CHAPTER 1 Introduction to the 340B Program: Current Perspectives

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The 340B program has been a part of the hospital pharmaceutical supply chain for more than 25 years. From a modest start, through steady program growth, the 340B program's impact has multiplied abundantly for participating covered entities. Growth of the 340B program in the hospital marketplace has been underpinned by the addition of new hospitals, the extension of hospital care delivery into ambulatory care areas covered by 340B, and innovative program development led by participants.

GROWTH OF THE 340B PROGRAM

As program participants explored practice boundaries and used technology to support effective management of patient data, dispensing, purchases, and inventory for the 340B program, the Health Resources and Service Administration (HRSA) Office of Pharmacy Affairs has proffered guidance. Their guidance has included technical details, tracking, and audit requirements with an eye to keeping the 340B program on course. The participant-driven nature of 340B program development, along with the diversity, breadth, and scope of the 340B program participants, has led to a complex "organic" set of guidance materials rather than a structured, well-designed whole. As a result, 340B hospitals now contend with a complex set of rules and guidance in implementing and managing the 340B program. The flexible nature of guidance, as opposed to clear, straightforward rules and regulations, has fostered an extensive education and support industry through programs, meetings, and on-line resources. Moreover, other support has come from software providers, consultants, and an array of program tools.

However, it is only in the past 5 years that circumstances have aligned to create today's impactful 340B program. The scope of 340B financial impact; greater HRSA oversight through audits; and the active interest of Congress, manufacturer stakeholders, and others in the healthcare community have created a high level of focus on covered entities' 340B program performance.

Current public dialogue regarding the 340B program revolves around the program's size and growth based on participant count, purchase amount, and total drug discount earned, along with the collateral interest in hospital use of savings and program entry requirements. The public dialogue from manufacturers and others has shifted to program intent, the use of 340B savings, and compliance with 340B rules and guidance as well as a focus on fostering transparency from participants—both covered entities and manufacturers.

A common criticism regarding the 340B program is that hospitals are "gaming the program" in ways that are not congruent with the original intent of the 1992 legislation. Absent a disagreement

regarding Congress's explicit wishes, the combination of modest detail in the original law with the sweeping changes in healthcare makes the current 340B program more pervasive and impactful than even the most enlightened drafter could have predicted.

With nearly half of nonprofit hospitals participating and 45% of all hospital drug purchases in 2016 coming under the program's auspices,[1-3] the 340B program has certainly grown beyond its initial concept and possibly beyond the wildest dreams of its authors and proponents from a quarter century ago. Depending on the viewer's perspective, the program has either outgrown its original intent[4] or has outperformed its earliest vision to become a key element of a hospital's ability to provide community benefit[5]—or both.

Regardless of this difference in perspective, policymakers and participants have come to take the 340B program seriously. The HRSA Office of Pharmacy Affairs and its surrogate, the 340B Prime Vendor program, have devoted substantive thought and resources to building the framework of the current 340B program within the boundaries and powers specified in the statute. Covered entities are well-advised to consult the tools, programs, and information provided on the Internet.[6,7] However, the original 1992 statute's lack of enabling language has limited the development of definitive rules for many aspects of the 340B program. This gap leads to a challenge for participants and critics in outlining program requirements and objectives in a definitive form. Practically speaking, there is flexibility in application of the most basic elements of the program, defining eligible patients, and covered outpatient drugs. HRSA plans to fill the 340B community's needs for direction through audit standards and active communication on compliance topics and best practices through the Prime Vendor. Readers of this *Handbook* are deeply engaged in 340B and probably believe the program contains some measure of uncertainty, even with HRSA's guidance. However, they are probably focused on meeting 340B program requirements for securing discounted medications to treat their eligible patients while seeking a conservative approach and best practices.

THE HEALTHCARE MARKET ENVIRONMENT

The healthcare marketplace, public health needs, and the resources to support and deliver pharmaceutical care in 2018 differ dramatically from 1992. The 340B tools available to participants have kept pace, particularly with increasingly sophisticated "split billing" virtual inventory and contract pharmacy management software. Nevertheless, the 340B program is a creature of the pharmaceutical care marketplace—a rapidly changing part of the U.S. healthcare system and an area that has transformed materially in 25 years.

Consolidation, acquisition, and diversification have defined the recent healthcare market. Insurers, pharmacy benefit managers (PBMs), retail pharmacies, distributors, and manufacturers have merged. Hospitals have also consolidated through mergers and acquisitions, developed into groups, and acquired related healthcare services and technology—becoming *integrated delivery networks* (IDNs). As the focus of care moved the ambulatory setting, hospitals have transitioned to providing these services through movement of inpatient services, growth and the purchase of physician practices, building of diagnostic and other services, and development of the associated competencies. As a program designed to support ambulatory care, this shift alone provides a key engine for 340B program growth.

A host of expensive, targeted biologics, specialty drugs, and biosimilars now treat diseases in a complex market where drug costs and prices are multiples higher than in years past. These expensive agents are where health plans, PBMs, manufacturers, and others seek to manage costs to deliver effective care and value. In this market, substantive price increases with rebates through the Medicaid Drug Rebate Program (MDRP) and PBMs have driven greater discounts and financial advantage. The *gross-to-net bubble* that supports MDRP and PBM discounts[8] also delivers a similarly scaled financial result to 340B hospitals. In addition to the actual prices and discounts supported under 340B, contract pharmacy relationships between covered entities and retail phar-