



CHAPTER 8

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340B Considerations in Retail and Specialty Pharmacy

BACKGROUND

As the U.S. healthcare system continues to evolve and as care transitions from the inpatient to ambulatory setting, health systems frequently consider operating specialty pharmacy and/or retail pharmacies. Ambulatory pharmacy business lines can create unique opportunities and challenges for 340B-covered entities. When 340B drug pricing can be applied to retail and specialty prescriptions, there is a material financial benefit due to the lower cost of goods sold. However, the 340B program's complex regulatory and guidance structure requires adequate resources to ensure compliance and protect the covered entity's qualification status across the enterprise. Based on the compliance risk associated with 340B, a thoughtful strategy for retail and specialty pharmacy programs should be developed and utilized when implementing these services.

The focus of this chapter is to provide an understanding of 340B in the context of an overall strategy for retail and specialty pharmacy services, to build a patient care and business model that uses 340B appropriately, and to provide a discussion of regulatory considerations and financial reporting.

RETAIL/SPECIALTY STRATEGY AND MISSION

A 340B-covered entity's mission in creating a retail or specialty pharmacy service is typically multi-fold. An ambulatory pharmacy can provide a unique, aligned set of services, leveraging the health system's larger patient care resources; it can also serve as a convenient location for patients and employees to obtain prescriptions. When a covered entity fills its own patients' prescriptions and manages the associated clinical, compliance, and quality activities, the organization gains access to a valuable pool of patient data that provides insights into drug-related quality indicators such as compliance and outcomes. With the cost benefits brought by 340B, an ambulatory pharmacy service line can generate a revenue stream to offset the uncompensated or undercompensated care that the organization provides and extend key pharmacy and patient care services to the uninsured and underinsured. Important considerations for optimizing the 340B program elements, specific to a retail and specialty pharmacy strategy, may include acute care discharge prescriptions and prescriptions generated from 340B-eligible ambulatory clinics of the covered entity.

Employee prescriptions might provide an opportunity in that the covered entity may have some ability (as the drug benefit sponsor) to influence where employees have prescriptions filled. However, to qualify for 340B coverage, an employee prescription must meet the same 340B qualification criteria as any other patient.

An organization's administrative, pharmacy, and compliance leadership team needs to assess the potential for 340B-qualifying prescriptions that will be generated, along with the offsetting non-340B prescriptions, to determine if retail pharmacy services are operationally and financially feasible. Specialty pharmacy services, including prior authorization activities, compliance management and monitoring, medication assistance, and other clinical and patient support services, may help to bring additional prescription volume into the traditional retail pharmacy program. However, the associated additional cost, resources, and expertise required should be evaluated in detail.

PATIENT CARE MODEL DESIGN

Supporting retail and specialty pharmacy services require a team of qualified professional personnel. Beyond the obvious pharmacists and technicians to support the operational aspects of filling and dispensing prescriptions, the endeavor requires prior authorization and medication assistance technicians, business office personnel to handle billing follow-up, auditing personnel for 340B compliance, information systems support, mail order services, and clinical pharmacists to serve as liaisons to the various clinical areas targeted by the specialty pharmacy business.

The hiring and training of prior authorization technicians and medication assistance technicians to help all of the medical center's patients is an important investment. The efforts of these individuals may not always result in a prescription fill generated for the institution. This may be due to being locked out of a pharmacy network by the patient's third-party payer, by a pharmacy benefit manager (PBM), or by a medication supplier. It may also be a patient's choice to take a prescription and related care to another provider. The staff of technicians should support a unified intake and approval process for prescribers so all patients are served at the highest level of care and so that the prescribers can rapidly, reliably, and consistently enroll patients and transition care. In any health-system retail pharmacy model, there is always a subset of patients who cannot or will not have their prescriptions filled at the organization's ambulatory pharmacy.

Specialist pharmacy clinicians and technicians are generally assigned to ambulatory areas, in particular, care areas providing clinical services that have medication-intensive patients. An organization can assess patient care, provider, and claims data to determine the services and clinics generating the highest volumes of specialty medications and evaluate the potential for 340B qualification. A targeted assessment and strategy based in these clinics can create the critical mass required to implement services and the corresponding revenue, which will support growth as the service matures and grows. The role of care area-based clinicians is to monitor patients, plan therapy, and facilitate the necessary resources and authorizations to ensure appropriate patient care success. This team can also support medication therapy compliance programs and resolve logistical, behavioral, cost, and other issues for patients to ensure reliable access to medications.

Specialty pharmacy requires information technology (IT) support to attain the proficient use of the electronic medical records system, pharmacy and medical claims systems, and retail and specialty pharmacy business information systems and automation. Case management software systems can support pharmacy personnel in monitoring side effects, managing recurring refill notices, establishing a mechanism for documenting interventions, and creating reports to demonstrate outcomes associated with specialty drug therapy. An organization entering the specialty pharmacy setting will need to determine whether to build or buy a pharmacy-specific case management system to monitor patients.

As an organization assesses its patient demographics and service model, mail service pharmacy should also be considered. The logistics of mail service pharmacy include developing a partnership with a delivery service, contracting with a mail order supply vendor, and planning for cold chain deliveries and other special handling requirements.