



The Future of the

- ▶ 340B program

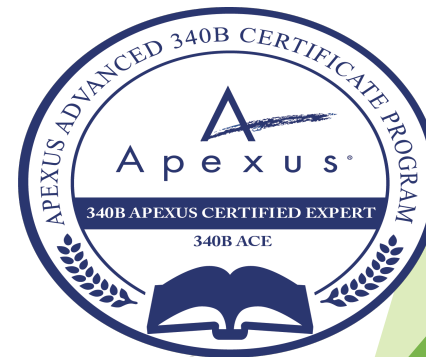
340B Speaker

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- 15 years 340B experience
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340B-The Beginning

- ▶ Birth of the Program: The enactment of Public Law 102-585 (the Veterans Health Care Act of 1992)¹ This act then became codified as section 340B of the Public Health Services Act (PHSA)² Note: PHS (Public Health Services) and 340B are used interchangeably
- ▶ Under Section 340B Manufacturers must enter into a Pharmaceutical Pricing Agreement (PPA) with the Secretary of HHS to be able to participate in the Medicaid and Medicare Part B program.
- ▶ According to HRSA “The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

340B – Who qualifies?

- ▶ Black Lung Clinics
- ▶ Children's Hospitals
- ▶ Comprehensive Hemophilia Treatment Centers
- ▶ Consolidated Health Center Programs
- ▶ Critical Access Hospitals
- ▶ Disproportionate Share Hospitals
- ▶ Family Planning Clinics (Title X only)
- ▶ Federally Qualified Health Centers
- ▶ Free Standing Cancer Hospitals
- ▶ Health Care for the Homeless Programs
- ▶ Migrant Health Programs
- ▶ Native Hawaiian Health Care Programs
- ▶ Public Housing Primary Care Programs
- ▶ Rural Referral Centers
- ▶ Ryan White Programs Part A, B, C, D, and F
- ▶ School Based Programs
- ▶ Sexually Transmitted Diseases Clinics
- ▶ Sole Community Hospitals
- ▶ Tribal Contracts/Compacts with Indian Health Services
- ▶ Tuberculosis Clinics
- ▶ Urban Indian Programs

What is the value of 340B?

- ▶ What is the value of a 340B priced medication?
 - Compared to Wholesale Acquisition Cost (WAC)?
 - Compared to Group Purchasing Organization (GPO) Cost?
 - WAC = 100% (Controlled by the drug manufacturer)
 - GPO = WAC -20%
 - 340B = WAC -50%

A highly performing 340B program has a benchmark savings of \$1M/50 beds/year

340B Product Distribution
Traditional Model



340B Product Distribution
Contract Pharmacy Model



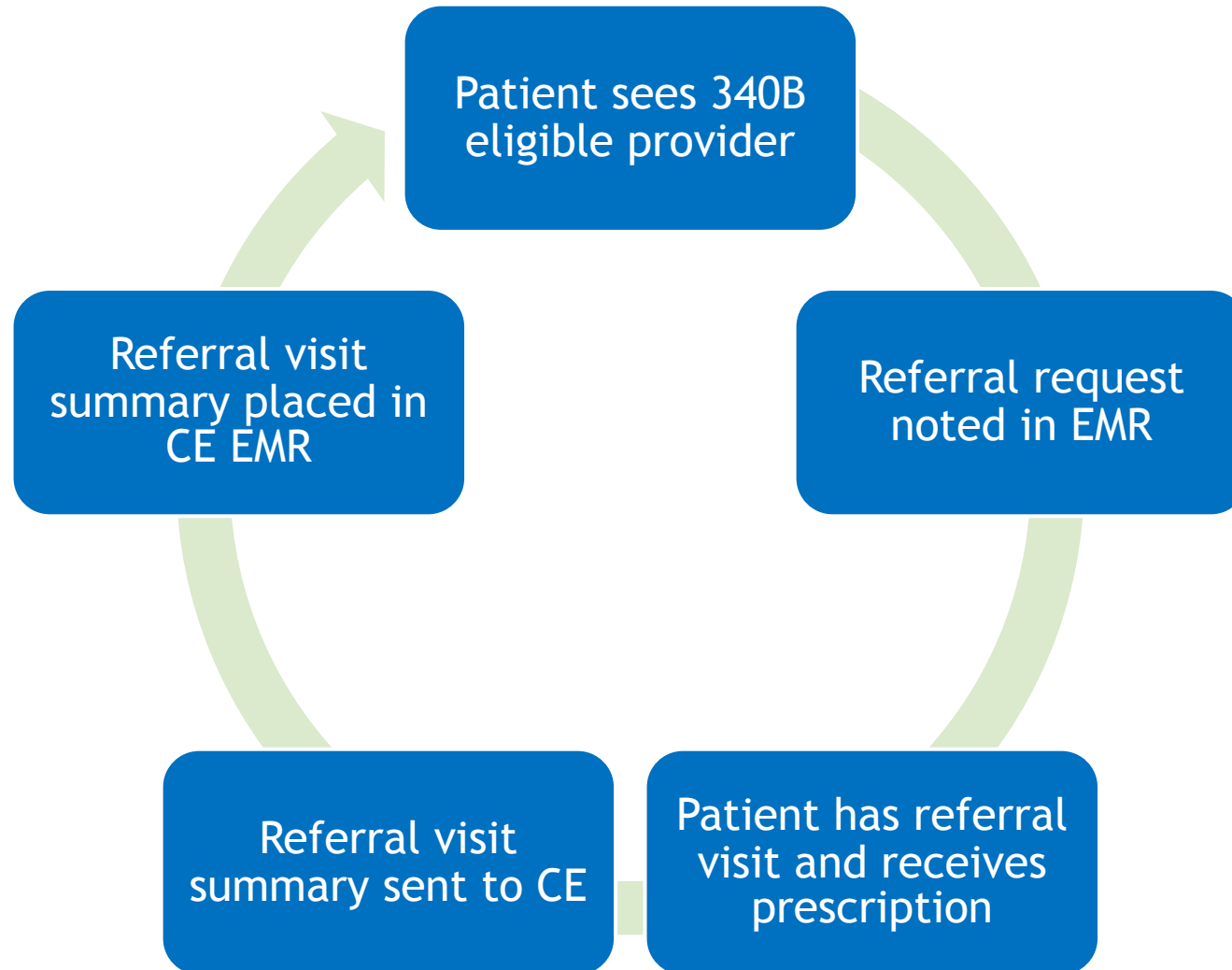
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Contract Pharmacy

- ▶ 340B-covered entities may elect to dispense 340B drugs to patients through contract pharmacy services, an arrangement in which the 340B covered entity signs a written contract with a pharmacy to provide pharmacy services.

Increase Expansion - Closed Loop Referrals



Big Pharma has taken notice

- ▶ The Esurient Eight:
 - ▶ Drug Manufacturers no longer offering 340B prices at Contract Pharmacies
 - ▶ AstraZeneca, Eli Lilly, Sanofi, Novartis, Amgen, Novo Nordisk, BI and Merck
 - ▶ Restricting the number and type of pharmacies to which they will ship 340B-discounted medications, dramatically restricting patients' ability to access them.
- ▶ 340B ESP Platform: Requiring health centers to provide ongoing over data, that many CE's fear will be used to deprive them of critically needed 340B savings.
- ▶ Kalderos attempt at a rebate model: Mandating CEs to pay WAC for medications up front and then pharma deciding if/when reimbursement will be provided.

Lawsuits pending

- ▶ Medicare statute verbiage prohibits covered entities from suing big pharma directly over 340B, forcing advocacy groups to step in
- ▶ Historically HRSA/HHS has stated they do NOT have the authority to enforce the 340B statute
- ▶ Lawsuits are pending in district courts on all manufacturers
- ▶ Progress made in AstraZeneca case: Judge said HRSA does have the authority but must go through proper procedure
- ▶ Anticipation of a Supreme Court Case



Efforts at the State Level

- ▶ HB 1881 in Arkansas passed on 4/27/21: First state to make it illegal for drug manufacturers to not honor pricing at contract pharmacies, Indiana and Tennessee have followed suit⁴
- ▶ “ A Pharmaceutical Manufacturer shall not: Deny or prohibit 340B pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B pricing contract pharmacy arrangement with and entity authorized to participate in 340B drug pricing”

What can be done in the meantime?

- ▶ In-house pharmacies
- ▶ Single pharmacy designations
- ▶ ADR reporting
- ▶ TPA support
- ▶ FOCUS ON PROGRAM LEAKAGE

References

1. [http://www.govtrack.us/congress/bills/102/hr5193.](http://www.govtrack.us/congress/bills/102/hr5193)
2. <http://www.hrsa.gov/opa/introduction.htm>
3. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf
4. <https://legiscan.com/AR/text/HB1881/2021>