



CHAPTER 17

Future-proofing Your 340B Program

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Throughout the history of the 340B program, the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) has made a sustained effort to clarify the rules, boundaries, and guidelines for covered entities' and manufacturers' participation. However, due to the limited nature of HRSA authority and the changing healthcare environment in which 340B operates, the resulting guidance, frequently asked questions (FAQs), and standards provide an outline but fall short of definitive and permanent guidance. HRSA's singular attempt to produce a broad "Mega Guidance" document was a casualty of the Trump administration's approach to regulatory reform.

Because HRSA has limited insight and no oversight of the operating requirements and business results of a hospital's 340B program, most guidance documents touch lightly on the daily complexities of health-system pharmacy and supply chain management, except for elements of eligible patient identification. FAQs, guidelines, and best practices offered by HRSA directly and through Apexus, the 340B prime vendor, constitute the largest body of written guidance. A substantial portion of the guidance exists only as FAQs and tools on the Apexus web site. These unofficial documents are subject to withdrawal or change by HRSA without formal notice. In some instances, the guidance is reactive; that is, it represents a response to a frequent question from 340B covered entities or may be a recurrent audit finding of concern to HRSA. The diversity of systems and practices mean that implementing a given practice or policy may vary widely between covered entities, and HRSA may seek to describe the specific actions or activities to meet guidance in more detail.

The consequence of this compliance framework along with the variation in health-system goals, diverse pharmacy software, and operations choices has led to the growth of a large network of "experts" including leading 340B peers, 340B consultants, 340B software and service industry leaders, and the officers and staff of various 340B and 340B-related groups. Varying perspectives, experience, and goals across the group lead to diverse opinions and recommendations, reflecting a variety of perspectives on risk, compliance, and business objectives. The 340B network provides support through user group meetings, webinars, online interest groups, and active consulting and outreach. These groups support the interpretation and actualization of the 340B guidelines by covered entities.

GUIDANCE WHEN IMPLEMENTING A PROGRAM

Given the general nature of formal guidance and the more informal authority of various tools and support documents, specific "how to implement and manage a 340B program" advice remains mixed. For the purposes of this discussion, consider that advice comes from two camps:

1. Experts in 340B with deep 340B knowledge, but modest or limited non-340B information technology (IT) supply chain knowledge and experience. This group includes 340B consultants, 340B industry experts, and 340B interest group staff.
2. Experts in the healthcare supply chain and informatics (e.g., supply chain professionals, IT professionals) with modest or limited 340B knowledge and experience. This group includes supply chain consultants, supply chain industry experts, and providers of medical record and financial software.

Each party attempts to optimize their primary area of expertise, while avoiding roadblocks and problems in their area of lesser interest and expertise. This places two burdens on the health-system pharmacy team overseeing the supply chain and patient care operations. *First*, they must serve as the source of 340B expertise; *second*, they must make certain that the resulting 340B-responsive processes and solutions are effective and efficient. In addition, the pharmacy leader may need to referee areas where the two approaches collide.

The 340B Program Handbook's chapter authors are experienced and familiar with the challenging discussions and compromises to be made in achieving balance. In the past, when 340B was lightly structured and infrequently audited, decisions were typically made to optimize patient care delivery or business results with modest 340B consideration. In the current situation of deeper and more complex 340B program guidance with regular HRSA audits, the converse is true. Hospitals often sacrifice the utility of supply chain efficiencies to preclude real and imagined 340B compliance concerns and undergo the potential loss of 340B savings. This approach mitigates the effectiveness of supply chain programs that address everything from inventory control to centralization of packaging and distribution services to efforts addressing drug shortages.

The volume of dialogue on “*How did you interpret 340B rules when implementing this (automation/software/supply chain) program?*” in electronic communications and at pharmacy and supply chain meetings is a telling indicator of the scope of the challenge. HRSA’s use of peer-to-peer consulting addresses practical guidance segmented by covered entity type, and Apexus Answers offer some additional support; however, in sum, neither fully resolves the business versus compliance balance for an individual 340B covered entity.

HRSA’s more recent active use of 340B audit standards—to foster a shared 340B community understanding grounded in HRSA’s use of specific information and data elements to signify compliance—has assisted in building common ground. However, changing evidence required and clarified standards fosters a need to stay in touch to sustain and interpret the most recent view.

340B PROGRAM SUCCESS STRATEGIES

Although not exhaustive, the list of ten practices below should ensure that your 340B program remains viable, performs well, and provides a sustained and meaningful contribution to the mission of the covered entity.

KEY POINT

A strong policy and practice backbone, combined with documentation, is a critical element of success.

1. ***Participate in and communicate with the 340B community.*** The first activity to undertake in maintaining a healthy 340B program over the long term is to stay current and maintain a continuing, active connection to the 340B community, including conversations about recent HRSA audits, updates to FAQs, and other HRSA guidance. This should