CHAPTER 4

The Basics of 340B Program Implementation

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Implementing the 340B program in a hospital or health system is not for the faint of heart. The opportunity to reduce pharmaceutical acquisition expenses for eligible patients is essential to the programs and services provided to underinsured and uninsured patients. 340B program savings may also be critical to your organization's financial health. However, since its inception in 1992, the 340B program has grown in importance for safety net providers and has become substantially more complex to undertake. The 340B program's business, operational, and compliance requirements are laid on top of the already complex requirements to manage patient care and meet the requirements of other government programs, payers, and regulators. Meeting 340B program requirements demands significant planning and resources to manage well. The discipline of integrating 340B into a well-executed pharmacy and patient care program is both a challenge and a significant project.

Adding 340B to the mix in a complex health-system pharmacy may require a reassessment of current practices and policies while also requiring choices, rework, and development of policies, practices, and tools not typically considered within the bounds of 340B implementation. This chapter is designed to serve as a comprehensive guide to practical and operational 340B program implementation steps and strategies; in particular, leading up to software implementation. This guide can serve as a valuable reference for entities new to 340B as well as those continuing to manage the annual twists and turns that have become commonplace in the 340B world.

HOSPITAL PROGRAM ELIGIBILITY REQUIREMENTS

The requirements for hospital participation in the 340B program are outlined in detail on the Office of Pharmacy Affairs (OPA) web site.[1] Rather than restate in its entirety, the requirements (see **Table 4-1**) have been summarized for clarity in areas that hospitals commonly find confounding.

Participating 340B hospitals may be owned or operated by state or local government. Non-profit community hospitals may also participate in the 340B program if they have either been formally granted governmental powers or have a contract in place with state or local government to provide healthcare to low-income individuals not entitled to benefits under Medicare or Medicaid. If a government contract is required for participation in the program, the authorizing official (AO) should begin working toward this agreement as a first step. Without a contract, or if the discussions and negotiations result in a delay in contract signature from a government official, the hospital may miss the quarterly enrollment deadline leading to a full quarter delay in eligibility and resultant savings.

Table 4-1. Hospital Entity 340B Enrollment Requirements

Entity Type	Nonprofit/Government Relationship	DSH%[1]	GPO Prohibition	Orphan Drug Exclusion
Critical Access Hospitals	Yes	N/A	No	Yes
Rural Referral Centers	Yes	>8%	No	Yes
Sole Community Hospitals	Yes	>8%	No	Yes
Free-standing Cancer Hospitals	Yes	>11.75%*	Yes	Yes
DSHs	Yes	>11.75%	Yes	No
Children's Hospitals	Yes	>11.75%*	Yes	No

* Children's Hospitals and Free-Standing Cancer Hospitals that do not publish a DSH% as part of their MCR filing may use alternate calculations to support their meeting this requirement. Please see the full text for additional details.

DSH: disproportionate share hospitals DSH%: disproportionate share adjustment percentage

Hospitals commonly ask for a template or sample agreement to present to the government agency, but the Health Resources and Services Administration (HRSA) does not provide a sample. HRSA does not seek specific content or access to healthcare as outlined above, but it does require the authorizing official to certify that such an agreement is in place. OPA will contact the government official soon after registration to confirm the agreement. Samples of current contracts can be secured from peers. Although the details of the agreement are not dictated by OPA, upon registration, the covered entity will certify that the contract provides for "healthcare services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX of the Social Security Act."[2] Language proposed in the August 2015 340B Omnibus Guidance states that the government contract "should create enforceable expectations for the hospital for the provision of healthcare services, including the provision of direct medical care."[3] Hospitals should consider including enforceable expectations for the provision of care to avoid the need to modify contracts in the future. Examples of enforceable expectations may include financial or patient volume commitments but are not specified in detail and remain at the discretion of the contracting parties.

With the exception of critical access hospitals, hospital covered entities are required to exceed a minimum disproportionate share adjustment percentage (DSH%) on their most recently filed Medicare cost report (MCR). The requirements, by hospital type, are outlined in Table 4-1. For pharmacy leaders not familiar with the MCR, the DSH% calculation is found on line 33 of worksheet E, part A. For urban hospitals in excess of 100 patient beds that do not routinely include a DSH% calculation on their MCR (e.g., children's hospitals, free-standing cancer hospitals), a special alternate calculation may be used. This methodology requires the entity to demonstrate that net inpatient revenue from certain state and local sources for indigent care exceeds 30% of total inpatient revenue. Hospitals that qualify under this method are commonly referred to as *Pickle Hospitals* in reference to the Congressman who sponsored the applicable language.[4]

Children's hospitals have the most complex entry requirements concerning DSH%. If the children's hospital submits a MCR with a DSH% that exceeds 11.75%, it is accepted by OPA.