CHAPTER 13 Developing a High-Performing 340B Program

Gregg Niemiec, BS, RPh and
Andrew L. Wilson, PharmD, FASHP

Beyond compliance with 340B rules and Apexus best practices, what constitutes a high-performing 340B program? How can a 340B covered entity (CE) combine measurement of financial value with effective compliance, while managing the non-340B objectives required of a high-performing pharmacy service? Compliance is a must, but efficiency and resource optimization are paramount in the delivery of pharmacy services. Adding another process domain to the pharmacy department creates additional management challenges and further complicates an already complex supply chain. In the 340B program, results that appear as "savings" are not solely a financial activity but come with some portion of compliance risk and may also represent an opportunity to improve pharmacy purchasing, the drug supply chain, and revenue cycle performance. Participation in the 340B program with the attendant activities and tasks to manage 340B business performance can bring unexpected benefits in pharmacy business performance to the organization. A 340B CE carries financial benefit that is designed to help a healthcare organization support care for uninsured and underinsured patients in their service area. A hospital that meets the current 340B eligibility criteria is hard pressed to argue against participation, with the material savings on the cost of drugs delivered to outpatients.

Business and 340B program decisions in a CE often revolve around the cost and performance of a patient care program or service. A hospital has numerous options to prepare reports that measure and visualize 340B program value, but what should be measured and how? Although pharmacy services and pharmacists can measure value to the healthcare system using performance metrics, 340B provides an additional value catalyst. The use of performance metrics supports process improvements and determines strategic priorities using key performance indicators (KPI). Targets and goals for KPI metrics can be built into team objectives and drive individual performance:

- How should the KPIs of 340B program performance be measured?
- How can you create the internal KPI benchmarks that identify trends and manage the controllable elements of 340B with focused attention on the ones that matter most?
- Can 340B program performance be benchmarked externally, and if so, how? It is important to match organizational factors of your health system with peers in addition to internal benchmarking.
- Which therapeutic areas, drugs, and processes should be tracked and trended?
- How can reports be used to drill into therapeutic class and individual drugs to see the impact of formulary and practice changes on 340B savings?
- Conversely, how might 340B alter or enable a new formulary strategy?

- What are the drivers of 340B savings, and where does savings opportunity leak through system gaps? Note that the operations and business performance factors to be assembled and examined may be affected by high-priced items with large 340B savings rates; a modest number of high-cost, high-discount drugs may drive overall savings.

Leadership knowledge of the focus and impact of 340B can be key to managing risk and utility, where savings and costs are concentrated, and understanding how this might change over time. Purchase at wholesale acquisition cost (WAC) is generally viewed as a failure or gap in the 340B systems that the hospital employs. *WAC savings leak* is likely modest if 340B software is set up properly and the hospital's revenue cycle and supply chain processes are well-managed, but will bear continued oversight and evaluation.

This chapter describes methods to calculate and assess 340B savings and the factors that drive 340B program performance along with health-system leadership communication strategy.

INFLUENCES ON 340B FINANCIAL PERFORMANCE

Variables that influence 340B financial performance are outlined in Table 13-1 (see discussion and table later in the chapter). Key influences include CE type, Medicaid carve-in/carve-out status, charge volumes, purchase price and activity by account type, group purchasing organization (GPO) price, patient diagnosis/therapy/acuity, service line and location, medical staff relationship to the organization, and payer status. Each variable has a differing impact on 340B savings and fosters change at different rates, affecting savings over time. To understand and quantify its impact on KPI benchmarks, each variable should be monitored regularly in a structured manner. As an example, the addition of new services or medical staff prescribing new therapies will influence the number and type of drugs purchased. Service locations added or removed from the "above the line" costs on the Medicare cost report and, therefore, provider-based status will also have material impact. A service that was provided by medical staff, which was not part of the organization's reimbursement structure, may become an eligible part of the health system such that billing and costs become 340B eligible. On a day-to-day basis, drug shortages affecting availability, resulting in switches between the drug products with different national drug codes (NDCs) can impact cost. Depending on the alternate NDC, variation in the GPO and purchase price can change significantly. The variables described have short-, mid-, and longer-term implications for 340B program performance and should be evaluated at different frequencies.

KEY POINT

340B program performance and savings is complex and depends on organizational factors beyond the 340B qualifications. Managing the 340B program to the highest benefit requires a sustained, systematic, data-based approach.

THE 340B PRICE

The calculation of 340B price for a drug is based on language from the Medicaid Drug Rebate Program (MDRP) and definition of a *covered outpatient drug*.[1] A drug's 340B price depends on how it is classified; as single source, innovator multiple source, non-innovator multi-source, a clotting factor, or a drug used exclusively in the pediatric population. A specific 340B price is calculated by subtracting the unit rebate amount (URA) based on its rebate percentage from its average manufacturer price (AMP). The AMP and 340B price calculation is described in more detail in Chapter 3.