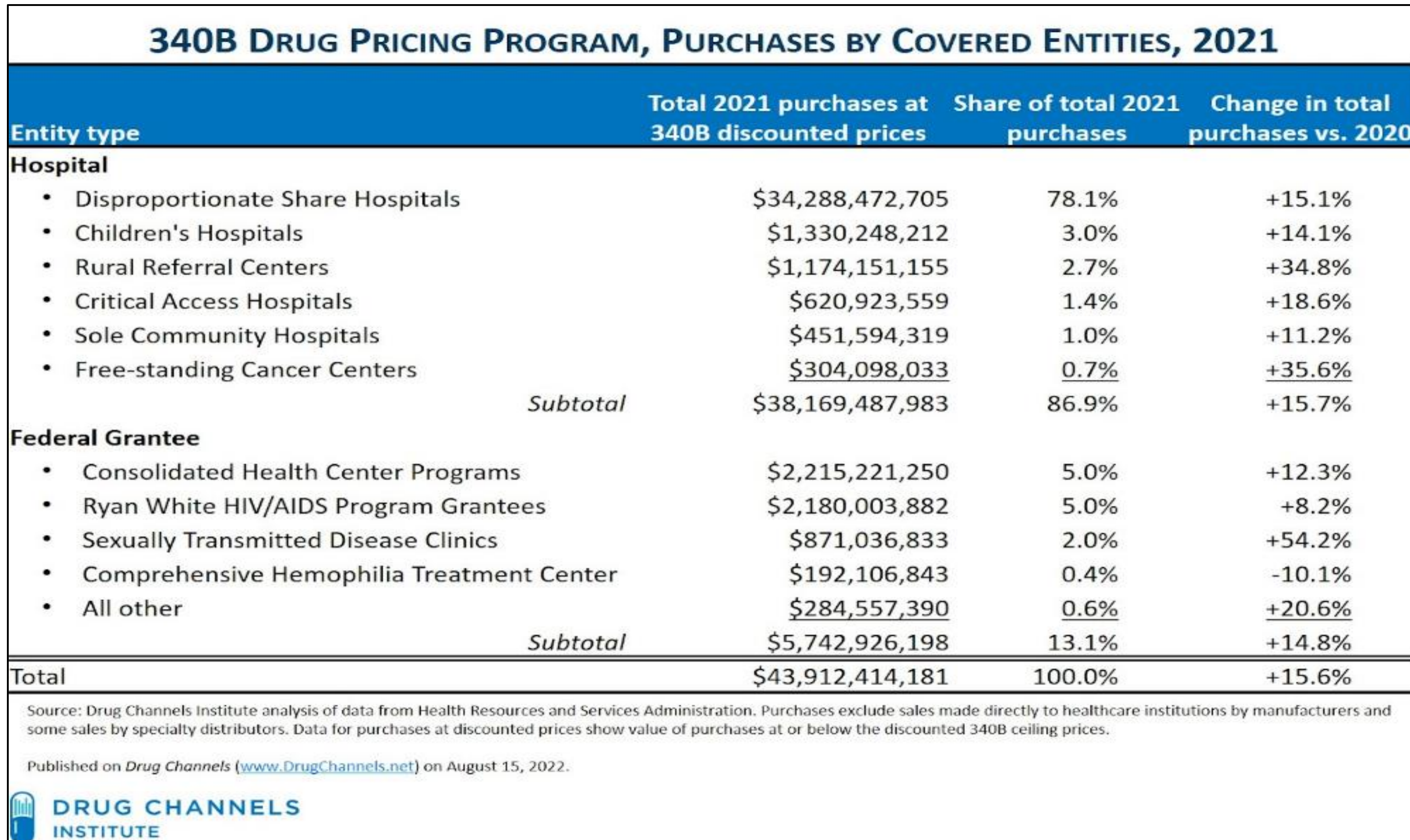
Impact of Growth – Covered Entities



340B Drug Pricing Program, Purchases by Covered Entities, 2021

Entity type	Total 2021 purchases at 340B discounted prices	Share of total 2021 purchases	Change in total purchases vs. 2020
Hospital			
• Disproportionate Share Hospitals	$34,288,472,705	78.1%	+15.1%
• Children's Hospitals	$1,330,248,212	3.0%	+14.1%
• Rural Referral Centers	$1,174,151,155	2.7%	+34.8%
• Critical Access Hospitals	$620,923,559	1.4%	+18.6%
• Sole Community Hospitals	$451,594,319	1.0%	+11.2%
• Free-standing Cancer Centers	$304,098,033	0.7%	+35.6%
Subtotal	$38,169,487,983	86.9%	+15.7%
Federal Grantee			
• Consolidated Health Center Programs	$2,215,221,250	5.0%	+12.3%
• Ryan White HIV/AIDS Program Grantees	$2,180,003,882	5.0%	+8.2%
• Sexually Transmitted Disease Clinics	$871,036,833	2.0%	+54.2%
• Comprehensive Hemophilia Treatment Center	$192,106,843	0.4%	-10.1%
• All other	$284,557,390	0.6%	+20.6%
Subtotal	$5,742,926,198	13.1%	+14.8%
Total	$43,912,414,181	100.0%	+15.6%

Source: Drug Channels Institute analysis of data from Health Resources and Services Administration. Purchases exclude sales made directly to healthcare institutions by manufacturers and some sales by specialty distributors. Data for purchases at discounted prices show value of purchases at or below the discounted 340B ceiling prices.

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- Hospitals account for 86.9% of program purchases
- Other grantees make up 13.1% of program purchases

State Activity to Date – PBMS and Manufacturers

- As 340B has grown, health care purchasers (commercial insurers, PBMs, TPA, ERISA plans) have attempted to account for and capture the value of these deep discounts in the purchasing practices and negotiations with hospitals, clinics and covered entities
- 28 states have enacted some form of “anti-discrimination” legislation, prohibiting PBMS and others from
  - Reimbursing covered entities/contract pharmacies at a lower rate
  - Charging fees to covered entities/contract pharmacies
  - Making sure that consumers are not restricted in using contract pharmacies
- Louisiana and Arkansas have enacted legislation prohibiting drug manufacturers from restricting access to 340B drugs at contract pharmacies – Laws being challenged in federal court by PhRMA

State Activity to Date – Transparency

- In 2023, for the first time, states enacted transparency legislation to try to understand the value of 340B within their state and how those dollars were being utilized
- In addition to the bill that moved forward in Connecticut, three states passed legislation that required some level of reporting by 340B Covered entities
  - **Maine** – Beginning in 2024, Hospitals must report 1) annual estimated savings from 340B; 2) a comparison of the hospital's estimated savings under 340B to the hospital's total drug expenditures, including examples of the hospital's top drugs; and 3) a description of how the hospital uses savings from the 340B program for the community benefit
  - **Minnesota** – Beginning in 2024, all covered entities must report aggregate information on drug acquisition costs, reimbursement received and payments to contract pharmacies; hospitals must report this information for their top 50 drugs
  - **Washington** - HCA must "establish an annual reporting requirement for all covered entities participating in the 340B drug pricing program that received Medicaid funds"