Everything You Wanted to Know About the 340B Drug Pricing Program

by Matt Sherer, MBA, MHA, and Teri U. Guidi, MBA, FAAMA

From posts to *ACCCExchange* to questions asked at ACCC meetings, it is clear that our member programs want more information about the 340B Drug Pricing Program. Here is the information you've been asking for: a description of the 340B Drug Pricing Program; how to qualify and apply for the program; implications of participating in the program; and clarification on how the Patient Protection and Affordable Care Act of 2010—universally known as the Healthcare Reform Law—has impacted the program.

What is the 340B Drug Pricing Program?

The 340B Drug Pricing Program resulted from enactment of the Veterans Health Care Act of 1992, which is in Section 340B of the Public Health Service (PHS) Act. Sometimes referred to as PHS Pricing, the program is managed by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) (*http://www.hrsa.gov/opa*). Section 340B of this legislation limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes, and qualified disproportionate share hospitals. The purpose of the 340B Program is to enable these entities to stretch scarce federal resources, reaching more eligible patients and providing more comprehensive services. For safety-net providers, participation in the 340B Drug Pricing Program results in significant savings—between 20 to 50 percent—on the cost of pharmaceuticals.[1]

Who Qualifies for the 340B Drug Pricing Program?

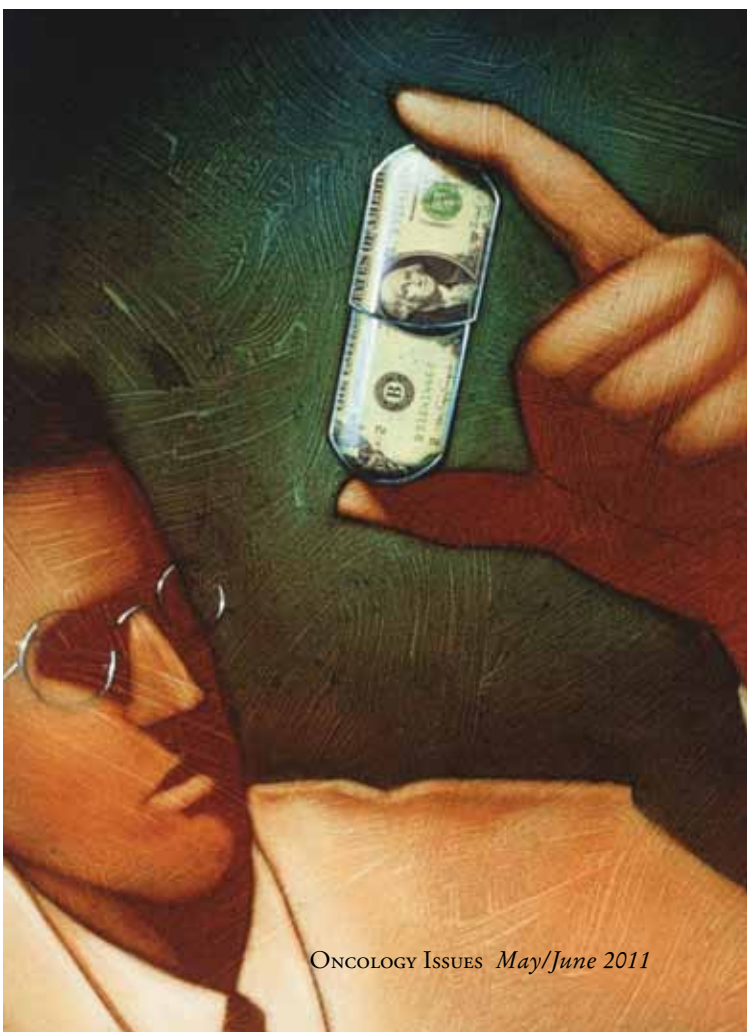
Several healthcare entities qualify for this program. For ACCC members, the most relevant entity would be a disproportionate share hospital. There are five key requirements to qualify for the 340B Drug Pricing Program and *all* must be met to qualify. Healthcare entities must:

1. Be a disproportionate share hospital with a disproportionate share hospital (DSH) percentage of at least 11.75 percent.
2. Own and operate participating outpatient clinics.
3. Opt out of using Group Purchasing Organizations (GPOs) for the purchase of these drugs.
4. Maintain a separate inventory (real or virtual) of drugs prescribed to 340B patients versus non-340B patients.
5. Ensure that 340B drugs are only used by appropriate patients.

While most private practice and for-profit entities *do not* qualify for the 340B Drug Pricing Program, other qualified entities include critical access hospitals, freestanding cancer hospitals, and sole community hospitals. The full list of qualified entities can be found online at: *http://www.hrsa.gov/opa/introduction.htm*.

How Does My Program Apply for the 340B Program?

Once you have ascertained that your organization is an eligible entity, you must submit the appropriate registration form and supporting documents to participate to the Office of Pharmacy Affairs, 5600 Fishers Lane,



Mailstop 10C-03, Rockville, MD 20857. Or fax the information to: 301.594.4982. Registration forms are available online at: *https://opanet.hrsa.gov/OPA/Registration/RegistrationMain.aspx*.

The key factor is being able to demonstrate the DSH percentage. (The DSH percentage is reported annually on all Medicare Cost Reports submitted by hospitals.) The application process is not overly complicated, but it can take time—particularly if the agency has questions about your application. Once your facility is approved, you will receive notification from HRSA that your program is now eligible. HRSA will also list your program as an eligible entity on the agency's website so that drug manufacturers can confirm eligibility.

What are the Benefits of Using the Program?

As stated previously, an outpatient infusion clinic can see a reduction of 20 to 50 percent off of their drug costs. These savings go straight to your bottom line and could allow your program to provide services that previously were cost prohibitive. These savings could also be reinvested in technology, staff, etc. Particularly as reimbursement amounts continue to decline, participation in the 340B Drug Pricing Program can be a competitive advantage.

How is the 340B Drug Pricing Program Managed?

Once enrolled in the program, hospitals and cancer centers must maintain detailed records of their qualified patients and how the drugs purchased under the 340B Program are used. The term "qualified patient" is critical as these drugs cannot be used on any non-qualified patients. A qualified patient is someone who:

1. Has an established relationship with the provider (i.e., with the DSH institution).
2. Has been seen by the provider at least once in the past 12 months.
3. Has their health record maintained by the organization.
4. Receives healthcare related to a condition for the medication received from a provider that is either employed by the organization or is under contract to provide services for the organization. (A private practice could potentially contract with a qualified DSH hospital to provide care but, again, many legal requirements must be met for this option to work.)

Diversion of these drugs to other locations and inpatient use are strictly forbidden.

What Changed in the Program Because of Healthcare Reform?

The Affordable Care Act of 2010 expanded the types of entities qualifying for participation in the program; expanded integrity and enforcement provisions; and mandated development of regulations to address complaints and dispute resolution.

Specifically, the law expanded the 340B Drug Pricing Program to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. For these covered entities, the term "covered outpatient drug" does not include orphan drugs (drugs designated for rare conditions by the Secretary under section 256 of the Food, Drug, and Cosmetic Act).[2]

The law requires HRSA to improve compliance by covered entities by developing:

1. Procedures to enable and require covered entities to regularly (at least annually) update their information in the HRSA database.
2. A system for HRSA to verify the accuracy of information in the database.
3. More detailed guidance to covered entities describing methodologies and options available for billing covered drugs to state Medicaid agencies in a manner that avoids duplicate discounts.
4. A single, standardized system by which covered entities can be identified by the drug companies, distributors, other covered entities, and HRSA for purposes of facilitating the procurement of covered drugs.

The law included new penalties that can be levied against covered entities that divert drugs to individuals who are not patients of the covered entity. Basically, the covered entity would be liable to the drug company for the amount equal to the reduction in the price of the diverted drug plus the amount of interest due, depending upon the circumstances.

The revisions in the Affordable Care Act of 2010 are the most significant since the inception of the 340B Drug Pricing Program.

Matt Sherer, MBA, MHA, is service line administrator, Oncology, Tallahassee Memorial Cancer Center, Tallahassee, Fla. Teri U. Guidi, MBA, FAAMA, is president and CEO, Oncology Management Consulting Group, Pipersville, Pa.

References

[1]U.S. Department of Health and Human Services Administration. *Introduction to the 340B Drug Pricing Program*. Available online at: *http://www.hrsa.gov/opa/introduction.htm*. Last accessed March 23, 2011.

[2]Morgan Lewis. *Healthcare Reform Law Leads to Significant Changes to the 340B Program*. Available online at: *http://www.morganlewis.com/pubs/WashGRPP_340BProgram_LF_14apr10.pdf*. Last accessed March 23, 2011.