CHAPTER 16

Manufacturer Considerations and Perspectives on the 340B Program

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The intent of this chapter is to provide a pharmaceutical industry viewpoint to a broad array of stakeholders. It is not intended as a guide for manufacturers implementing their program participation or as the definitive manufacturer perspective on the 340B program. Information and opinions are based on the author's opinions and published government reports, industry studies, and think-tank information and statistics. Due to the nature of the 340B program, all of the analysis is open to interpretation; contrasting and potentially conflicting data and perspectives; and alternative viewpoints.

In general, pharmaceutical industry executives support programs that provide access to care and pharmaceuticals for underserved, needy, and disadvantaged patients. Health Resources and Services Administration (HRSA) grant programs serve the neediest individuals with the greatest health risks. Access to 340B drugs with significant discounts allows these programs to stretch their limited grant dollars. Likewise, hospitals that are deeply invested safety net providers in their communities benefit from the same discounts under the 340B program to stretch resources to provide access to care.

When the 340B program was enacted in 1992, health policy makers, professional and trade organizations, hospitals and healthcare providers, and the pharmaceutical industry paid it little attention. The 340B program appeared to be a niche program providing support for federal grant program awardees serving uninsured and indigent patients in underserved communities. In the year following its enactment, fewer than 100 disproportionate share hospitals (DSHs) enrolled in the program. **Figure 16-1** illustrates the growth of hospitals in the 340B program from inception through 2011 (after that growth leveled off). The 2015 Medicare Payment Advisory Commission (MedPAC) report to Congress on the Overview of the 340B Drug Pricing Program stated that in 2014, there were 14,061 hospitals and affiliated sites in the 340B program, comprising 2,140 hospital organizations.[1] The growth of the 340B program and the nature of its impact in the marketplace had extended beyond what even the most ardent boosters might have anticipated. The current estimate is that more than 40% of U.S. hospitals participate in the program.

340B PROGRAM PERSPECTIVES

Focusing on the 340B program today, the pharmaceutical industry's interests and concerns may be grouped into five broad areas:

1. The growth of the program and appropriate use and access to 340B-discounted drugs.
2. Concern about future guidance, regulations, and challenges to HRSA authority.

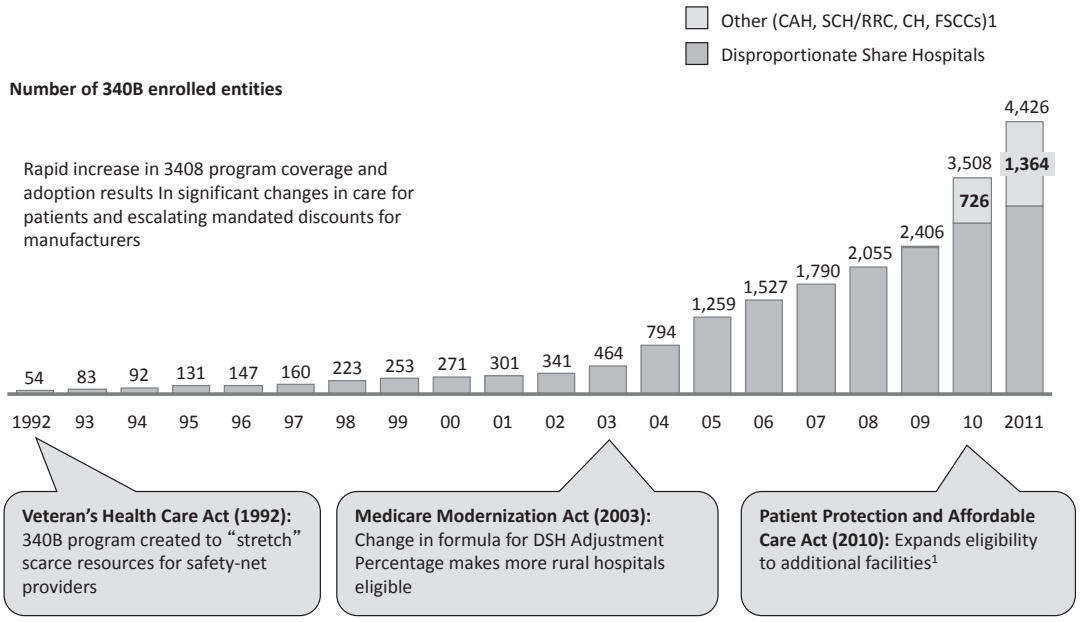

FIGURE 16-1. Rapid Growth in Enrollment, First 20 Years of the 340B Program

3. The transfer of 340B discount proceeds to third parties through business arrangements such as contract pharmacies.
4. Implementing complex 340B program requirements correctly.
5. Managing refunds triggered by prior period restatements.

Examples of the facts underlying these concerns are outlined in the following discussion.

A study published in *Health Affairs*, stated the following:

> Hospital-affiliated clinics that registered for the 340B program in 2004 or later served communities that were wealthier and had higher rates of health insurance compared to communities served by hospitals and clinics that registered for the program before 2004. Our findings support the criticism that the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics.[2(p1786)]

Adam Fein, a pharmaceutical industry analyst and consultant, reported in the blog *Drug Channels* that the 340B prime vendor Apexus supplied data that purchases in the 340B program reached at least $12 billion in 2015, 67% higher than 2013 purchases.[3] In comparison, over the 10-year period from 2005 to 2015, total hospital drug purchases grew by 31%, while 340B purchases grew 400%.[3,4]

HRSA has offered a number of significant 340B program rules addressing the areas of ceiling price calculations and penalties imposed on drug manufacturers, the 340B program administrative dispute resolution process, and Omnibus Guidance that addresses a number of areas including site eligibility, program integrity, and definition of eligible patients. Depending on how HRSA finalizes its guidance, stakeholders might challenge the rules. Recent litigation related to interpretation of the orphan drug rule and HRSA's authority to impose rules not sanctioned by Congress questioned how guidance imposes an immediate and significant burden on manufacturers. HRSA must consider their mandate and areas of regulatory authority and the risk of litigation from covered