White Paper: Making Sense of the 340B Drug Program

Introduction

This article is intended to educate those involved in or considering involvement in one or more 340B prescription drug programs about issues important to participating retail pharmacies. It is not intended to suggest whether or not any pharmacy should be involved in a 340B prescription drug program or what compensation a pharmacy or pharmacist should expect.

General Program Information

Drug products distributed under the Public Health Service Act, Section 340B (commonly known as the 340B program) are preferentially priced drugs that are priced much lower than retail market prices and are available to patients who qualify as 340B recipients. These patients become qualified by accessing healthcare from a 340B-approved facility (i.e. community health centers, disproportionate share hospitals, which are defined as hospitals that serve a disproportionate share of indigent patients, etc.) and are seen by a 340B-qualified physician. Anyone, regardless of his or her income level, can qualify as a patient to receive these specially-priced drugs as long as they are the patient of a physician who works at a 340B-approved facility. Prescriptions supplied by these physicians can be filled at most community retail pharmacies, but the 340B pricing can only be accessed through an arrangement between the pharmacy and the 340B-approved facility. This process plays out in two scenarios.

Scenario One:

A cash-only patient (no third party coverage) is seen by a physician within a 340B facility and presents at a community retail pharmacy with a prescription for a 340B-approved drug. If that pharmacy is contracted with the 340B-approved entity, the pharmacist would then most likely dispense the 340B-approved drug to the patient at a price discounted in relation to the 340B price for that drug. The pharmacy would dispense the drug (typically from its own current stock for the first fill) and subsequently have the drug replaced by the 340B entity with the same drug, which would cost much less at 340B special pricing.

The quantity of a particular drug dispensed to 340B patients and replaced by the 340B program in relation to non-340B prescription inventory would be kept in "virtual" inventory. In other words, the amount of a particular drug replaced by the 340B entity to the pharmacy would have to reconcile with the amount of that drug dispensed to 340B qualified patients. In this scenario, the 340B patient would simply receive lower pricing due to 340B pricing. The drug may be paid for by the patient, a community health center or other entity. The pharmacy would typically receive a dispensing fee agreed to by the 340B entity by contract. Other financial arrangements between the pharmacy and 340B entity may include first-time inventory coverage payments, a percent of the drug cost, or other contractually agreed upon terms.

Scenario Two:

The 340B qualified patient presents a prescription to a participating pharmacy under all of the same conditions as the previous scenario except that this patient has third party coverage –

some third party (an insurance company, a Pharmacy Benefit Manager on behalf of a payer such as an employer, a government program, or some other payer) is responsible for payment to the pharmacy. In this case, the pharmacy would adjudicate the prescription on-line at the normal retail price, the processor would process the claim, and the pharmacy would receive payment based on retail market-based pricing, as with any other prescription. This traditional retail market price would typically be much higher than the 340B price if the drug was 340B qualified, creating a "spread" pricing situation) between the 340B price and the normal retail price. This spread typically benefits the 340B-approved facility.

The 340B entity would typically replace the drug with a 340B version of the drug and the pharmacy would pay the 340B entity the amount that the pharmacy received upon adjudicating the claim at normal retail pricing less the dispensing fee and/or other amount the pharmacy was contractually entitled to keep.

Example: The pharmacy adjudicates a prescription in accordance with contract pricing (i.e. AWP-15% + $2.00) and is paid based on this contractual amount. Assuming the AWP of the drug is $200.00 then the pharmacy would be paid:

AWP -15% + $2.00 =
$200.00 - $0.15 ($200.00) + $2.00 =
$200.00 - $30.00 +$2.00 =
$170.00 + $2.00 = $172.00 total approved for the prescription

If the patient pays a $30.00 copay, then the pharmacy would receive $142.00 in payment from the third party payer (i.e. $30.00 + $142.00 = $172.00 total payment to the pharmacy).

Assume that the 340B price for the drug is $20.00. The pharmacy would receive the 340B drug in replacement for the dispensed drug. The pharmacy would agree to pay the $172.00 back to the 340B entity less an agreed upon dispensing fee (for purposes of this example, assume an $18.00 dispensing fee).

$172.00 - $18.00 = $154.00 would go back to the 340B entity
$154.00 - $20.00 (340B cost of the drug) = $134.00 profit or "spread" to the 340B entity.

The one unknown in this process is how much the "middleman," the 340B PBM, makes in the equation. Whatever amount that is will reduce the "spread" to the 340B entity by that amount. If that amount were $15.00 per claim then:

$134.00 - $15.00 = $119.00 final profit or "spread" to the 340B entity.

Disproportionate share hospitals, community health centers, and other approved entities are looking for ways to make their bottom line whole. The 340B process described above could obviously add up to large sums of money quickly. Remember, anyone who sees a 340B qualified physician can access 340B prescription services, not just the indigent. And, the above explained process encourages recruitment of patients with private sources of payment because that is where windfall profits come from.

The following outlines opportunities and challenges for pharmacies if they become involved in the provision of prescriptions to patients who qualify for 340B benefits.

Opportunities
The 340B-approved entities discussed above generally want to work with community pharmacies to implement these programs. A provider of services under this scheme must hold a retail pharmacy permit and contract with third party payers before the billing and replacement process can occur. Therefore, community pharmacies are an important player for this process to work.

Most 340B entities want to work with pharmacies in good faith and hope to create a "win-win-win" situation for the entity, pharmacies, and patients. However, they may not understand the potential problems for provider pharmacies, which are described under the "Challenges" section.

Under Scenario one (cash prescriptions), there are fewer concerns for the pharmacies involved, but some still exist. This scenario creates a potential business increase and an opportunity for pharmacy services to be extended to those in the community who may not be able to otherwise afford them. This could reduce uncollectable debts for local pharmacists and even potentially other providers and businesses in the community by freeing up patient dollars for other purposes (i.e. food, clothing, physician visits, etc.). The pharmacies and pharmacists involved need to weigh the benefits and risks and determine if this fits into the business and community health initiatives that they are interested in.

In short, if a pharmacy can contract with one or more of these entities with terms that it is happy with, then this may be a rewarding venture that allows the pharmacy to serve its community well. The second scenario (third party payer involvement) may also provide an opportunity to participate at a greater level with 340B entities. Through a well-reasoned and fairly negotiated contract, it could potentially provide even better revenue than the first scenario. The 340B entities that pharmacies contract with will probably be reasonable with pharmacy payment and, in many cases, actually want the pharmacies to make a fair return for their participation in the program by sharing in the "spread." But, this second scenario presents even more challenges.

Challenges
Scenario one: While the cash payment scenario is much cleaner than the third party payment scenario, there are still things to consider. The replacement drug concept provides several thought-provoking issues. When a pharmacy dispenses drugs from its inventory for which it paid full retail market price and those drugs are replaced by the 340B entity, there is an inventory overhead cost that must be considered, and the drug probably will have to be replaced by another "full priced" restocking before the 340B reconciliation can occur.

Remember, the 340B entity usually only replaces when quantities are dispensed sufficient to justify a full bottle replacement or after a predetermined amount of time has passed. Therefore, a prescription dispensed that leaves a partial bottle sitting on the shelf for several months may become a total loss for the cost of the remainder of the bottle. However, this can be addressed in contract with the 340B entity.

Also, one must consider that when drugs are replaced by the 340B entity and not purchased from the wholesaler, then total purchases from the wholesaler go down. There will eventually be contractual issues with the wholesaler such as purchase guarantees or tiered buying discount criteria that can raise the price on *all* purchases, not just the drugs related to 340B.

Another issue that must be worked through is whether or not there is a problem with a pharmacy receiving drugs bought by another entity. The Arkansas State Board of Pharmacy will have to determine

if this is a legitimate practice or not. There has not been a lot of discussion about 340B inventory but it will have to be dealt with and clarified.

Scenario two: All of the previously mentioned issues with cash 340B prescriptions apply in this scenario. In addition, other very problematic issues arise when there is a third party payer. Pharmacy benefit managers (PBMs) are virtually unregulated and can do by contract virtually anything they decide to do. It has long been recognized that most pharmacies have very little power in the negotiation of a pharmacy/PBM contract.

There is a real concern that when a PBM is the actual payer to a pharmacy for 340B prescriptions that are billed to a PBM, soon the PBMs or their clients will start to question whether or not full price should have been paid when a patient is 340B eligible and the drug is being replaced accordingly. If the PBM, "on behalf of its client," decides to recoup money from a pharmacy as an "overpayment" on a prescription, the pharmacy will be the party that is at risk – not the 340B entity – because the contract lies solely with the pharmacy. This presents a devastating possibility of an audit for hundreds of thousands of dollars over time if a pharmacy does significant 340B business. Of course, this can be addressed in contract with the 340B entity if this pharmacy is willing to ask that the audit risk be covered by the 340B entity and if the 340B entity is willing to accept the risk. Keep in mind that the pharmacy could be subject to huge recoupments even though it retained only a relatively small amount of the money.

Authored by APA Executive Vice President Mark Riley, Pharm.D. July 2012.