Most everyone in pharmacy has heard of the federal 340B drug pricing program. For much of its 20-year existence, the program—which hinges on a large facility’s ability to qualify with the purpose of stretching health care dollars to better serve poor and indigent patients—has not been terribly applicable to the alternate-site infusion field.

Now, through a few pointed regulatory and legislative changes, 340B is expanding. An increasing number of covered entities are participating, and as providers join forces across the continuum to deliver patient-centered care, the cost-saving benefits of the program are being put to work in new ways. As more and more players access 340B, news about the program and how it’s changing the competitive landscape is reaching the markets that we touch. Unfortunately, outdated facts and misinformation about the program persist (see box, this page).

340B DRUG PRICING AND HOME INFUSION PHARMACY

A LOOK AT HOW THESE NEW REGULATIONS MAY IMPACT INFUSION THERAPY

By Michael Rigas, Pharm.D.

MYTHS AND FACTS ABOUT THE 340B PROGRAM

There are some long-held beliefs about the 340B program in the field, but not all of them are true today. Here are some facts that might surprise you:

- 340B was designed for outpatient drugs
- 340B pricing applies to infusion and specialty drugs, not just oral medications
- You don’t have to be a hospital-based pharmacy to treat patients under the 340B program
- A patient’s income and insurance status do not affect whether they are covered under 340B
- 340B covered entities can contract with more than one outpatient pharmacy
- 340B patients can be treated in the home or in an ambulatory suite

As a growing array of covered entities may seek to partner with home infusion pharmacies to ensure quality infusion care is provided to patients for whom 340B drugs were purchased, it behooves us to know how such a relationship might work. Needless to say, they are complex, involve significant hurdles, and require resources to develop and maintain. Regardless of whether you are contemplating a partnership with a 340B covered entity or seeking to understand how this program may be brought to bear in your business landscape, this article provides clarity by outlining the program basics and how they might apply in the alternate-site infusion field.

PROGRAM BASICS

The 340B Drug Pricing Program was created as part of the Veterans Health Care Act of 1992, and is codified as Section 340B of the Public Health Service Act. Managed by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA), the program provides eligible safety-net providers substantial savings by limiting the cost of covered outpatient drugs.

These “covered entities” include disproportionate share hospitals (DSHs)—those that provide a certain amount of charity care—children’s hospitals, freestanding cancer hospitals, and qualifying rural facilities, such as critical access hospitals, rural referral centers, and sole community hospitals. In addition, there are a number of niche health care programs that qualify because they receive federal funding to serve specific...
patient populations the 340B program is designed to assist. For example, HIV clinics and state-run AIDS drug assistance programs, black lung clinics, hemophilia centers, and urban Indian organizations (go to http://www.hrsa.gov/opa/index.html for a full list with links to details and qualifying criteria for each).

The purpose of 340B is to enable covered entities to stretch scarce resources in order to reach more patients and provide more comprehensive services. It’s important to note that OPA does not regulate how the savings are to be used, although it suggests that covered entities may reduce prescription drug prices to patients, increase the scope of services offered, serve more patients, and offset losses. The agency reports that covered entities spent an estimated $6 billion in 340B drug purchases in 2009—returning between $1.2 and $3 billion to the provision of health care.

The program offers significant discounts. OPA estimates that participants average savings of 25% to 50% on the cost of outpatient drugs. The 340B price is a ceiling price from which many covered entities negotiate downward—entities that participate in the voluntary prime vendor program typically pay 15% below the ceiling price, and certain covered entities are permitted to buy drugs through group purchasing organizations (GPOs).

Pharmaceutical manufacturers voluntarily make their product available under 340B, but are required to do so if they participate in the Medicaid drug rebate program—although the same drug cannot be subject to both discounts. Essentially, any drug maker that wants its product on a state Medicaid formulary must also participate in 340B. As a result, most outpatient medications, including oral, injectable, and infused drugs, are available at 340B pricing (lists of 340B drugs are available at 340B pricing as long as they meet the aforementioned patient criteria.

The current patient definition was put forth by HRSA in 1996, and has not been changed since. A 2011 Government Accountability Office (GAO) report, recommended that the HRSA offer “new, more specific guidance on the definition of a 340B patient,” so program participants should expect further clarification in the future. For more information on how patients are defined, go to http://www.hrsa.gov/opa/eligibilityandregistration/index.html.

The 340B program covers not only drugs dispensed by outpatient pharmacies for patient self-administration but also drugs administered by physicians in hospital outpatient settings. The covered entity must develop a tracking system to ensure that drugs purchased through the program are not used for inpatients or for Medicaid patients—this inventory requirement extends to pharmacies contracting with the covered entity.

There are two program prohibitions: diversion of 340B eligible drugs to non-eligible patients and duplicate discounts relative to Medicaid patients. Diversion occurs when dispensing drugs to individuals who are not patients of the covered entity or dispensing drugs in an area that is not covered. Duplicate discount refers to receiving a 340B discount and a Medicaid rebate on the same drug. Covered entities must maintain records that demonstrate compliance with all program requirements. These records may be subject to audit by the manufacturer or the government. Likewise, pharmacies that contract with covered entities—under a “ship to/bill to” arrangement—are subject to audits for identification and prevention of diversion and/or duplicate discounts. Again, as the program expands, participants should expect stepped-up auditing as per the 2011 GAO report.

Maintaining compliance can become complex in a hurry. Patients must be screened for eligibility, drug purchasing and inventory records must be kept separate (some state programs require separate physical inventories), claims must be split-billed and then reconciled, often requiring payment adjustments—all in a fashion that meets federal and state regulations. Because participating in the program involves a high level of administrative oversight and operational processes—with sizeable investments and repercussions for mistakes—many providers choose not to pursue it. And, as mentioned previously, until recently, 340B was typically only of interest to health system-related pharmacies.

**New Regulations, New Opportunities**

Changes in the regulations governing the program may create new avenues for infusion providers to partner
with 340B covered entities. The Patient Protection and Affordable Care Act (PPACA), signed into law in March 2010, expanded the 340B program in several ways. First, it added several new hospital types to the definition of covered entities. The program now includes qualifying children’s hospitals, free-standing cancer centers, critical access hospitals, rural referral centers, and sole community hospitals. In addition, it lowered the DSH adjustment percentage required by some newly covered providers—rural referral centers and sole community hospitals—from 11.75% to 8%. PPACA also expanded covered entity status to outpatient clinics, provided they are an integral part of the hospital and reimbursable on the Medicare cost report.

Taken together, these measures have significantly increased the number of covered entities participating in the program. In 2009, before PPACA became law, 13,817 entities were enrolled in 340B, but in 2011 that number reached 16,314—an 18% increase in just two years. OPA projects nearly 19,000 covered entities participating by 2013.1 It’s important to note that these projections were made in 2011—well before the full impact of PPACA implementation. There is speculation that as uninsured patients access coverage under the 2014 mandate, covered entities may lose their ability to qualify for continued participation in the program. While this may be possible in some entities that qualified primarily due to their indigent population, the GAO noted that it expected other facilities might remain or become eligible as Medicaid is expanded, since service to Medicaid patients is a variable in the disproportionate share calculation.3

In addition to the bump in eligible facilities, another new regulation, issued by HRSA and effective April 5, 2010, allows covered entities to contract with multiple pharmacies to fill outpatient prescriptions for their patients—and to supplement their in-house pharmacies. Previous regulations limited covered entities to one such relationship, but citing increased patient access to drugs and clinical services, the agency eased up on that requirement.

The new regulations have opened a floodgate of new pharmacy relationships. The number of contracted pharmacies participating in 340B jumped from 2,646 to 6,915 between 2010 and 2011. And, by 2011 approximately 15% of covered entities had contract pharmacy arrangements.2 OPA expects that these figures will nearly double by 2013—projecting more than 11,500 contracted pharmacies by 2013. That’s a stark contrast from a decade ago when fewer than 200 pharmacies contracted with 340B covered entities.1

As the program becomes more commonplace, more reliable information regarding how it works is also coming to the forefront. New opportunities and newfound truths may work together to open some doors for infusion providers, many of whom have assumed 340B was “off limits” or “more trouble than it’s worth.” Of particular interest is the fact that 340B discounts apply to the covered entity and not the patient. Therefore, discounted drugs can be prescribed to a diverse pool of 340B eligible patients.
patients, not just those who are uninsured or “indigent” (provided they meet the criteria listed above). In fact, patients can be employees of a covered entity and/or have commercial insurance coverage. This means that third-party payers can be billed at their full contracted rate.

Furthermore, the drugs that can be purchased with a 340B discount are not limited to oral medications, filled in a retail pharmacy. Qualifying drugs include FDA-approved prescription drugs, over-the-counter drugs written on a prescription, biological products that can be dispensed only by prescription, and FDA-approved insulin. Since injectables and IV drugs administered in an outpatient clinic or home qualify, it’s possible for home infusion providers to consider building relationships with 340B covered entities.

Contracting with a 340B Covered Entity

According to OPA, a covered entity may elect to dispense 340B drugs to patients through contracted arrangement for pharmacy services. This helps facilitate program participation for covered entities that do not have access to available or appropriate “in-house” pharmacy services, those that wish to supplement their own in-house services, or those that want to use multiple contract pharmacies to increase patient access to 340B drugs. For more information on contract pharmacy services go to http://www.hrsa.gov/opa/implementation/contract/.

What would a relationship with a 340B covered entity look like? Partnerships can be structured many different ways, but the same basic ground rules apply. Most importantly, the covered entity must maintain legal title of the 340B drugs as required by the program. The contract pharmacy may receive the drugs in order to provide them—along with pharmacy services—to patients of the covered entity. This is known as a “bill to/ship to” agreement. 340B drugs cannot be resold or used to fill prescriptions for patients who are not 340B eligible at the covered entity.

In addition, if a contract pharmacy dispenses drugs to Medicaid beneficiaries, steps must be in place to ensure that double discounting does not occur. HRSA contract pharmacy guidelines state that a covered entity may not use a contract pharmacy to dispense to Medicaid beneficiaries unless that contracted pharmacy has reached agreement with the state Medicaid agency with respect to a method to prevent a duplicate discount situation from occurring.

As expected, these regulations create compliance issues that call for intricate inventory management, dispensing, and billing systems as well as accurate record-keeping. The contract pharmacy must work with the covered entity to establish a tracking system suitable to prevent diversion of 340B drugs and duplicate discounts on the drugs. It must also provide the covered entity with reports (e.g., quarterly billing statements, status reports of collections and receiving, and dispensing records), and the covered entity will periodically compare its prescribing records with the contract pharmacy’s dispensing records to detect potential irregularities. Contract pharmacies must adhere to all federal, state and local laws, and requirements, and assure that all 340B records are accessible and readily available for audits by government and outside parties.

Both HRSA and drug manufacturers have the authority to audit covered entities, and in the past that burden largely fell on manufacturers. However, the 2011 GAO report recommended that HRSA provide additional oversight. In the Spring of 2012, the agency began conducting selected audits. Given the Administration’s push for overall program integrity paired with the natural potential for abuse in a rapidly expanding program, providers should expect stepped up oversight of the 340B program and be prepared to demonstrate compliance. For more information on program integrity and audits, go to www.hrsa.gov/opa/programintegrity/index.html.
A contract pharmacy may provide services beyond dispensing to the covered entity or patients at the option of the covered entity. This creates a host of possible relationships for delivering patient care. Examples might include:

- **Retail pharmacy.** A provider with a retail presence could fill prescriptions for outpatient oral/self injectable medications. While this is typically the purview of community pharmacies, infusion pharmacies serving specific patient groups, such as HIV or tuberculosis, that fall under 340B could contract with a covered entity to dispense medications to their patients for a fee. This is especially effective in meeting the needs of rural communities and lays the groundwork for building new patient and referral source relationships.

- **Hospital-owned IV/specialty pharmacy.** An IV pharmacy owned by a covered entity could treat 340B patients without having to be a contracted pharmacy. Many of these pharmacies are creating relationships with their self-insured parent entities that make them the pharmacy of choice for health system employees. This was an area of great interest in the 2011 GAO study and HRSA notes on its FAQ page that, “The 340B program is limited to patients of the covered entity and has never been a general employee pharmacy benefit or self-insured organization pharmacy benefit. Evidence of an employer relationship or insurer relationship is not a consideration in determining whether the patient is eligible for 340B drugs.” These arrangements should be considered carefully, especially given the expectation that HRSA will issue a new, clearer definition of 340B patients in the near future.

- **Hospital-managed ambulatory infusion center.** An independent IV provider could contract with a covered entity to provide patient care in the covered entity’s outpatient clinic. The provider would be paid for management and staffing, and thus, avoid involvement with the reimbursement function or inventory management issues. If a third-party payer exists, the covered entity can bill it for the drug and service component. Depending on the contract, the covered entity may also pay the contracted pharmacy a dispensing fee for each 340B prescription filled.

- **Provider-managed ambulatory infusion center.** Similar to the above but more extensive, an independent provider could run an ambulatory clinic to which a covered entity refers patients. In addition to patient care, the provider would be responsible for inventory management and third-party billing when applicable. The provider would return the drug margin (the difference between the 340B price and the contracted reimbursement rate) to the covered entity; it could also bill the payer for the service com-
ponent (per diem). Depending on the contract, the covered entity may also pay the contracted pharmacy a dispensing fee for each 340B prescription filled.  
• **Home infusion therapy pharmacy.** A contract that establishes a relationship between a home infusion therapy pharmacy and the covered entity would allow the infusion pharmacy to manage the infusion treatments of patients of a covered entity at home as an agent of the covered entity, using the covered entity’s 340B purchased drugs, contracts, and billing systems.

Additional opportunities may present themselves as new health care delivery models emerge and providers focus on patient-centered care across many sites of care. Of special interest are accountable care organizations (ACOs), which because they involve separate entities create new legal conundrums. In order to address this, HRSA issued a clarification document in the Spring of 2012, noting that, “Inclusion of a covered entity within an ACO does not make the entire ACO eligible for receiving discounted drugs under the 340B program and does not permit ACO-associated entities, which do not satisfy the eligibility requirements of section 340B(a)(4), to access 340B program discounted drugs.”

**Clearly Defined and in Compliance**

Naturally, any contracted pharmacy arrangement should clearly specify which party is responsible for providing care, management, and other administrative services, such as staffing and billing, under multiple conditions. In order to engage in contract pharmacy services, the entity and pharmacy(ies) must have a written contract that aligns with the compliance elements listed in guidance, and must register the contract pharmacy on the OPA database. OPA will not review the agreements but strongly urges the engagement of legal counsel to ensure that all federal, state, and local requirements are met. To see the federal guidelines for contracting, go to www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf.

As mentioned previously, compliance is key. Our industry is committed to ethical behavior, and by participating in the 340B program, providers open themselves up to audits. There are tools and software packages available that can aid in inventory management, patient eligibility, and recordkeeping related to this intensely scrutinized program (see the Resources box on p. 37 for more information).

Building a relationship with a 340B covered entity is not a panacea for reducing your own cost of goods, nor is it a quick process. There are numerous hurdles to be negotiated prior to entry; maintaining the relationship requires significant investments in recordkeeping and administrative oversight; and—given the resource requirements on the front end—it’s a long-term proposition. This means choosing partners that are solidly rooted in the program and not likely to experience a change in status due to shifting demographics as relates to the qualifying criteria for the program. It’s especially important to consider this last point as the implementation of PPACA continues and more uninsured patients become insured, potentially altering the payer mix for many covered entities.

Regardless of how they are structured, forging partnerships with 340B covered entities can offer lasting opportunity. By helping covered entities increase access to specialty and infusion therapies for their patients, providers can play a critical role in stretching the precious resources that go to patient care, and demonstrate—in new ways—the value we bring to the delivery of patient-centered care in the lowest cost setting. And, by the very level of cooperation needed to successfully partner with a covered entity, willing and capable providers can prove themselves to be trusted collaborators.

**References**


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