340B Drug Pricing Program: Interpreting Regulations and Exploring Opportunities

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The Director’s Forum series is edited by Robert J. Weber and Scott M. Mark and is designed to guide pharmacy leaders in establishing patient-centered services in hospitals and health systems. This article focuses on an important program for expanding pharmacy practice models to uninsured and underinsured patients. The 340B program provides assistance to hospitals on drug pricing to allow organizations sufficient additional savings to channel to patients in need. The regulations surrounding eligibility, drug pricing, and pharmacy contracting are complex and can make participating in 340B seem intimidating and unattractive to potentially eligible organizations. By gaining further understanding of the intricacies of the 340B Drug Pricing Program, pharmacists and other health care providers can utilize the program to maximize the benefit for both their patients and their organization.

News reports of economic downturn and increased unemployment affect patients’ access to medical care; many patients do not have health insurance or do not have adequate coverage to meet their needs. These uninsured and underinsured patients are a concern to pharmacists as limited access to vital medications leads to noncompliance, hospital readmissions, and increased financial burden to the United States health care system. As a profession, we are obligated to care for all patients, regardless of ability to pay, and must determine strategies to do so and maintain a positive “bottom line.”

The Veterans Health Care Act of 1992 has attempted to accomplish this obligation by establishing a section that requires pharmaceutical manufacturers to assist in providing medications to indigent patients. This section of the Act is listed as 340B and creates the 340B Drug Pricing Program. The 340B Drug Pricing Program requires manufacturers to provide discounted pricing on outpatient drugs to federally designated and qualified organizations, called “covered entities.” Covered entities include federally qualified health centers, hospitals that have a large share of indigent patients (also known as disproportionate share or DSH hospitals), and several categories of facilities or programs funded by federal grant dollars. The 340B Drug Pricing Program intends to improve medication access for underserved populations while providing a financial boost for institutions to sustain or increase care to poor patients.

The Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) provides oversight and manages the 340B program. HRSA, an agency of the US Department of Health and Human Services (DHHS), is the primary federal agency for improving access to health care services for patients who are uninsured, isolated, or otherwise medically vulnerable. HRSA provides direct funds to organizations as well as a series of grant programs that study the effect of changes on the quality and availability of health care.

The details, process, and procedures involved in 340B Drug Pricing Programs (known as 340B) is often a source of confusion to pharmacy directors. This article provides a brief overview of 340B programs by (1) describing drug pricing strategies in 340B programs; (2) describing eligibility requirement for 340B programs; (3) reviewing the concept of contract pharmacies and the Prime Vendor Program; and (4) reviewing the challenges of implementing a 340B

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program. The 340B program may be a strategy for a pharmacy director to use to enhance the pharmacy practice model to uninsured or underinsured patients.

**340B DRUG PRICING PROCESS**

The benefit of the 340B program for covered entities is the discounted pharmaceutical pricing provided by manufacturers. Current legislation requires manufacturers to provide drugs to covered entities at a price at or below a calculated 340B "ceiling price." This ceiling price provides for an appropriate discount while covering manufacturers’ production costs. Sometimes covered entities pay prices above the ceiling price, and there has been discussion about this over-charging practice. Paying above the ceiling price may be due to the OPA and the manufacturers not previously being required to publish 340B ceiling prices. As a result, covered entities could not confirm that the contracted purchase price between themselves and the manufacturer for a particular drug was at or below the 340B ceiling price. The 2010 Affordable Care Act (ACA) created a requirement for OPA to compare the ceiling prices with actual manufacturer pricing data, to monitor sales transactions between manufacturers and covered entities, and to take action on identified pricing discrepancies. This provision is expected to decrease the rate of overcharging by manufacturers under 340B contracts.

The ACA also changes the way 340B prices are calculated. First, the Average Manufacturer Price (AMP) calculation has been revised, resulting in what will generally be a higher price per drug. However, the AMP price discount percentage will increase, from the current 15.1% to 23.1% for most brand-name prescription drugs, from 15.1% to 17.1% for brand-name pediatric drugs and clotting factors, and from 11% to 13% for generic and over-the-counter drugs. If the manufacturer’s best price for a drug is lower than AMP minus 23.1% and if the price of the drug has increased faster than the rate of inflation, manufacturers and wholesalers must offer even greater discounts on brand-name drugs.

**ELIGIBILITY REQUIREMENTS FOR 340B PROGRAMS**

**General Eligibility**

Covered entities that qualify for 340B include a variety of different providers that typically serve populations with a significant need for affordable access to health care. The purpose of the 340B program is to enable these entities to stretch limited resources, reaching more eligible patients and providing more comprehensive services. Many covered entities fall into one of the subgroups of the Federally Qualified Health Centers (FQHC). Within the FQHC are FQHC Look-alikes, Consolidated Health Centers, Migrant Health Centers, Health Care for the Homeless, Healthy Schools/Healthy Communities, Health Centers for Residents of Public Housing, and Office of Tribal Programs or Urban Indian Organizations. Other federal grantees that qualify for 340B include family planning projects, HIV treatment centers under the Ryan White Care Act (RWCA), black lung clinics, hemophilia diagnostic treatment centers, native Hawaiian health centers, entities receiving title XXVI assistance, and entities receiving funds under section 317 or 318.

Section 7101 of the ACA of 2010 expanded the definition of covered entities to include children’s hospitals, free-standing cancer centers, critical access hospitals, sole community hospitals, and rural referral centers. However, the ACA excluded coverage of orphan drugs under 340B. Orphan drugs, as defined in the Food, Drug, and Cosmetic Act (FD&C Act), are drugs for the treatment of rare conditions that do not have adequate alternative drug treatment options. This exclusion of orphan drugs from the 340B provision was applied to children’s hospitals as well, even though children’s hospitals had been previously enrolled under a provision of the Social Security Act (SSA) amended by the Deficit Reduction Act. This legislative oversight had a major financial impact on children’s hospitals, because orphan drugs often make up a large percentage of the total drug budget at pediatric facilities. However, a recent legislative correction reinstated 340B discounts to children’s hospitals for orphan drugs.

**Calculating Eligibility as a DSH Under 340B**

DSHs also qualify for the 340B program. Qualification as a DSH is determined by calculating a hospital’s disproportionate share adjustment. The Medicare disproportionate share adjustment is an additional Medicare payment to hospitals that treat a high percentage of low-income patients. The Medicare disproportionate share adjustment provision under section 1886(d) (5) (F) of the SSA was enacted by section 9105 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 and became effective for discharges occurring on or after May 1, 1986.

According to section 1886(d) (5) (F) of the SSA, there are 2 methods for a hospital to qualify for the Medicare disproportionate share adjustment. The
primary method is for a hospital to qualify based on a formula that results in the DSH patient percentage. The formula for calculating the disproportionate share adjustment is:

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\text{DSH Patient Percent} = \left( \frac{\text{Medicare SSI Days}}{\text{Total Medicare Days}} \right) + \left( \frac{\text{Medicaid, Non-Medicare Days}}{\text{Total Patient Days}} \right)
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In order to qualify for the 340B program, a hospital must have a disproportionate share adjustment greater than 11.75%. The disproportionate share adjustment indicates that greater than 11.75% of the hospital’s patients provide reduced reimbursement or partial payment. The alternate special exception method is for large urban hospitals that can demonstrate that more than 30% of their total net inpatient care revenues come from state and local governments for indigent care (other than Medicare or Medicaid).

**Enrollment**

When determining whether or not they should enroll, organizations need to weigh the benefits and drawbacks of participating in 340B. Organizations should calculate their projected savings and focus particularly on the potential savings from high-cost drugs. In some cases, hospitals or other qualifying entities may be a member of a large group purchasing organization (GPO) that has negotiated sub-340B pricing for many of their pharmaceuticals. In this case, the organization will likely not benefit from enrollment in 340B and may actually have a disincentive to participate. However, a qualifying entity without much purchasing power and high drug prices could see a substantial financial benefit from participating in the 340B Drug Pricing Program.

Organizations should then weigh these potential savings against the time and costs that will be required to ensure appropriate billing, adequate record keeping, and effective inventory management. The complexities of 340B can make compliance with the regulations difficult and can result in utilization of additional organizational resources to maintain compliance. Therefore, facilities that expect to see minimal to moderate savings from 340B may find that enrollment in the program is not worth the effort and costs associated with complying with the regulations. However, eligible organizations with high outpatient pharmaceutical costs and large economies of scale are likely to reap major financial benefits from participation in the 340B Drug Pricing Program.

Determining eligibility can be complex for organizations, due to the many rules and regulations surrounding 340B eligibility and enrollment. Organizations that have determined they would like to participate in 340B and are eligible can begin the enrollment process by first visiting the 340B program homepage on the HRSA Web site at http://www.hrsa.gov/opa/introduction.htm. Once determined to be eligible, the organization must submit the appropriate registration form and any other necessary documentation to participate to the OPA.

**340B Strategies**

**Contract Pharmacies**

Covered entities can reap the benefit of the 340B discount program by purchasing drugs under 340B for administration to patients of the covered entity. However, certain criteria must be met in order for drugs to be purchased under 340B. First, medications purchased under 340B must be used in the outpatient setting. Examples of outpatient medications include medications purchased by an in-house outpatient pharmacy for dispensing of outpatient prescriptions, medications administered in the emergency department, medications administered in outpatient surgery centers, and medications administered in hospital-based clinics. Additionally, any medication purchased under 340B must be prescribed for a “patient” of the covered entity as defined by OPA. A patient of a covered entity is defined by OPA as the following: “an individual who has established a relationship with the covered entity, such that the covered entity maintains records of the individual’s health care; an individual who received 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 the responsibility for the care provided remains with the covered entity; and the individual receives health care services from the covered entity which is consistent with the services for which grant funding or federally-qualified health center look-alike status has been provided to the entity.” For example, an in-house outpatient pharmacy that is part of a covered entity cannot dispense medications purchased under 340B from a prescription that is written for an individual by a physician at an outside health care facility, since this individual does not qualify as a “patient” of the covered entity.

As issued by HRSA guidelines in 1996, covered entities can also employ the financial incentive created by 340B by establishing a “contract pharmacy.”
contract pharmacy is contracted with a designated covered entity to purchase medications under 340B for patients of that covered entity. Contract pharmacies cannot purchase medications under 340B for individuals who are not considered “patients” of the covered entity under the OPA definition. As cited in the Federal Register, contract pharmacies should follow several suggested model agreement provisions. In the recommended model, a contract pharmacy performs the inventory management, billing, prescription filling, and dispensing for the covered entity that writes the prescriptions. The reimbursement and copayments received for the prescriptions are transferred to the covered entity, and the covered entity is directly billed for the cost of the inventory at the 340B purchase price, as well as a predefined dispensing fee paid to the contract pharmacy. This model can be highly successful for smaller clinics and other nonmedical center covered entities that do not provide outpatient pharmacy services. However, this model can be unprofitable for the covered entity if the reimbursement margin is lower than the dispensing fee or if the covered entity chooses to provide pharmaceuticals at a discounted rate to indigent and uninsured patients. The Anti-Kickback Statute prevents contract pharmacies from providing financial incentives to covered entities in exchange for referral of Medicare or Medicaid patients to the pharmacy. Additionally, patients have freedom of pharmacy choice, and a patient of a covered entity may opt out of using a contract pharmacy if he or she so chooses.

The original legislation set forth by HRSA in 1996 established that covered entities were limited to one contract pharmacy. Covered entities could establish either an in-house pharmacy or an external contract pharmacy for provision of 340B services. Effective April 2010, new legislation allows covered entities to contract with multiple pharmacies for the purchase of medications under the 340B Drug Pricing Program. This new legislation stemmed in part from the experience of the Alternative Methods Demonstration Projects (AMDPs), which were established by HRSA in 2001. AMDPs allowed covered entities that applied and were approved by HRSA to pursue alternatives to contracting with a single pharmacy. These alternative models included the use of multiple contract pharmacy service sites, the utilization of a contract pharmacy to supplement in-house pharmacy services, and/or the development of a network of 340B covered entities.

The full impact of this new legislation on both covered entities and contract pharmacies is not fully understood. However, the potential for improved patient access to pharmaceuticals, as well as opportunities for covered entities to create new revenue streams and increase 340B patient capture, is significant. The expanded scope of 340B contract pharmacies has the potential to provide significant financial benefit for both covered entities and contract pharmacies. As large retail pharmacy chains begin to contract with covered entities, the covered entities will be able to increase outpatient prescription capture and realize new revenue streams from revenue sharing with the contract pharmacy. By identifying “patients” of a covered entity and flagging prescriptions for these patients, covered entities can capture 340B revenues shared with contract pharmacies. Additionally, contract pharmacies will have the potential to drive prescription volume and increase profitability through charging dispensing fees to the covered entities in exchange for pharmacy services.

However, introduction of multiple contract pharmacies creates complexities in billing, ensuring patient eligibility, purchasing, and inventory tracking. In response to these challenges, several contract pharmacy administrator companies have sprung up to provide 340B administration services to hospitals and contract pharmacies. Contract pharmacy administrators provide software and administrative support that allow for adherent to federal replenishment and dispensing requirements, pharmacy reimbursement for drug purchases, and appropriate allocation of drug reimbursement.

**Prime Vendor Program**

The mission of the 340B Prime Vendor Program (PVP), as stated on the official prime vendor program Web site (https://www.340bpvp.com/public), is to “improve access to affordable medications for covered entities and their patients.” The PVP operates much like a GPO by utilizing the collective bargaining power of the members to negotiate with manufacturers for lower prices. To enroll in the PVP, a facility must be a covered entity under 340B. Enrollment is voluntary.

The PVP is managed by Apexus Inc, a nonprofit subsidiary of Provista. In 2004, Apexus won a bid for a direct contract awarded by OPA to serve as the Prime Vendor for 340B. As the Prime Vendor for 340B, Apexus acts as a GPO for covered entities. Participation in the PVP is free for the purchaser, because the program is funded by the fees charged to distributors and suppliers for their participation.
CHALLENGES POSED BY 340B PROGRAMS

Inventory Management

Participation in 340B presents several different challenges for pharmacies. The first is the maintenance of separate inventories for 340B and non-340B drugs. When dispensing to both patients of covered entities and patients of noncovered entities, pharmacies must ensure that medications purchased under 340B are dispensed to patients of covered entities only. This is referred to as a “carve-out,” where a 340B pharmacy will still provide pharmacy services to patients of noncovered entities but must ensure that the drugs for these patients are not purchased under 340B.

There are 2 models to ensure that a pharmacy can carve-out non-340B drugs and still abide by the rules set forth by the Veterans Health Care Act of 1992. The first solution is for the pharmacy to maintain separate physical inventories for the 2 subsets of patients. In this model, the pharmacy can easily track which medications are purchased for each set of patients and can thus ensure that drugs purchased under 340B are dispensed only to patients of the covered entity. However, this model requires pharmacies to carry a larger inventory, which results in decreased inventory turns and purchasing inefficiencies.

The second solution is to maintain separate virtual inventories for 340B and non-340B drugs. Maintaining separate virtual inventories requires utilization of software that can track which medications are dispensed to patients of the covered entity versus noncovered entity patients. When a patient of the covered entity fills a prescription, that inventory must be decremented from the 340B virtual inventory. Then, the medication will be purchased under a 340B account to “back-fill” the inventory that was dispensed to the patient of the covered entity. The virtual inventory system of providing services to 340B and non-340B patients presents several disadvantages, including more complex record keeping, increased staff time, and more robust software requirements.

However, this method is advantageous over maintaining actual separate inventories due to the reduced inventory and the subsequent space that is created.

Similar issues can arise when hospital pharmacy departments must maintain separate inpatient and outpatient inventories. Since the 340B Drug Pricing Program covers outpatient drugs only, DSH hospitals and other covered entities that purchase both inpatient and outpatient drugs must ensure that any drugs purchased under 340B are for outpatient use only. Information technology solutions, such as split-billing software, are available to assist pharmacy departments in maintaining compliance with these requirements.

Duplicate Discounts

Another major challenge facing contract pharmacies is the avoidance of duplicate Medicaid discounts. As discussed previously, manufacturers are required under law to provide medications to covered entities at a discounted rate below the calculated ceiling price. In most instances, the 340B discount is the only medication discount provided by the manufacturer. The issue arises when dispensing medications purchased under 340B to Medicaid patients, due to the Medicaid manufacturer rebate. In this instance, if the pharmacy purchases the drug under 340B and then submits a claim to Medicaid for full reimbursement, CMS will then request a rebate from the manufacturer under the Medicaid Drug Rebate Program.

The Medicaid Drug Rebate Program, created in 1990, requires drug companies to enter into a rebate agreement with the Secretary of the DHHS as a pre-condition for coverage of their drugs by Medicaid. The rebate agreement specifies that, for each brand-name outpatient drug covered under Medicaid, the manufacturer of the drug must pay a rebate to Medicaid based in part on the manufacturer’s “best price” for that drug. However, the contingency of the Medicaid rebate on the establishment of a “best price” by the manufacturer created a disincentive for manufacturers to offer large discounts to buyers from health care providers that served low-income populations. In response to this conundrum, Congress created the 340B Drug Pricing Program, which allows manufacturers to sell drugs to covered entities at a discounted price without establishing a new Medicaid best price.

If a pharmacy dispenses a 340B drug to a Medicaid patient and bills Medicaid at the normal rate, the manufacturer will face a duplicate discount by providing a discount to the pharmacy on the purchase price of the drug, as well as providing a rebate to CMS. To avoid this duplicate discount, the contract pharmacy must reduce any claim submitted to Medicaid to account for the difference between the claim price and the Medicaid best price. Tracking of this duplicate discount can be complex and is easily missed by pharmacies if the right processes are not in place to identify Medicaid patients and adjust claim value accordingly.

Diversion

As described previously, legislation requires that 340B drugs are administered to patients of a covered...
entity as defined by OPA. Diversion of 340B drugs is the sale of drugs purchased by a covered entity under 340B to a noncovered entity. The spirit of the Veterans Health Care Act of 1992 was to provide financial benefit to covered entities that served underrepresented patient populations. The intent was not to allow for covered entities to serve as distributors of 340B drugs to other health care providers at the cost of the manufacturers. However, 340B drug diversion, whether intentional or unintentional, is a major issue facing the OPA.1

Diversion can also occur in the form of physician self-referral. Physician self-referral is prohibited under OBRA 1989, in a set of provisions referred to as the Stark Law. Physicians can potentially divert medications under 340B through self-referral of patients from a noncovered entity to a covered entity. This would create a situation where the referred individual would appear to be a patient of the covered entity but has in fact been referred illegally and is therefore not a patient of a covered entity. The Office of Inspector General (OIG) is charged with maintaining the integrity of the DHHS and monitors closely for 340B drug diversion.

FUTURE OF 340B

Health care reform has created several changes to the 340B Drug Pricing Program, including the creation of the ACA. In addition to ACA’s impact on determining which entities qualify for 340B, the ACA has created a formalized process for dispute resolution and expanded the enforcement of 340B compliance for both covered entities and manufacturers. Future changes to 340B could be looming as the health care landscape continues to evolve, and therefore the future of the 340B program is not fully known. Future directions of 340B could include the expansion of drug discounts to inpatient drugs or a complete dissolution and restructuring of the complex 340B program.

CONCLUSION

The 340B Drug Pricing Program can provide significant cost savings to covered entities while improving health care access to the indigent and underserved population. The regulations surrounding eligibility, drug pricing, and pharmacy contracting present complexities that can make participating in 340B seem intimidating and unattractive to potentially eligible organizations. By gaining further understanding of the intricacies of the 340B Drug Pricing Program and performing an analysis of their own facility, pharmacists and other health care providers can utilize the program to maximize the benefit for both their patients and their organization.

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