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Presented at WSMOS MAC Meeting 2018
Before 340B

- **Pre-1990:** Pharmaceutical manufacturers provided voluntary steep discounts to directly to Federally funded clinics and public hospitals serving large numbers of low-income and uninsured patients.

- **1990 Medicare Rebate Program:** Required pharmaceutical manufacturers to provide rebates to states for Medicaid beneficiary drug purchases, as a condition of participation, based on a "best price" calculation that did not take into account the already discounted prices.

- **1992 Congressional Hearings:** Pharmaceutical Manufacturers raised prices, 32% on average, erasing the discounts.
The Advent of 340B


The law protected specified clinics and hospitals, expected to serve the nation’s most vulnerable populations from the drug price increases and, in essence, restored the discounts as a condition of Medicaid participation.
The Intent of 340B

The purpose of the 340B Program is to permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384(II), at 12 (1992).

Interpretation #1: Savings are to reward providers who deliver care to government program enrollees and allow them to provide comprehensive services.

“If ‘nonprofit’ hospitals are essentially profiting form the 340B program without passing those savings to its patient’s, then the 340B program is not functioning as intended.” Senator Charles E. Grassley.

Interpretation #2: The legislation is intended to provide low-income individuals with access to prescription drugs.

The difference goes to the heart of the matter: What should covered entities do with the rebate dollars?
“Covered Entities”

- All Covered Entities are Public or Non-Profits
- Initially: VA and “others”
- Federally Funded Community Health Plans
- Native Hawaiian and Indian Health Centers
- Ryan White HIV/AIDS Clinics
- Comprehensive Hemophilia Centers
- Black Lung Clinics
- Sexually Transmitted Disease Clinics
- Title X Family Planning Clinics
- Tuberculosis Clinics
More Covered Entities

- Disproportionate Share Hospitals with DSH >11.75%
- Children’s Hospitals with DSH >11.75% (Added 2005)
- Rural Referral Hospitals and Sole Community Hospitals with DSH >8% (Added with ACA)
- PPS Exempt Cancer Hospitals and Critical Access Hospitals with DSH >11.75% (Added with ACA)
- Critical Access Hospitals with no DSH% requirement (Added with ACA)
- Hospital Outpatient Clinics that are within a 30 mile radius of the eligible hospital.
DSH Percentage

- DSH percentages are calculated based on each hospital’s Disproportionate Patient Percentage (DPP).
- DPP is an equation that focuses on the percentage of hospital inpatients qualifying for SSI and Medicaid.
- The percentage of Medicare patient-days for patients that are eligible for SSI is added together with the percentage of total hospital patient days represented by Medicaid eligibles who are not also eligible for Medicare.
- For Hospitals with DPP greater than 20.2, the DSH adjustment formula is \( \text{DSH} = 5.88 + (0.825)(DPP - 20.2) \).
- For small rural and urban Hospitals, \( \text{DSH} = 5.88 + (0.825)(DPP - 15.0) \).
- 11.75% requires a DPP of 27.32 or 22.11 for small Hospitals.
 Covered Patients
(Clear and Straightforward)

- All patient’s of the 340B Covered Entity, both insured, underinsured, or uninsured,… except...

- Not Medicaid patients (Drug industry is already giving the State a discount)… unless...

- Dual eligible Medicare/Medicaid
Covered Patients  
(Broad and Nebulous)

- An individual is a patient of a 340B covered entity only if:
  - the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; **and**
  - the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the covered entity; **and**

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

- Drug purchased under 340B Program are limited to **outpatient** use and provided to eligible patients.
- FDA-approved prescription drugs and OTC drugs written on a prescription.
- Biological products that can be dispensed only by a prescription (other than vaccines).
- Drugs given in the hospital outpatient department.
- Discharge prescriptions to the extent that the drugs are for outpatient use. 340B covered entities should have auditable records that demonstrate compliance with this requirement.
- Some manufacturers may voluntarily offer discounted prices on inpatient drugs or medical supplies, such as syringes, that are not 340-covered drugs, but that is a choice and is not related to the 340B Program.
- Recent clarification: It is prohibited to use a GPO to purchase 340B drugs.
The Medicaid Patient

They can “carve out” this volume and purchase outside of the 340B discount, allowing the entity to be reimbursed at normal Medicaid rates.

Alternatively, they can “carve in” and purchase under 340B. If so, they must be listed on a Medicaid exclusion file that exempts their drugs from the Medicaid rebate program. Entities that “carve in” are subject to different reimbursement rules under Medicaid that essentially becomes a pass through to the State.
The Discount

- Applied to AMP: AMP is based on sales to retail pharmacies, excludes sales to hospitals, HMOs and physicians, PBMs, other insurers, clinics, and mail-order prices, and excludes prompt pay discounts. Discounts received by pharmacies, however, would be include
- Base rebate: currently 23.1% for branded drugs and 13.1% for generics; or
- “Best price” rebate: Average Manufacturer Price - Best Price (branded drugs only); and
- Penalty applied for drugs with prices that increase faster than the consumer price index.
- provided on a prospective basis, and covered entities can use other mechanisms to further reduce drug prices.
- The Health Resources and Services Administration (HRSA) estimates that covered entity discounts range from 20% to 50% off typical market prices.
GPOs, Medicaid and 340B Provide Discounted Acquisition Costs

Adapted from a slide by Safety Net Hospitals for Pharmaceutical Access
Source: Data derived from Prices for Brand-Name Drugs Under Selected Federal Programs, Congressional Budget Office (June 2005)
The Discount

- It is excluded from the ASP calculation used for reimbursement in the physician office and for separately paid drugs in HOPPS.
- Was included in the hospital charge information used to set HOPPS reimbursement until it was discarded.
- Will tend to increase prices for other segments of the market (just as the Medicaid rebate initially did for a variety of providers, leading to the 340B program itself).
- Has been pointed to by some as a reason that some manufacturers are leaving various markets, potentially exacerbating shortage issues.
The Growth of 340B

- The original legislative history in 1992 makes reference to approximately 90 hospitals being eligible.
- In 2005, there were 591 participating.
- This number increased to 1,673 by 2011, and 2138 by July 2014, representing 42% of all hospitals in the United States.
- The total number of covered entities nearly doubled in size between 2001 and 2011, from 8,605 to 16,572.
- However, Growth since ACA has largely been rural hospitals with less than 25 beds and DSH Hospitals has decreased from 1003 to 974.
- 340B sales as a % of the 329B US Drug Market has been flat at 2%.
- In Theory, Medicaid expansion from ACA decreases number of uninsured patients and increases the number of 340B eligible entities.
Contract Pharmacy Relationships

- Effective April 5, 2010, 340B covered entities are permitted an unlimited number of contract pharmacies to expand their reach to patients in the community.
- Use of one or more contract pharmacies does not alter the basic 340B requirements for covered entities – they continue to purchase drugs, take title of these drugs, and assume all responsibility for 340B compliance.

Source: Avalere Analysis of HRSA Enrollment Data as of November 5, 2013

Each relationship between a 340B entity and a contract pharmacy is counted separately for this analysis. Some pharmacies have relationships with more than one 340B entity, those pharmacies are counted more than once in this analysis.
340B Participation Growing Rapidly

There are 10,957 unique entities participate in 340B as of October 2013- a single entity can have multiple 340B-enrolled locations, called “sites” or “affiliates”. There are nearly 24,000 sites enrolled as of October 2013. Since 2009, there have been nearly 10,000 new sites enrolled in the 340B program.

Source: Avalere Analysis of HRSA Enrollment Data as of November 5, 2013
340B Expansion: DSH Hospitals and HOPD

Source: Analysis of data from the 340B provider list maintained by the Office of Pharmacy Affairs in the Health Resources and Services Administration by Rena Conti, PhD.
The Complaints: About the Program

- It has grown beyond need and intent.
- It is driving up drug prices.
- HRSA has extended the rebates beyond statutory limits: Orphan Drugs.
- The $$ should follow the indigent patient.
- Program lacks regulation.
Major consolidation in the market

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Physician employment at hospitals jumps 34% in a decade

Analysis: Hospitals employ more than 25% of active physicians

Topics: Employment, Physician Issues

January 26, 2012
The Complaints: About the Hospitals

- 340B Hospitals aren’t living up to an expectation that they provide charity care.

- 340B is fueling predatory acquisition of independent oncology practices.

- Thereby increasing the cost of oncology care overall and out of pocket costs of patients in particular.
Distribution of Outpatient vs. Inpatient Revenues, 1992 - 2012

Source: Avalere Health analysis of American Hospital Association Annual Survey data, 2012, for community hospitals.
A comparison of local population socioeconomic characteristics served by 340B qualified DSH, affiliated clinics and all US in 2012

Conti & Bach. The Changing Populations Served by the 340B Discount Program
March 27, 2013

CONGRESS BLOG
THE HILL'S FORUM FOR LAWMAKERS AND POLICY PROFESSIONALS

340B Drug Pricing Program Needs Updating, Says ASCO
Roxanne Nelson | September 15, 2014

By Adam J. Fein, president, Pembroke Consulting, Philadelphia

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<th>Carolina Medical Center</th>
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In December 2012, the SAC brought concerns about the 340B program to the ASCO Board.

The Board agreed this issue demanded attention, and asked the CPC to address.

The CPC subsequently formed a diverse Workgroup representing several Committees and groups at ASCO.
340B Workgroup Members

Dr. Jeffery Ward, CPC Chair
Dr. Roscoe Morton, CPC Immediate-Past Chair
Dr. Anupama Kurup, CPC Chair-elect
Dr. James Frame, SAC Chair-Elect
Dr. Ray Page, SAC Chair
Dr. Gina Villani, GRC & HDAG
Dr. Blase Polite, Cost of Cancer Care Task Force & HDAG
Workgroup Findings

The 340B program is an essential lifeline for many hospitals and ASCO should oppose efforts to scuttle the program without making provision for these institutions.

There are numerous serious concerns with the program that need to be addressed.

There are anecdotes of 340B abuse, but most of 340B hospitals are following the letter, and the majority of them the spirit, of the law.

An ASCO Policy Statement was written by the group, approved by CPC, adopted by the ASCO Board and published in March 2014.
Policy Statement on the 340B Drug Pricing Program by the American Society of Clinical Oncology

In considering the future of the 340B Drug Pricing Program, the relevant issues raised by policymakers and various advocates fall into the following general categories:

• Whether the program satisfies the original intent of the legislation.
• Whether the size of the program is appropriate.
• Whether adequate safeguards are in place to ensure appropriate compliance and oversight of the program.
• Whether unique considerations related to cancer care warrant special attention by policymakers.
When considering the future of the 340B Drug Pricing program, policymakers should focus on how to best meet the original intent of the program to provide resources and incentives to deliver high-quality care for uninsured, underinsured and low-income patients.

Congress & HRSA should require covered entities to provide a full, comprehensive accounting of the amount of 340B savings and the percent reinvested into care for uninsured, underinsured, and Medicaid patients on an annual basis.
Policymakers should adopt policy changes that address the size and future growth of the 340B Drug Pricing Program.

Congress should discard the current DSH formula, and other parameters derived from inpatient data, for determining eligibility for an outpatient program.

Replace with a formula that considers the percent of underinsured / uninsured patients treated in the outpatient setting.
Recommendation #3

- Improve compliance and oversight by issuing guidance to clarify relevant definitions and provide funding for key oversight activities related to the 340B Drug Discount Program.

- Congress & HRSA should define and clarify the term “patient” and other important criteria.

- HRSA should receive appropriate level of funding/staffing to engage in necessary oversight.
Policymakers should place special emphasis on understanding and responding to any adverse impacts that the 340B Drug Pricing program may have on patient access to high-quality oncology care.

Decreasing numbers of independent oncology practices may be attributed in part to financial pressures and incentives due to expansion of the program.

Policymakers should consider if recent/current expansion of the program affects availability of community oncology practices.

340B program could be better targeted to truly needy patients by appropriately identifying those entities that serve such patients - regardless of site of care (i.e. institutional vs. private practice).
2014’s Political Reality

- There is a hospital in every Congressional District.
- 340B is a very popular program, in part because it requires almost no taxpayer dollars.
- PhARMA has less political cache than any time in recent memory.
- HRSA is likely to release the Mega-Rule clarifying definitions.
- Congress has increased funding for regulatory audits and is unlikely to increase it further for a program that has no money in it for the government to recoup.
- Reform of 340B is not going to save struggling independent practices, and could only serve to remove a soft landing place if done wrong.
2018’s Political Reality

- There is still a hospital in every Congressional District.
- 340B has become a partisan issue with Republicans attacking it and Democrats defending it.
- PhARMA has bankrolled a campaign to muddy the intent of the law and blame drug prices and high patient copays on 340B.
- HRSA never did release the Mega-Rule, is hobbled by court decisions that limited statutory authority.
- Bad apples among unregulated hospitals threatens the program.
- CMS has decreased Medicare reimbursement for drugs purchased through 340B to ASP-22.5 and proposes to change it to ASP-28.
- Reform of 340B is not going to save most struggling independent practices, and could only serve to remove a soft landing place if done wrong.
Things We Should Not Support

- Changes to 340B that harm hospitals and cancer programs that operate in the spirit of the program.
- Changes to 340B that takes away dollars that provide services to cancer patients.
- The expectation that we will see drug prices go down if 340B is scuttled.
- Being manipulated by Pharma and Drug Distributors.
- Become politically partisan. It will have negative long term consequences.
- Interests that seek to divide and de-legitimze Oncology’s voice.
CMS’ MONEY GRAB IS NOT REFORM

This is a thinly veiled attempt to destroy, not reform the program.

It punishes all 340B institutions, taking a hatchet to the program when a scalpel is needed.

It cuts 1.6 billion dollars of money targeted for services for underinsured and disadvantaged patients to include cancer patients.

It will have a negative impact on cancer patient access when the hospitals that needed 340B the most, close cancer services.

It makes the hospital outpatient oncology’s new low-cost provider.