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The 340B Prescription Drug Discount Program

Origins, Implementation, and Post-Reform Future

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The 340B Drug Pricing Program is a federal program that allows specific categories of safety-net providers—including some hospitals, clinics, and health centers—to procure outpatient prescription drugs at discounted prices. Drug prices under 340B are generally less than the net cost of drugs paid by state Medicaid programs.[1]

Stakeholders and policymakers have been discussing and debating the intended purpose and appropriate scope of the program since its inception in 1992. As we discuss later, the program was designed to correct an unintended consequence of the 1990 Medicaid prescription drug rebate program that resulted in higher drug prices for the U.S. Department of Veterans Affairs (VA) and safety-net providers. Some lawmakers involved in the design of 340B hoped that lower drug prices would help safety-net providers to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2]

The discussion surrounding 340B escalated to debate and often disagreement as provisions expanding eligibility for 340B were included in the 2010 Affordable Care Act (ACA). This RAND Perspective describes the purpose, history, and current implementation of the 340B program in a single, clear, and objective document. The Perspective will be most relevant to policymakers interested in learning about 340B, the current pressures facing the program, and the challenges facing policymakers and elected officials.

Which Providers Can Participate in 340B?

The hospitals and federal grant recipients that are eligible to participate in 340B are known as "covered entities."[3] There are 16 specific covered entity categories, including six hospital categories and ten categories tied to federal grant programs.[4]

Each covered entity category has its own eligibility requirements. For the federal grantee categories, eligibility for 340B is determined by eligibility for or receipt of federal grant funding.

Summary Points

- The 340B Drug Pricing Program lowers drug prices for specific categories of "covered entity" hospitals and clinics. Covered entities can access 340B drug pricing for all of their eligible patients, including those with insurance.
- The number and types of covered entities have expanded over time, most recently as a result of the Affordable Care Act.
- Thirty-eight percent of U.S. outpatient hospital visits flow through 340B-participating, disproportionate share hospitals.
- Among the several pressing policy and implementation issues related to the 340B program are the recent exclusion of orphan drugs and an increasing emphasis on transparency and compliance.

For example, federally qualified health centers are eligible for 340B because they receive grant funding under Section 330 of the Public Health Service Act. Eligibility in the six hospital covered entity categories hinges on statutory criteria within 340B and the Social Security Act. For example, the definition of "critical access hospital" follows Section 1820(c)(2) of the act.[5]

Five of the six hospital categories (all but critical access hospitals) have an additional "disproportionate share hospital" (DSH) adjustment percentage requirement for 340B eligibility. The DSH adjustment percentage increases Medicare payments for hospitals providing relatively high levels of care to low-income Medicare and Medicaid patients. For example, sole community hospitals and rural referral centers are eligible to participate in 340B if they meet the appropriate statutory definitions *and* if they are eligible for at least an 8-percent disproportionate share adjustment. DSHs must be a unit of state or local government, or be a nonprofit hospital with a state or local government contract to provide care to the uninsured or indigent population.

Which Drugs Are Covered by 340B?

The 340B program is restricted to outpatient prescription drugs. Drugs that are included in bundled payments to hospitals for inpatient care are not included. In addition, drugs used to treat rare diseases ("orphan drugs") were excluded from 340B for the new covered entity categories introduced by the ACA (the ACA expansion is described below).[6] While drug manufacturers can choose whether or not to offer 340B discounts, many participate because 340B participation is a requirement for Medicaid coverage and participation in the U.S. Department of Defense and VA prescription drug contracting programs.[7] Under the Medicaid Prescription Drug Rebate Program, manufacturers are able to obtain state Medicaid coverage for their prescription drugs by entering into an agreement with the Centers for Medicare and Medicaid Services (CMS) and providing rebates directly to states when their drugs are purchased by Medicaid.[8]

Which Patients Participate in 340B?

While eligibility to participate in the 340B program is defined at the level of the health care facility rather than the individual, not

every individual receiving care at a covered entity can receive drugs purchased through the 340B program. The Health Resources and Services Administration (HRSA) adopted a formal patient definition in 1996 to prevent diversion of 340B-purchased drugs to patients who do not receive outpatient health care services from a covered entity.[9] Only individuals who have an established relationship with the covered entity (i.e., the covered entity maintains the patient's health record), receive care from a provider associated with the covered entity, and receive a range of health care services beyond prescription drugs are eligible to receive 340B-purchased drugs.[10] Many individuals with private or public health insurance will meet these eligibility requirements and can therefore access 340B-purchased drugs alongside uninsured and indigent patients. There are no patient eligibility criteria based on financial need.

How Large Are 340B Discounts?

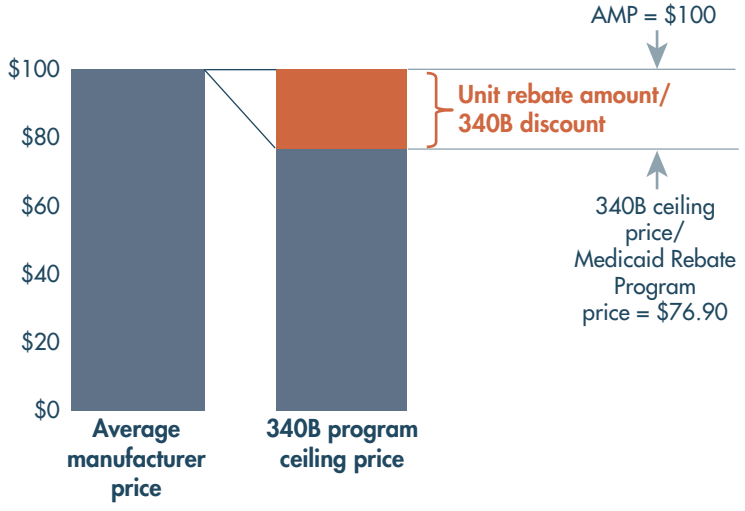
The 340B program sets a ceiling on the price that covered entities pay for outpatient drugs. The ceiling price is the average manufacturer price (AMP) minus the Medicaid unit rebate amount. Given that state Medicaid programs often reimburse at a level higher than AMP (the Medicaid ceiling price is no less than 175 percent of AMP, called the federal upper limit) and then claim the Medicaid drug rebate, the net drug cost to Medicaid is usually greater than the 340B ceiling price.[11]

For generic drugs and prescribed over-the-counter drugs, the Medicaid rebate is 13 percent of AMP. For brand-name drugs, the rebate is the larger of 23.1 percent of AMP (with exceptions based on inflation and for certain types of drugs, including new formulations of older drugs), or the difference between AMP and the best price offered to any other purchaser. All prices and discounts are calculated for each National Drug Code (i.e., for each combination of active ingredient, formulation, manufacturer, and package). Figure 1 illustrates the 340B discount for an innovator drug when other provisions do not apply and the 340B discount is based on 23.1 percent of AMP.

Clinics and hospitals that do not participate in 340B can seek other approaches to obtaining discounted outpatient prescription drugs. Institutional purchasers can negotiate directly with manufacturers or join group purchasing organizations (GPOs) to purchase drugs, devices, and supplies at discounted prices.

Covered entities acquire drugs at or below the 340B price. They can then bill insurers (for patients with insurance) for payment. A 2011 study from the U.S. Government Accountability Office (GAO) concluded that at least some covered entities (13 of the 29 entities interviewed as part of the study) generate revenue

Figure 1: An Example of a 340B Discount



related to 340B drugs, including payments from other payers as well as out-of-pocket payments, in excess of drug-related purchase and distribution costs.[12]

How Does the Program Work?

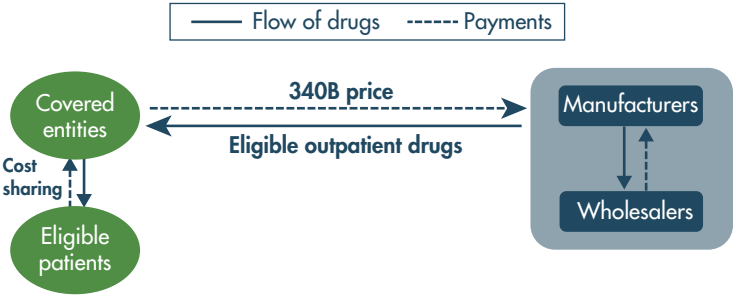
The 340B program is administered by the Office of Pharmacy Affairs (OPA) under HRSA, part of the U.S. Department of Health and Human Services. OPA determines and monitors 340B covered entity eligibility, secures pharmaceutical pricing agreements between manufacturers and the government, and maintains a database of covered entities.

Covered entities can purchase drugs at 340B prices directly from manufacturers or through drug wholesalers. Covered entities can negotiate further discounts directly,[13] through GPO contracts, or they can use the Prime Vendor Program to negotiate prices below the 340B ceiling price. This program, established by HRSA, negotiates subceiling 340B prices and other benefits for contract sales through drug wholesalers and other vendors. Regardless of their approach to purchasing drugs, covered entities should never be charged more than the 340B statutory ceiling price.

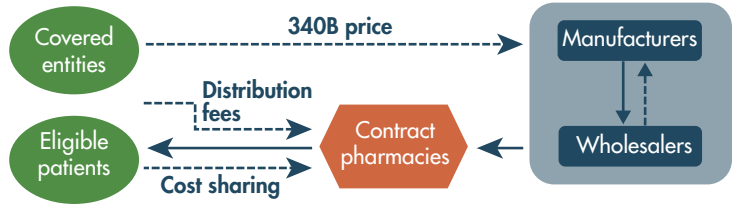
Covered entities can choose from three different approaches to purchasing and distributing 340B drugs. Figure 2 tracks the flow of money and drugs under the two most common approaches. In the first, covered entities purchase drugs directly from manufacturers and wholesalers at the discounted 340B price. Covered entities then either dispense drugs through in-house pharmacies or, in the case of outpatient physician-administered drugs, administer drugs directly to patients. Patients may face out-of-pocket cost sharing to obtain drugs from covered entities: The 340B program controls

Figure 2: Two Most Common Approaches to Purchasing and Distributing Drugs Under the 340B Program

Approach 1: Distribution through covered entities (in-house pharmacies or administration)



Approach 2: Distribution through contract pharmacies



the ceiling prices paid by covered entities, but not the prices that covered entities charge their patients.

In the second approach, the covered entity purchases and takes legal ownership of drugs at the discounted 340B price. Physically, however, the drugs never reach a covered entity's facilities. Instead, the drugs are shipped to retail community pharmacies. Covered entities contract with these pharmacies to dispense their 340B drugs. Thus, patients receive drugs from the contract pharmacies rather than from the covered entity. Patients may also face out-

of-pocket cost sharing when they obtain 340B-purchased drugs through contract pharmacies.

The Evolution of 340B

Original Legislation and Implementation

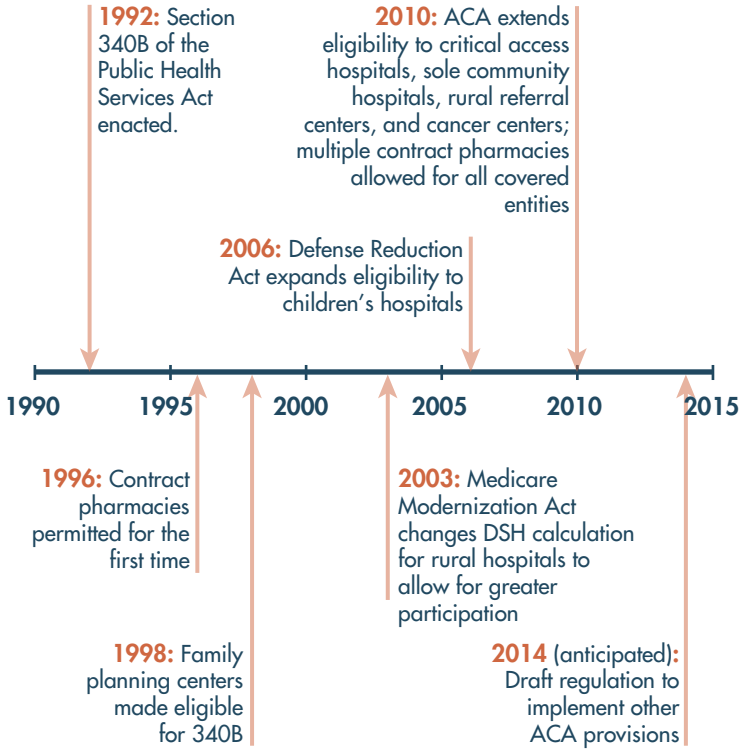
The 340B program was enacted as part of the 1992 Veterans Health Care Act,[14] which established section 340B of the Public Health Service Act.[15] 340B was a response to the 1990 Medicaid Drug Rebate Program, which required drug manufacturers to offer Medicaid discounts on outpatient drugs that would at least match the "best price" offered to any other buyer.[16] Manufacturers responded by limiting discounts to some buyers that historically received large discounts, including safety-net providers and the VA, to avoid eroding the prices that they could charge to Medicaid. As a result, safety-net providers and patients saw prices for prescription drugs increase. 340B's authorizing legislation extended discounts equivalent to Medicaid rebates to the VA and various other public health care systems in addition to safety-net providers.[17]

Congress intended for 340B to provide financial support to covered entities so they could "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[18] Congress recognized that covered entities "provide direct clinical care to large numbers of uninsured Americans,"[19] and it appears lawmakers hoped that 340B would maintain or improve the care received by uninsured and indigent patients. However, 340B was designed to focus on covered entities rather than uninsured or other patient populations, with the hope that covered entities would use 340B savings to improve and expand care in general, benefiting uninsured, indigent, and other patients. Other government safety-net policies and programs, including Medicare and Medicaid DSH payments and HRSA Section 330 grants, are similar to 340B in that they provide general resources to clinics and hospitals with the goal of improving and expanding health care in the safety net and in general.

Program Expansion

As outlined in Figure 3, the 340B program has expanded both directly (in terms of new covered entity categories) and indirectly

Figure 3: 340B Timeline



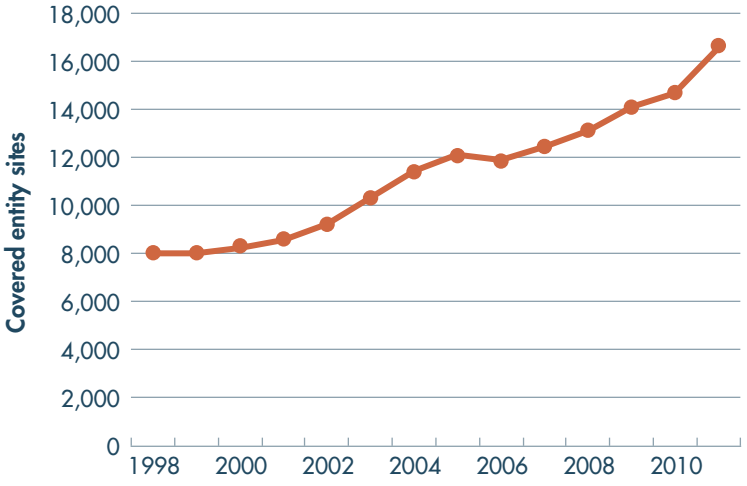
(in terms of broader eligibility criteria for existing covered entity categories). In 2003, the cap on DSH rates for smaller (fewer than 500 acute-care beds), predominantly rural hospitals was raised from 5.25 percent to 11.75 percent (see the section titled, "Which Providers Can Participate in 340B?" for a discussion of DSHs). This did not create a new facility type but did increase DSH participation rates.[20] The program continued to expand in 2005, when children's hospitals became eligible to participate under the following conditions:

1. They are affiliated with state or local government.
2. They provide a specified amount of indigent care.
3. They do not acquire covered drugs through a group purchasing order.

In 2010, the ACA further expanded the list of eligible facilities to include free-standing cancer hospitals, critical access hospitals, sole community hospitals and rural referral centers.

Today, HRSA is working to establish a formal set of regulations to standardize the definition of an eligible patient, compliance requirements for contract pharmacy agreements, hospital eligibility criteria, and eligibility of off-site facilities. According to the GAO, the number of 340B covered entity sites has doubled in just over ten years, to more than 16,500 (Figure 4).[21] Similarly, the number of contract pharmacy agreements has rapidly expanded from 1999 to 2013, as shown in Figure 5. The increase accelerated after April 2010, when HRSA allowed 340B entities to contract with multiple pharmacies.

Figure 4: Growth in 340B Covered Entity Sites



SOURCE: U.S. Government Accountability Office, 2011.
NOTE: Because a single covered entity can have multiple physical addresses, for example for different clinic locations, there are more covered entity sites than there are covered entities. Figure 4 illustrates growth in the number of covered entity sites.

340B Continues to Change

Delivery Channels

Prior to 1996, covered entities had to distribute drugs through in-house pharmacies or providers. In 1996, covered entities without in-house pharmacies were permitted by HRSA to contract with a single outside pharmacy to dispense 340B drugs to patients. Under the contract pharmacy model, covered entities own the drugs dispensed to patients through contracted pharmacies, or they "replenish" the pharmacy's stock of drugs that are dispensed to 340B patients. Drugs are shipped from manufacturers directly to community pharmacies. After evaluating several demonstration programs, HRSA further loosened limits on contract pharmacies in

2010 by allowing covered entities to contract with multiple outside pharmacies.[22] The shift to multiple contract pharmacies per covered entity accelerated growth in the number of contract pharmacy agreements (Figure 5).

Compliance and Monitoring

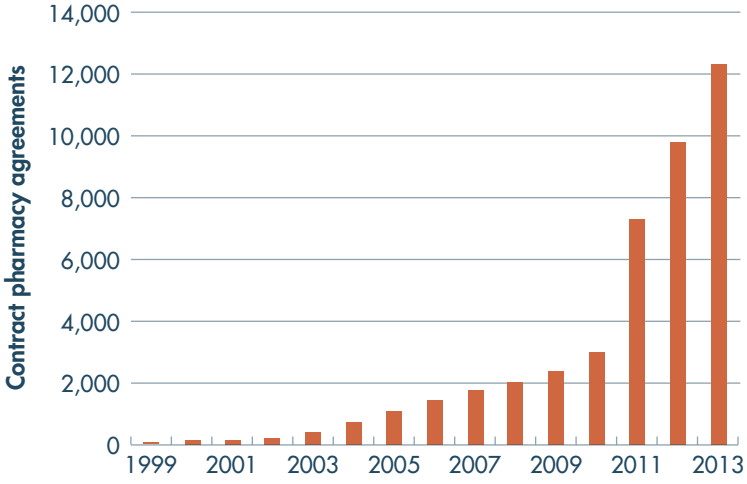
Covered entities need to monitor their dispensing activity to meet several statutory program requirements. The four main requirements are:

- **Report to HRSA to prevent duplicate Medicaid discounts:** Drugs purchased via 340B cannot also trigger a Medicaid Prescription Drug Rebate Program payment. Covered entities must report whether they use 340B-purchased drugs for Medicaid fee-for-service beneficiaries to the HRSA Office of Pharmacy Affairs.
- **Meet all patient definition requirements:** Drugs purchased through 340B can only be distributed to individuals as written with a formal relationship with the covered entity, must receive a range of services from the covered entity consistent with the entity's scope of services, and must obtain the prescription from a health care provider that is employed by the covered entity or under contract or other arrangement with the covered entity.
- **Exclude all GPO purchases** for outpatient drugs for DSHs, pediatric hospitals, and cancer centers.[23]
- **Exclude orphan drugs** from 340B purchases for critical access hospitals, free-standing cancer hospitals, sole community hospitals, and rural referral centers. We discuss the orphan drug exclusion in more detail later.

A 2011 GAO study found that HRSA's oversight of 340B was "inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements."[24] Prior to 2011, HRSA relied on the "self-policing" of covered entities and drug manufacturers to ensure program compliance. In response to recommendations in the GAO report, HRSA now conducts selective audits of covered entities to confirm compliance with these program requirements. The results of these audits are posted on the HRSA website.[25] Starting in 2012, covered entities must recertify their eligibility every year, must immediately notify HRSA if they experience changes in eligibility, are required to register new outpatient facilities and contract pharmacy agreements on a quarterly basis, and are urged to perform annual internal audits of their 340B programs.[26]

Recent 340B program changes have introduced new covered entity compliance requirements. For example, covered entities

Figure 5: Number of Contract Pharmacy Agreements



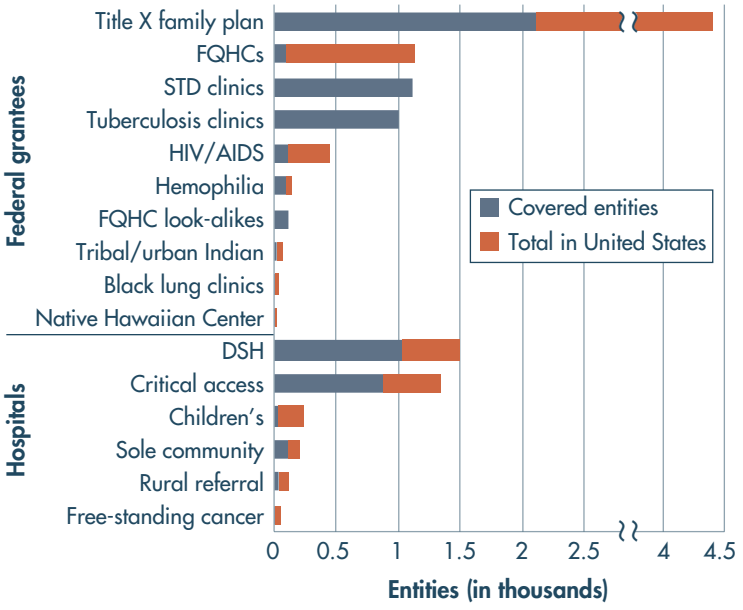
in the categories added by ACA must keep records related to the use of orphan drugs as described below. In addition, growth in the number of contract pharmacies increases the complexity of monitoring and compliance to prevent diversion. A recent U.S. Department of Health and Human Services Office of the Inspector General report found variation in the methods used by covered entities and contract pharmacies to track 340B-purchased drugs.[27]

Current Scope of the 340B Program

Today, 7,898 covered entities with more than 16,869 covered entity sites participate in the 340B program. Figure 6 lists categories of covered entities and indicates how many entities in each category are listed in the HRSA database as of August 2013. Covered entities serve different numbers of patients and provide different volumes of services. Using data on hospital outpatient visits,[28] we estimate that hospitals participating in the 340B program account for approximately 48 percent of total outpatient hospital visits in the United States. 340B-participating DSH hospitals alone account for 38 percent of total U.S. outpatient hospital visits.

GAO reports that 340B accounts for $6 billion in outpatient drug spending, or about 2 percent of 2011 U.S. spending ($263 billion).[29] This translates to savings of $1.6 billion under the assumption that 340B pricing is in line with Medicaid Prescription Drug Rebate program discounts.[30] The estimated savings from 340B are equivalent to 4 percent of federal and state resources funneled through major health care safety-net financing mechanisms, including HRSA Section 330 grants and Medicare and Medicaid DSH payments (Figure 7).

Figure 6: 340B Participation Rates by Covered Entity Category



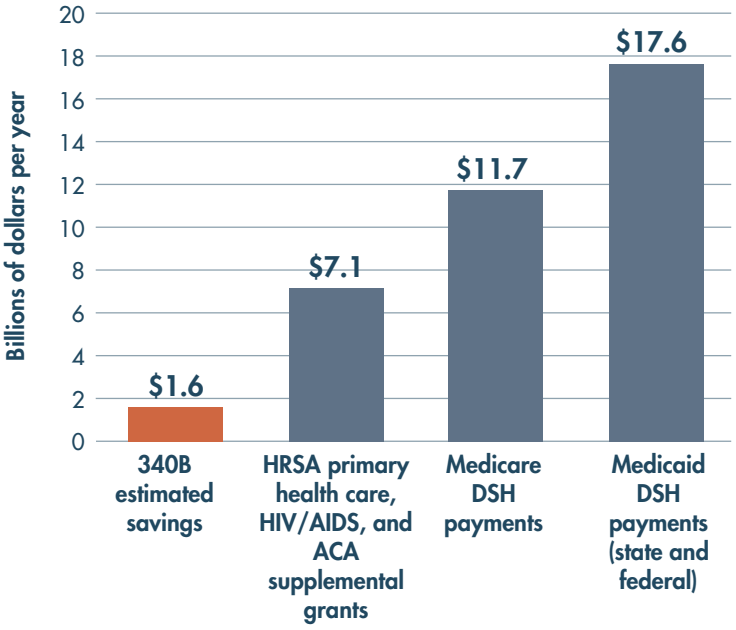
NOTES: FQHC = federally qualified health center
STD = sexually transmitted diseases

Key Policy Considerations

We find myriad issues and challenges surrounding the 340B program. Many stem from regulatory or legislative changes to the program over time. It is important to underscore that every federal program needs and requires careful oversight to ensure that the law is being implemented correctly.

Facility versus patient eligibility. Enactment of the 340B legislation has led to varying interpretations by elected officials, participating pharmaceutical manufacturers, and health care providers, each with divergent perspectives on 340B benefits. Some

Figure 7: Comparison of Estimated Annual 340B Savings and Payments Through Select Safety-Net Programs



NOTE: We estimate likely 340B program savings to covered entities by dividing total spending on drugs through the 340B program into generic components (20 percent of sales) and innovator components (80 percent of sales) using 2009 IMS Health's national sales perspective estimates on aggregate innovator and generic market shares. We applied the 340B discount percentages (13.0 percent for generics and 23.1 percent for innovators) to calculate the savings that are potentially attributable to 340B ($1.6 billion). For the purpose of comparison, we describe the magnitude of these estimated savings relative to the total annual federal spending on HRSA Bureau of Primary Health Care Section 330 grants (assuming the $11 billion in supplemental HRSA grants under ACA will be paid over five years), HRSA ACA supplemental funding, federal Medicare DSH payments, and federal and state Medicaid DSH payments. We do not include estimates of state and local health care safety-net financing (other than state Medicaid DSH contributions).
SOURCES: Estimates for primary health care and HIV/AIDS grants from HRSA Data Warehouse, *State Profiles*, web page, undated. As of June 24, 2014: http://stateprofiles.hrsa.gov/
Medicare DSH payment estimate based on RAND analysis of data from Centers for Medicare and Medicaid Services, *2010 Medicare Cost Report.* Medicaid DSH payments from Centers for Medicare and Medicaid Services, *CMS-64 Quarterly Expense Report*, web page, undated. As of June 24, 2014:
http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Data-and-Systems/MBES/CMS-64-Quarterly-Expense-Report.html
Program spending estimates are about $6 billion annually, according to U.S. Government Accountability Office, 2011.

manufacturers contend that, under the law, generous discounts on prescription drugs are inappropriately used by hospitals to generate revenue outside of Congress's original intent to serve indigent populations, due to the inclusion of Medicare and private insurance patients.[31] Conversely, many safety-net providers maintain that any additionally generated revenue contributes to the procurement of comprehensive services for vulnerable populations at safety-net hospitals and public health entities. As we noted, both motivations—ensuring that indigent and low-income patients have access to health care services, as well as supporting safety-net providers generally—are consistent with stated congressional intent.[32] This issue centers on the fact that 340B eligibility applies to covered entities rather than patients or payers.

Sliding scales and self-pay discounts: While covered entities may use discounted self-pay and sliding scale programs to expand pharmacy services to working poor and indigent patients, these features are not part of the 340B program. If discount arrangements are not implemented by covered entities and contract pharmacies, uninsured patients may pay the full, non-340B price for drugs.[33]

Split billing and compliance. Covered entities that provide both inpatient and outpatient services are eligible to receive the 340B discount price only on outpatient drugs. In response to these regulatory requirements and restrictions, health information technology and billing vendors offer tools to help covered entities flag specific health care services and prescriptions as eligible for 340B pricing. The end result is "split billing," where covered entities have to maintain auditable records to justify billing some outpatient drug volume through 340B while billing the remainder of their drug volume through other means. While these tools and billing approaches maximize the total savings to covered entities within

the 340B program parameters, they also represent a cost to covered entities as they implement technology to ensure compliance with 340B requirements.

The ACA expansion of 340B eligibility to new covered entity categories also directed HRSA to develop regulations applicable to the new entity categories to restrict 340B price discounts for typically expensive orphan drugs designated by the U.S. Food and Drug Administration (FDA) that are used to treat rare diseases and conditions.[34] HRSA released a new rule in July 2013 intended to "protect the financial incentives for manufacturing orphan drugs."[35] The rule increases the level of complexity of the 340B program, introduces new documentation requirements, and highlights 340B implementation challenges. Because the exemption applies only to orphan drugs used to treat FDA-designated orphan indications (specific populations, uses, and conditions of drugs), covered entities must maintain auditable records on the clinical circumstances and patient demographics surrounding each use of an orphan drug. Only uses of orphan drugs for non-orphan indications are eligible for 340B pricing. Covered entities that do not wish to record this information or are unable to do so must purchase orphan drugs outside of the 340B program.

The exclusion also highlights challenges in defining a set of "covered outpatient drugs." Orphan drugs used for orphan indications are not considered "covered outpatient drugs" and can therefore be purchased through GPOs. However orphan drugs used for other indications are considered "covered outpatient drugs" and therefore cannot be purchased through GPOs. As a result, the same covered entity may need to split its purchasing of a single drug across two channels to comply with the exemption.

Lack of transparency on 340B discounts. 340B discounts are based on AMP, which is calculated by drug manufacturers and reported directly to CMS. Because AMP is proprietary, covered entities do not have a point of reference to know whether the prices they pay to wholesalers reflect the appropriate 340B discounts. In 2010, Apexus, the current 340B prime vendor, implemented a secure web portal where manufacturers voluntarily post AMPs.[36] Covered entities participating in the Prime Vendor Program can view these prices. While the ACA includes provisions that expand HRSA's oversight and monitoring of drug prices reported by manufacturers, a real-time, web-based pricing portal has yet to be implemented.

Covered entities can negotiate discounts beyond the 340B pricing even in the current program framework, and it is difficult to know when covered entities rely on 340B pricing or are able to get a better price elsewhere. Sub-340B pricing can occur in two scenarios. First, the 340B prime vendor may negotiate discounts below 340B pricing. The 340B Prime Vendor Program (currently Apexus) gives all 340B covered entities access to single, coordinated contracts; negotiates subceiling discounts on 340B-eligible drugs; and coordinates discounts on drugs and supplies that are not covered by the 340B program.[37] Participation in the Prime Vendor Program is optional. Second, manufacturers can provide sub-340B discounts to 340B covered entities. Manufacturers can provide subceiling discounts without additional penalties because 340B program sales are excluded from Medicaid's rebate calculations, as well as nonfederal AMP calculations for VA and Department of Defense contracts.

340B Under Health Reform

Many of the ACA's provisions related to the 340B program—for example, the addition of new covered entity categories—already have been implemented. These direct changes to 340B have expanded the scope of the 340B program. One analysis suggests that drug purchases under the program will double from $6 billion in 2010 to $12 billion by 2016.[38] The ACA's reductions in Medicare and Medicaid DSH payments to hospitals may increase the importance of 340B savings for some safety-net providers.[39]

Other impacts of health reform, however, may restrict 340B program growth. The combined effects of Medicaid expansion in some states, health insurance marketplaces, and the individual mandate will reduce the number of uninsured Americans and, in some states, increase the number of Medicaid-insured individuals. The likely net result of the coverage expansion on the 340B program is not immediately clear. On the one hand, demand for health care in general and for prescription drugs in particular may increase among covered entity patients, some of whom will be newly insured as a result of the coverage expansion. On the other hand, newly insured individuals may seek care from hospitals and clinics that are not covered entities. In terms of eligibility, more hospitals will become eligible for 340B as Medicaid expansion in some states pushes DSH adjustment percentages over the eligibility threshold.

Conclusion

The federal 340B program has, for many years, sparked some level of controversy, but never as much as now. Drug manufacturers and safety-net providers are using a wide array of tools and outlets—including interest groups, lobbying, and media—to share their divergent perspectives on the purpose and appropriate role of 340B. While interest groups are becoming more vocal, the federal government is simultaneously implementing changes in program administration and oversight in response to internal and external calls for transparency and accountability. HRSA plans to release new regulations for comment that will address several key 340B components, including patient eligibility, hospital eligibility, and contract pharmacy monitoring.[40]

Our goal in crafting this Perspective is to present objective information on the history, current status, and future trajectory of 340B. This information is critical to set the appropriate tone for productive policy discourse. We hope this Perspective serves as a helpful resource to this end.

The road ahead for safety-net providers is fraught with uncertainty. As Congress and state legislators continue to cut Medicaid reimbursement, many previously uninsured individuals are becoming eligible for Medicaid or are purchasing coverage via insurance marketplaces. Research on the long-term impacts of the ACA on 340B is a necessity.

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[13] The exception is that DSHs, children's hospitals, and free-standing cancer hospitals cannot use group negotiated pricing for any outpatient drugs, but they can access negotiated pricing through the Prime Vendor Program.

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[28] RAND estimate using the HRSA 340B covered entity dataset, the CMS Medicare Impact File, and the AHA Annual Survey. Only about half of hospitals with DSH adjustment percentages reported in the Impact File meet the 340B eligibility threshold of 11.75 percent (prior to the ACA adjustment percentage reductions). We assume that 340B-participating hospitals with DSH adjustment percentages above this threshold qualify for 340B under the DSH hospital covered entity criteria. The ACA did not reduce the DSH adjustment percentage requirement for all hospitals. The new rural hospital types (critical access hospitals, rural referral centers, and sole community hospitals) were added with an 8-percent threshold. The traditional DSH entities remain above 11.75 percent, along with the new pediatric and cancer hospital covered entity categories.

[29] Medicaid.gov, undated.

[30] Actual savings from 340B may be higher or lower than this estimated amount. In terms of price, 340B acquisition costs may be lower than the Medicaid post-rebate price. The savings from 340B hinge on the amount paid by covered entities under 340B relative to the best price available to covered entities outside of the 340B program. Actual savings will be smaller if hospitals and clinics are able to access significantly discounted prices outside 340B.

[31] Avalere Health, *The 340B Drug Discount Program: A Review and Analysis of the 340B Program,* 2013.

[32] U.S. House, 1992.

[33] U.S. Department of Health and Human Services, 2014.

[34] "340B Drug Pricing Program," Title 42, Code of Federal Regulations, part 10, October 1, 2013.

[35] Exclusion of Orphan Drugs for Certain Covered Entities Under 340b Program, 2013.

[36] Apexus, *340B Prime Vendor Program,* web page, undated. As of June 25, 2014: https://www.340bpvp.com/about-us/

[37] Hoadley, J., *The Prescription Drug Safety Net: Access to Pharmaceuticals for the Uninsured,* National Health Policy Forum, 2007.

[38] Avalere Health, 2013.

[39] The ACA Medicaid DSH reductions were delayed until 2016. See Centers for Medicare and Medicais Services, "Medicaid Provisions in Recently Passed Federal Budget Legislation," informational bulletin, December 27, 2013. As of June 26, 2014: http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-12-27-13.pdf

[40] Health Resources and Services Administration, *340B Drug Pricing Program: Important Benefit, Significant Responsibility*, web page, January 9, 2014. As of March 11, 2014: http://www.hrsa.gov/opa/update.html

About This Perspective

This Perspective is intended to objectively describe the history, current status, and future trajectory of the 340B Drug Pricing Program, with the objective of fostering productive policy discourse related to the program. It was commissioned by Sentry Data Systems.

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