CHAPTER 11

340B Considerations for Rural Hospitals

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LEGISLATIVE HISTORY

In 2010, the Patient Protection and Affordable Care Act (PPACA) amended the Public Health Service (PHS) Act to add several new hospital types to the definition of covered entities for 340B. Section 340B(a)(4) now includes certain qualifying children's hospitals, free-standing cancer centers, critical access hospitals (CAHs), rural referral centers (RRCs), and sole community hospitals (SCHs). Under section 340B(a)(4)(N) of the Public Health Service Act, as amended by the ACA, the prohibition against participation in group purchasing organization (GPO) arrangements that applies to 340B-eligible disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals does not apply to critical access hospitals, rural referral centers, or sole community hospitals.[1]

KEY POINT

Because the GPO prohibition does not apply to rural hospitals, they can "shop" across their GPO catalog in addition to 340B pricing. 340B software settings and ordering practices should be tailored accordingly.

UNIQUE CHARACTERISTICS OF RURAL HOSPITALS

The three types of hospitals discussed in this chapter are essential providers in the rural health safety net. Although they are located in smaller markets than their urban counterparts, the demands for providing care are equally or even more complex. Rural hospitals are often the only source of care in small communities where the residents are more likely to be uninsured or underinsured and have below average income and health status.[2] Rural hospitals have fewer physicians, specialists, and advanced clinical capabilities, all while serving more elderly and Medicare patients.[3]

The economic and health service situation in rural areas is generally more critical than in urban areas. There are rural-urban disparities in health conditions associated with several preventable or chronic conditions compounded by the parallel disparity in healthcare infrastructure and professional capacity to attend to these increased needs.[4] Due to the geographic, demographic, and cultural obstacles faced by rural providers, the opportunity to capitalize on pharmaceutical savings through programs like 340B is vital.

The inpatient length of stay in a rural hospital is typically short or even limited by law; as such, there is a greater emphasis on outpatient and primary care services at these hospitals—areas the 340B program is intended to support. Rural hospitals increasingly treat cancer and specialty patients as their communities are experiencing the shift from private practice to hospital-based clinics. Rural hospitals providing access to infusion services for their patients are on the rise; however, because many of these treatments are orphan drugs, the benefit from 340B may be limited. Orphan drugs are described in more detail later in the chapter.

What Characteristics Influence Rural Hospital Participation in 340B?

Rural hospitals have been eligible for 340B since the fall of 2010, yet not all hospitals are enrolled; if they are enrolled, not all of them actively participate in the program.[5] Academic research into potential reasons for the modest level of enrollment suggests that it arises from the fact that the same law expanding 340B to rural hospitals also added new integrity provisions and certain restrictions on the ability to use 340B. The PPACA requires annual recertification of all 340B enrollees, audits of program participants, compliance with the orphan drug exclusion, and potential penalties for covered entity noncompliance.

Rural hospitals participating in 340B have higher overall revenue, a higher volume of outpatient services where drug use is connected (e.g., ambulatory surgery, emergency departments, primary care clinics, home healthcare), the presence of chemotherapy services (where the 340B discount is most valuable), higher pharmacy staffing, and a deeper understanding of the 340B program.[5,6]

KEY POINT

Rural hospitals face unique challenges in implementing 340B due to personnel limitations, strained finances, and expertise. Thoughtful planning should be undertaken before entering the 340B program.

Additional outreach and education are necessary to increase awareness of rural hospitals' eligibility and to help ensure pharmacy directors and administrators can make informed decisions about participation. Entities must be able to weigh the potential cost-savings benefits alongside costs of compliance since there are both benefits and drawbacks of participating in 340B.

What Makes Running a 340B Program in a Rural Area Unique?

Critical access hospitals, sole community hospitals, and rural referral centers have several common challenges related to resources. This broad characteristic may make the implementation and management of a compliant 340B program more challenging.

First, most rural small hospitals are faced with limited personnel resources. In many cases, the pool of pharmacists and pharmacy technicians can be limited. Even when fully staffed, pharmacist and technicians need to master multiple tasks and do not have the luxury to devote full-time attention to one area. Instead, pharmacy staff needs to multitask between job functions with pharmacists performing some technical duties, and technicians performing other duties such as purchasing. Staffing balance is often delicate in rural hospital environments—any disruption can cause priorities to focus solely on direct patient care and forgo less urgent tasks such as 340B management, auditing, and compliance oversight.