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PRESCRIPTION DRUG PRICING

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THE 340B DRUG DISCOUNT PROGRAM

The 340B drug discount program mandates the sale of outpatient prescription drugs to safety-net providers at reduced prices.

Facilities and programs known as 340B-eligible "covered entities" routinely provide prescription drugs regardless of a patient's ability to pay. However, drugs purchased at 340B prices can be dispensed to insured patients, and purchasers may bill those insurers—including Medicare—at higher rates. The program has grown rapidly, and the use of the discount by a relatively small set of large public hospitals has raised questions about whether the 340B discount is having unintended ripple effects on patient care and provider markets.

Background

The 340B drug discount program is unique to the US pharmaceutical marketplace and an important topic for understanding many dynamics of drug pricing. The program, named for the legislation that created it in 1992 (section 340B of the Public Health Service Act), requires manufacturers to sell products to selected purchasers (safety-net providers and programs identified in statute) at a discounted price.

The program was designed to address an unintended consequence of the 1990 Medicaid rebate law. Before that law, many manufacturers offered discounts to safety-net providers, recognizing that they supply prescription drugs to indigent patients who often cannot pay. However, because the 1990 rebate law requires manufacturers to provide Medicaid with rebates equal to the lowest price in the market (the "best price"), pharmaceutical companies began to cancel discount agreements with other purchasers to avoid providing the same discount to the entire Medicaid market.

Section 340B requires manufacturers to sell products to a broad set of facilities and programs at a price no higher than the net price paid by Medicaid, after rebates. (Manufacturers can sell to 340B-eligible purchasers at even deeper discounts if they choose, without triggering a new Medicaid "best price.") The discount is required for all outpatient prescription drug products—a designation that encompasses more than the traditional retail pharmacy medicines, such as infusion therapies, provided they are not part of an inpatient stay.

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The statute lists sixteen eligible purchaser groups, including federally qualified health centers, various disease-specific programs (AIDS Drug Assistance Programs, black-lung clinics, and hemophilia treatment centers), and publicly owned hospitals with a disproportionate-share hospital (DSH) percentage of at least 11.75 percent. As a group, they are referred to as "covered entities."

"The 340B program has expanded dramatically since 1992."

As of 2016 there were almost 35,000 individual sites registered by the Health Resources and Services Administration (HRSA) as eligible for the discount; many are affiliates of a single parent organization. According to HRSA, drug purchases at 340B prices totaled approximately $12 billion in 2015. Assuming a 25–50 percent discount on those purchases, HRSA estimates savings of $6 billion for covered entities. (Actual 340B prices are not available, because of their close relationship to Medicaid "best prices" and a legal prohibition against sharing Medicaid rebate calculations publicly.)

340B: What You Need To Know

Several important features of the 340B program factor into debates over its role in the broader prescription drug market.

THIRD-PARTY REIMBURSEMENT

Drugs purchased under the 340B program are not exclusively for the uninsured. While the focus of the program is on entities that provide services regardless of patients' ability to pay, 340B-eligible purchasers can and do bill third parties, including Medicare and commercial insurers. (By law, 340B-eligible purchasers cannot bill Medicaid more than the 340B price.) The ability to obtain third-party reimbursement for drugs purchased at 340B prices is a critical component of the program for participating providers; the difference between their price and the reimbursed amount is an important source of income. It is also a factor in policy debates about the program, as the 340B discount is essentially a subsidy for safety-net providers, but one not derived directly from taxpayer funds.

RAPID EXPANSION AND CONCENTRATION

The 340B program has expanded dramatically since 1992, and—somewhat counterintuitively—the Affordable Care Act (ACA) in 2010 led to a significant increase in use of the discount, even as the population covered by insurance increased. This was due in part to deliberate expansion of the program to include new purchasers (specifically, critical access hospitals and rural treatment centers). However, a bigger impact resulted from the expansion of Medicaid: More public hospitals became 340B-eligible DSH hospitals because the number of treated Medicaid patients is a factor in the DSH calculation.

The number of DSH hospitals enrolled in 340B almost doubled from 2005 (583) to 2014 (966), according to the Medicare Payment Advisory Commission (MedPAC). As much as 70 percent of 340B purchases (by dollar value) are made by DSH hospitals, even though they represent less than half of the hospitals enrolled in the program, and a far smaller portion of the total number of covered entities.

INCREASED PROGRAM OVERSIGHT

From 1992 through 2010 the 340B program operated largely on the honor system. For manufacturers, even verifying a purchaser's eligibility could be difficult, since there was no formal certification or listing requirement. The lack of transparency also led to concerns that discounts were being used inappropriately and that manufacturers were unfairly denying sales at 340B prices. The ACA established formal certification and audit requirements, with both purchasers and manufacturers subject to audits. Covered entities are now required to reimburse manufacturers if an audit finds inappropriate use of discounts.

UNCLEAR HRSA REGULATORY AUTHORITY

The 340B program has operated largely via direct implementation of the statute and informal communication by the HRSA Office of Pharmacy Affairs. After the ACA's enactment, HRSA began drafting formal regulations defining key aspects of the program, including how to determine who counts as a "patient" of a 340B purchaser for purposes of the discount. Before those draft regulations could be issued, however, a federal court ruled (in a case brought by the pharmaceutical industry challenging a separate 340B policy) that HRSA lacks authority to issue 340B implementing regulations, except in specific areas explicitly authorized by Congress.

In light of that ruling, HRSA abandoned the broader regulation; instead, the agency issued many of the proposed program definitions in the form of a draft guidance. However, that draft was withdrawn at the beginning of the Trump Administration. The lack of formal regulatory authority for HRSA calls into question whether the agency could enforce program definitions if the guidance is finalized. That has led to calls for legislation to grant HRSA explicit authority to issue and enforce regulations governing the program.

Important Issues For The Future Of The 340B Program

Several unresolved issues and unanswered questions will shape the 340B program going forward.

WHO BENEFITS FROM THE DISCOUNT?

According to the Congressional Report language accompanying the 340B statute [H.R. Rep. No. 102-384(II), at 12 (1992)], the purpose of the discount is "to stretch scarce federal resources." Covered entities interpret that language as indicating that they are supposed to benefit from the ability to seek third-party reimbursement amounts significantly higher than the 340B price, to provide funding to enhance their mission. Critics argue that the program has strayed far from providing access to drugs for safety-net providers and their patients and has instead become a new funding stream for public hospitals, including those that provide relatively limited amounts of uncompensated care.

CHANGES IN ONCOLOGY PROVIDER MARKETS

The post-ACA expansion of the 340B program has coincided with a shift in treatment patterns for oncology, from community-based private practices to hospital outpatient departments. Many community oncologists see a cause-and-effect relationship, arguing that they can't compete with the margins available to 340B-eligible hospitals, which can purchase high-price cancer therapies at deeply discounted prices. Program defenders argue that the factors driving changes in the delivery system are complex and go far beyond the single issue of 340B pricing.

POTENTIALLY INAPPROPRIATE CARE

The "spread" between the 340B price and the third-party reimbursement raises questions about inappropriate or overly intense use of medications, especially in Medicare. Arguably, 340B pricing encourages providers to choose a higher-cost agent, even when a lower-cost therapy is available, because the spread will be larger and the profit margin therefore higher. The concern exists generally in Medicare Part B, but it is magnified by the size of the spread for 340B providers. Part B providers receive a payment that is 6 percent more than the national Average Sales Price (ASP). In contrast, 340B providers receive a discount of at least 23 percent off the calculated Average Manufacturer Price (AMP), an average of 34 percent, and often much higher (up to 100 percent)—but the same Medicare reimbursement as other providers.

Key Terms

- **Covered Entities:** The catch-all term for purchasers eligible for 340B discounts. By law, there are sixteen classes of eligible purchasers, ranging from small, disease-focused providers (such as hemophilia treatment centers and black-lung clinics), to community health centers, to larger public hospital systems.

- **Ceiling Price:** The maximum price a manufacturer can charge a 340B entity for a covered drug. The formula to calculate the price is intended to match the net price paid by Medicaid after rebates.

- **Prime Vendor:** The 340B law established a prime vendor program to aggregate the buying power of the covered entities. The prime vendor negotiates discounts below the 340B price on some products, and also negotiates discounts on non-pharmacy products on behalf of covered entities. Since 2003, HRSA has contracted with a non-profit start-up, Apexus, as the Prime Vendor. In addition to the purchasing function, Apexus serves as an information resource for covered entities and 340B manufacturers, and often plays a role in developing solutions for complexities in operating the program on behalf of HRSA.

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Written by **Mike McCaughan**, Prevision Policy LLC. Editorial review by **Stacie Dusetzina**, University of North Carolina Eshelman School of Pharmacy; **Jane Horvath**, National Academy for State Health Policy; **Laura Tollen**, consulting editor, *Health Affairs*.

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7500 Old Georgetown Road, Suite 600 | Bethesda, Maryland 20814-6133 USA |