In an effort to provide quality healthcare to vulnerable populations, the government enacted the Public Health Services Act in 1992. Section 340B of this Act (also referred to herein as “the Program”) requires drug manufacturers to provide outpatient drugs at deeply discounted prices to eligible health care centers, clinics, and hospitals (collectively termed “covered entities”), enabling them to save between thirty and fifty percent on their pharmacy costs. Despite the significant savings available to those healthcare providers whose mission is to serve indigent, homeless, and uninsured populations, the Program has historically not been fully utilized. Linger ing misperceptions and misunderstandings about the regulations and requirements associated with enrollment and participation continue to linger, but in fact, may no longer be valid. In April 2010, the 340B guidelines were revised and updated, particularly in regard to pharmacy providers. The new guidelines expanded the list of federal entities that could access this program, as well as opportunities for regional and community pharmacies to get involved. Consequently, pharmacies that previously investigated the Program, but decided against participation, may now have incentive to take another look. The 340B program in its present form allows mechanisms for community pharmacies to grow their businesses, to find new and innovative methods of delivery, and to become a more comprehensive pharmacy in providing overall patient care. As needy populations continue to grow, so too will the demand for health care centers, pharmacies, and hospitals that are willing and able to treat them. Depending on the state of health care reform currently before the Supreme Court, estimates suggest that the groups of the uninsured, undocumented, and economically unstable will continue to grow. Public hospitals, particularly those in rural areas that are so prevalent in South Carolina, often struggle to remain profitable. As you well know, community pharmacies in these areas are also often finding difficulties in an environment of closed networks and poor reimbursement. Despite these facts, fewer than 25% of Community Health Centers participate in the Program, which is representative of community pharmacy participation. It is not difficult to speculate why this might be. The program is not well understood with respect to enrollment, requirements, and regulations. Additionally, there is a perceived complexity in understanding the overlap between Medicaid and the 340B program, and the difference in billing, inventory, and reporting requirements. Further, most pharmacies consider costs of technology and additional staff that may be necessary to implement the program, which may minimize any return on investment. Fortunately, the technology and staffing issues have become increasingly less significant with the emergence of new technology more readily available at lower costs.
To appreciate what these guideline changes could mean to community pharmacy, one must first understand the basics of the Program, which has the purpose of stretching “scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” The Health Resources and Services Administration (HRSA) retains overall responsibility for the program, which is administered by the Office of Pharmacy Affairs (OPA) within HRSA. OPA’s stated mission is to 1) administer the 340B program; 2) develop innovative pharmacy delivery models and provide technical assistance; and 3) to act as a federal resource for pharmacy issues. The 340B program is open to “covered entities” that receive federal funds for specific health care missions or who are dependent on federal funds to serve uninsured, low income or Medicaid patients. The list of covered entities now includes the following:

Hospitals:
- Disproportionate Share Hospitals (DSH) that serve indigent and underserved communities
- Children’s hospitals and Cancer hospitals
- Critical Access hospitals
- Sole community hospitals
- Rural Referral Centers

Non-Hospitals:
- Qualified Health Centers (FQHC)
- Ryan White CARE Programs (Parts A, B, & C)
- State-operated AIDS drug assistance programs
- TB, black lung, family planning and sexually transmitted disease clinics
- Hemophilia treatment centers
- Pubic housing primary care clinics
- Homeless clinics
- Urban Indian clinics
- Native Hawaiian health clinics

The Program is considered a “patient defined” program. In other words, only those individuals who meet all of the criteria as defined in the regulations are eligible to receive the discounted drugs on an outpatient basis. To meet the eligibility criteria, a “patient” must:

- Be an outpatient at the time the drug is administered or dispensed;
- Have received health care services from a 340B covered entity

Additionally:
- The service must have been provided by an employed or contracted clinician of the covered entity;
- The covered entity must have a record of the care rendered; and
- The transaction (prescription dispense or drug administration) must not result in a rebate collected by a Medicaid program

For designation as a covered entity, an organization that receives federal funds must be enrolled with the Office of Pharmacy Affairs. Community pharmacies by themselves cannot become a covered entity; however, they can enter into a contractual agreement with a covered entity. The original guidelines only allowed a covered entity to contract with a single outside commercial pharmacy if they did not have an existing in-house pharmacy. With the new guidelines, covered entities may now contract with multiple pharmacies even while maintaining an in-house pharmacy to maximize patient access to low cost drugs. One restriction that remains in place is that a pharmacy with a contractual arrangement with a covered-entity may not dispense 340B drugs to any patient who receives healthcare from another covered entity.

Some general guidelines pertaining to pharmacies that participate in the 340B program are as follows:

- The covered entity must inform patients of their freedom to choose a pharmacy provider. If a patient does not elect to use a contract pharmacy, the patient may fill the prescription at a pharmacy provider of the patient’s choice.
- The contract pharmacy must provide the covered entity with reports relating to the contract pharmacy services, including billing statements, status reports of collections, and receiving and dispensing records.
- The contract pharmacy, with the assistance of the covered entity, must maintain a tracking system suitable to prevent diversion of 340B drugs to individuals who are not patients of the covered entity.
- 340B drugs may not be dispensed to Medicaid patients unless the covered entity, the pharmacy, and the state Medicaid program have established an arrangement to prevent duplicate discounts.
- The contract pharmacy must maintain separately all pertinent records from the pharmacy’s own operations, and must make those records available to the covered entity, OPA, and pharmacy manufacturers in the case of an audit.
Generally, the way it works is when a pharmacy dispenses a drug for a 340B patient, the covered entity replaces the drug through its wholesaler, which amounts to a virtual inventory. The pharmacy does not make a profit per se on the sale of the drug, but is compensated through a negotiated co-pay, which can be quite reasonable. The pharmacy takes payments for the covered entity and sometimes, depending on the contract and accounting, subtracts its dispensing fees from the funds delivered to the covered entity. Obviously, nothing is quite as simple as it would first appear, but not surprisingly, there are a number of companies that specialize in establishing the Program in pharmacies.

It is important to note two major prohibitions exist within the Program. The first prohibition protects the drug manufacturer from having to “double discount” drugs, which basically means that either the state Medicaid agency receives its rebate or the health center receives its 340B discount, but not both. The second prohibition protects against the illegal sale, transfer, or diversion of discounted drugs to any individual or entity that does not qualify under the Program. While the ultimate responsibility for program compliance lies with the covered entity, it is incumbent upon the contract pharmacy to establish strong recordkeeping and inventory systems in order to remain compliant with the guidelines of the program and to report regularly this compliance to the covered entity.

So how will retail and community pharmacies be affected? With the new regulations that allow covered entities to contract with multiple pharmacies, there exists a large potential for expansion. There are signs that the Federal government would like to expand the Program further; however, as one would expect, the pharmaceutical industry is not supportive of expansion and may be conducting a concerted campaign against to the Program’s recent wider applications. Be that as it may, Pharmacies that are willing to investigate this program and access the myriad resources available will be poised to move forward building partnerships in which both the pharmacy and the covered entity will stand to benefit. Along with new patients and new revenue from existing patients, the Program provides an opportunity to partner with health centers and hospitals, and most importantly, use these saved funds to provide additional services to patients for improved care, which is the goal of the Program.

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