CHAPTER 2

A Historical Perspective on the 340B Program's Purpose

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The 340B drug discount program recently celebrated its 25th anniversary. Until the last 5 or 6 years, the rationale for establishing the 340B program has never been challenged. To the contrary, stakeholders and policymakers have embraced the program's purpose and sought ways to expand its reach. Like an adolescent faced with competing pressures and demands, the 340B program is going through an identity crisis. The pharmaceutical industry asserts that the program is being used more widely than Congress intended. Some within the government contend that the program should be used to reduce Medicaid and Medicare drug spending. Safety net providers, on the other hand, cite the program's legislative history in support of their view that 340B savings are intended to pay for the uncompensated care they deliver to vulnerable patients. This chapter undertakes a historical assessment of the 340B program's role and purpose from the perspective of key stakeholders.

COVERED ENTITIES: THE 340B PROGRAM SUPPORTS UNCOMPENSATED CARE FOR VULNERABLE PATIENT POPULATIONS

From the standpoint of safety net hospitals, community health centers, and other providers participating in the 340B program, Congress established the program based on a simple concept. Namely, because manufacturers derive significant revenue from selling their drugs within the U.S. healthcare market, they should do their part to support the U.S. healthcare providers and programs that deliver essential services to indigent and other vulnerable patients who cannot afford to pay for such services. 340B program participants, referred to in the law as "covered entities," are highly dependent on Medicaid, Medicare, federal grants, state and local subsidies, and other tax-supported funding sources. By providing discounts on their drugs, manufacturers alleviate some of the burden on taxpayers of paying for vital covered entity services that would otherwise be uncompensated. Covered entities take care of some of the most challenging patient populations—ranging from the poor who face a host of socioeconomic barriers to care, to those who struggle with complex and expensive illnesses such as hemophilia and HIV, to those who need special services to access and receive appropriate care. By enacting the 340B program, Congress understood that covered entities are on the frontline of caring for these vulnerable populations and are in the best position to use 340B program savings to invest directly in the services that patients need most. This understanding is reflected in the program's legislative history, which explains that the purpose of the program is to enable covered entities to stretch scarce resources so they can reach more eligible patients and provide more comprehensive services.[1]

KEY POINT

Covered entities take care of some of the most challenging patient populations—ranging from the poor who face a host of socioeconomic barriers to care, to those who struggle with complex and expensive illnesses.

Therefore, it is not surprising that prior to the current debate over the 340B program's purpose, numerous healthcare initiatives spearheaded by the Administration, Congress, and the private sector have resulted in 340B program growth. Some of the more important initiatives are described below.

- ***HRSA grant condition requiring 340B participation—***In 2000, the Health Resources and Services Administration (HRSA) published a rule requiring HRSA grantees and sub-grantees to either join the 340B program or provide good cause for nonparticipation. Grantees that choose not to participate in the 340B program must demonstrate the appropriateness of their drug purchasing practices.[2] Virtually all grantees and sub-grantees eligible to participate in 340B have enrolled in the program as a result of this grant condition.
- ***Dispensing 340B drugs through contract pharmacies—***HRSA issued guidelines in 1996 permitting covered entities to dispense their 340B drugs through contracted pharmacies, but limited such arrangements to no more than one per covered entity site.[3] In 2010, HRSA issued guidelines that significantly expanded the contract pharmacy program by eliminating the one-to-one limitation and replacing it with what is commonly called the "one-to-many" rule, under which covered entities can enter into as many contract pharmacy arrangements as they desire.[4] Contract pharmacies allow covered entities to fill more of their patients' prescriptions with 340B drugs.
- ***Alternative methods demonstration projects—***In 2001, HRSA launched a program that allowed covered entities to experiment with different contracting models on a demonstration basis.[5] Prior to publication of the 2010 contract pharmacy guidelines, alternative methods demonstration projects (AMDPs) were the only vehicle for one-to-many pharmacy arrangements. AMDPs were also used to allow two or more covered entities, serving a common patient population, to form a network that could enroll in the program in its own name and not have to keep separate inventories for the respective patients of network members.[6]
- ***HRSA promotion of 340B to states—***HRSA previously provided funding to the National Conference of State Legislatures (NCSL) to promote 340B state initiatives and to monitor state legislation that affected the 340B program. Although HRSA no longer provides these grants, NCSL continues to host a web site that tracks 340B legislation at the state level.[7]
- ***Heinz Foundation promotion of 340B partnerships—***The Heinz Foundation has assisted governors in determining whether and to what extent their states might achieve savings through the 340B programs. For example, the Heinz Foundation prepared a 2005 report for the state of Rhode Island estimating that it could save up to $18.8 million over a five-year period by expanding its use of the 340B program to inmates, the elderly, and others.[8]
- ***Expanded hospital eligibility under the Affordable Care Act (ACA)—***Under the original 340B legislation, only one category of hospitals qualifies as 340B covered entities, namely, public or nonprofit acute care hospitals with a disproportionate share hospital percentage above 11.75%.[9] The ACA added four new categories of covered entities: free-standing cancer hospitals, critical access hospitals, sole community hospitals, and rural referral centers.[10] The ACA also formally recognized children's hospitals as covered entities under the 340B program.[11]