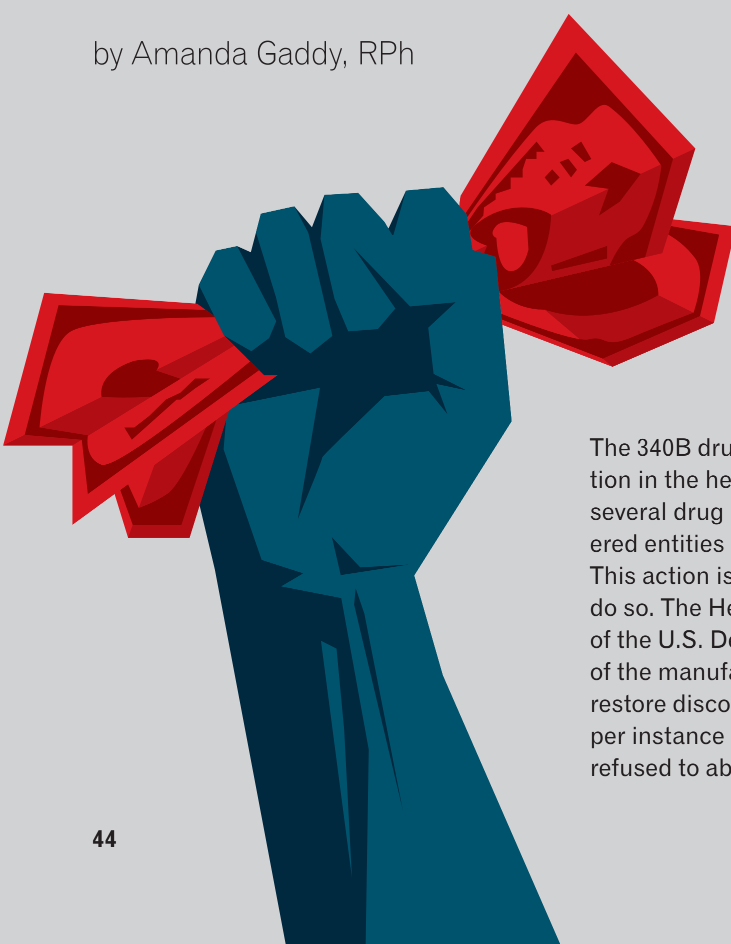
340B OR NOT TO BE

Program can benefit independent pharmacies and communities – but due diligence is essential

by Amanda Gaddy, RPh



The 340B drug discount program has been garnering plenty of attention in the health care universe in recent months. Beginning last July, several drug manufacturers stopped offering 340B discounts to covered entities on medications dispensed at some contract pharmacies. This action is in direct opposition to the law requiring manufacturers to do so. The Health Resources and Services Administration, an agency of the U.S. Department of Health and Human Services, contacted six of the manufacturers in May 2021 stating the drug manufacturers must restore discounts and repay lost savings or be subject to fines of $5,000 per instance of overcharge. As of this writing, the manufacturers have refused to abide by the statute and are in litigation with HRSA.

WHAT IS 340B?

While the 340B program is well known, a bit of a primer might be useful. The 340B drug discount program was established in 1992 by Congress as part of the Veterans Health Care Act. It requires drug manufacturers participating in the Medicaid drug rebate program to provide discounts on outpatient drugs purchased by qualifying health systems, known as covered entities, serving vulnerable patient populations. The program's intent is to utilize the resulting savings to reach a larger number of patients, provide more comprehensive services, and improve medication access. HSRA and the Office of Pharmacy Affairs administer the program.

WHICH ENTITIES ARE ELIGIBLE FOR 340B?

What types of facilities are eligible to become a 340B covered entity? It consists of safety net providers who serve the most vulnerable patient populations. These include the following:

Health centers/grantees

- Federally qualified health centers
- Federally qualified health center look-alikes
- Tribal/urban Indian health centers
- Ryan White HIV/AIDS program grantees

Hospitals

- Children's hospitals
- Critical access hospitals
- Disproportionate share hospitals
- Free-standing cancer hospitals
- Rural referral centers
- Sole community hospitals

(A complete list is available at www.hrsa.gov/opa/eligibility-and-registration/index.html.)

HOW CAN COMMUNITY PHARMACIES PARTICIPATE?

A covered entity can contract with one or more pharmacies to establish contract pharmacy partnerships. In this partnership, the contract pharmacy receives a fee for each eligible prescription dispensed to patients of the covered entity. This fee is negotiated between the covered entity and the contract pharmacy, and its calculation is critical to the viability of the arrangement between the contract pharmacy and the 340B covered entity. For example, the fee must be greater than the pharmacy's retail margin (including cost to dispense) without 340B as this negotiated dispensing fee becomes their new margin.

CONTRACT PHARMACY MECHANICS

When a prescription is determined to be 340B eligible, the pharmacy must transfer the prescription revenue to the covered entity. This revenue includes all third-party and copayments less the negotiated dispensing fee. The covered entity is then responsible for replenishing the inventory used for 340B eligible prescriptions by purchasing the inventory on the less expensive 340B wholesaler account. Thus, for this contact pharmacy and covered entity relationship:

SAVINGS =
(Third party payments
+ copay amounts*)
minus
(340B cost of goods**
+ dispensing fee*)**

*Sent from CP to CE
**Paid by CE to Wholesaler
***Paid by CE to CP

Along with generating revenue for the covered entity by billing third-party payers and collecting patient copays, pharmacies can provide medications to the uninsured/underinsured at little to no cost when dispensed inventory is replenished by the covered entity despite the patient's ability to afford the medications. Access to medications improves adherence and outcomes and decreases overall health care costs.

WHO BENEFITS AND HOW?

Ultimately, an entire community will benefit, including the patient, when the program is structured correctly. For covered entities, the savings and revenue are used to provide additional services often unattainable without 340B. But in many cases, the 340B program is responsible for keeping the covered entity's doors open. According to a 2019 survey by 340B Health, all hospitals reported using 340B savings for low-income patients living in rural communities. Seventy-six percent of critical access hospitals (defined as 25 beds or less) responded that 340B savings were what prevented them from closing.

HOW 340B BENEFITS A COMMUNITY

There are a number of ways that 340B provides community benefits.

- It increases access to medications at little to no cost for the uninsured/underinsured, which improves adherence and outcomes.
- It provides funds for any non-reimbursed services, including medication therapy management, medication reconciliation, clinical medication synchronization programs, adherence packaging, or delivery.
- It allows for the expansion of primary care or specialty services.
- It helps provide funding to offer initiatives such as diabetes self-management education and support, and diabetes prevention programs.

HOW WILL 340B AFFECT MY PHARMACY FINANCIALLY?

The pharmacy receives a negotiated fee for each 340B eligible claim. The fee should, on average, be greater than the pharmacy would have made without 340B. And because the covered entity pays for the replenishment inventory, the pharmacy's cost of goods sold on those prescriptions is zero, thus, the pharmacy's margin on existing prescriptions (those that would later be 340B eligible) would increase under the 340B arrangement.

WHAT ARE POTENTIAL PITFALLS OR CHALLENGES?

For some programs, inventory is only replenished after a full package/bottle has been dispensed. This could result in "floating cash" to the covered entity without inventory replenishment. For example, if 30 pills of a 100-pill bottle are dispensed to a 340B eligible patient, in some arrangements, the pharmacy must pass the revenue for those 30 tablets to the covered entity without the covered entity being able to replenish the drug until 70 more tablets are dispensed. As a result, pharmacies must monitor outstanding inventory due and ensure reconciliation is occurring on a regular basis.

Potentially, 340B shipments could result in a pharmacy experiencing excessive inventory, also called inventory swell. This can occur due to the 340B qualification process being performed by third party 340B administrators retrospectively. When prescriptions qualify days after dispensation, the replenishment inventory is also delayed. This can result in the pharmacy potentially ordering the dispensed item from its wholesaler and subsequently receiving the 340B shipment of the same medication.

Dispensing fees must be higher than margins without 340B for the program to be beneficial. Thus, when calculating margins without 340B, wholesaler rebates must be considered, as these directly affect net margins. Comparing the 340B dispensing fee to the margin based on invoice cost alone omits valuable information, leading to an inaccurate analysis.

WHAT ARE THE KEY ELEMENTS TO A SUCCESSFUL 340BPROGRAM?

There are potential benefits to communities with 340B, but due to the complexity of the program, it can be challenging if not structured correctly and monitored closely.

Here are some keys to creating a successful 340B contract pharmacy program:

- Develop a partnership with the 340B covered entity. Along with filling prescriptions for covered entity patients, identify other services and collaborate with the covered entity to improve outcomes and decrease overall costs.
- Determine if the negotiated fee is appropriate. There is not a "'one fee fits all' solution." The fee should be based on the program type, all claims, or specific claims, and the mix of claims. On average, the dispensing fee should be greater than the pharmacy's current margin (without 340B).
- Identify claims with DIR fees and reconcile if within the terms of the agreement.
- Track unreplenished inventory. Third party 340B administrators are software companies that manage 340B programs for covered entities. TPAs often offer reconciliation processes, but they don't always account for partial packages of inventory due to the contract pharmacy. The agreement with the covered entity should include language on how to reconcile these partial packages.
- Monitor pharmacy inventory levels to ensure minimal inventory swell. Return any inventory received in excess on the pharmacy's retail account for a credit.
- Be cognizant of which inventory is being shipped on the 340B account and reduce the retail order to prevent inventory swell.
- Review payment terms of agreement. Terms for payment from the pharmacy to the covered entity should allow sufficient time for pharmacies to receive payment from third-party payers.
- Train and educate staff. For example, 340B replenishment inventory is billed to the covered entity, but it is not free. The 340B inventory replaces what the pharmacy has already paid the wholesaler. Having a staff knowledgeable about the 340B program and its inner workings is critical.

CURRENT CHALLENGES AFFECTING 340B

As mentioned previously, eight drug manufacturers have stopped offering 340B discounts to covered entities on medications dispensed at some contract pharmacies. Each manufacturer has different restrictions and requirements which makes the issue even more challenging to navigate.

Congress has been looking into this situation. Reps. Abigail Spanberger (D-Va.) and David McKinley (R-W.Va.) are leading the charge against manufacturers who have stopped providing 340B discounts to covered entities. They are also challenging discriminatory payments to 340B providers and contract pharmacies by pharmacy benefit managers, private insurance payers, and sponsors of Medicare Part D plans. They introduced the PROTECT 340B Act (H.R. 4390), which would prevent differential payment and treatment of 340B providers and contract pharmacies. (More details are available at bit.ly/calls2protect340b.) Check out NCPA's daily email newsletter *qAM* for the latest developments.

Despite the current uncertainties, I encourage you to explore the opportunities in your community to partner with covered entities to maximize savings and fund services that improve health care outcomes. However, crafting the agreement with a covered entity should be done carefully to minimize risks to your pharmacy. Never sign an agreement without understanding its implications.

To find 340B opportunities in your area, search the HRSA/Office of Pharmacy Affairs website at 340bopais.hrsa.gov/home. To learn more and stay up to date on issues affecting the program, go to www.hrsa.gov/opa/. ■

Amanda Gaddy, RPh, is the co-founder of Secure340B, a company focused on helping pharmacies navigate the 340B program to better serve their communities. She is also the director of clinical services for the Georgia Pharmacy Association's Academy of Independent Pharmacy, where she acts as an education resource, assisting pharmacies with their clinical programs and supplying auditing support to ensure their business runs smoothly. She can be reached at amanda@secure340b.com.