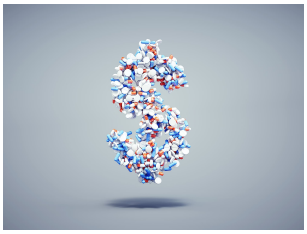

Could the Expansion of 340B Lead to its Ultimate Demise?

Jan 30, 2020

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The 340B Drug Pricing Program is a federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. The savings are so significant that health care organizations are doing everything in their power to take advantage of the discounts which, in turn, is causing the government to take a closer look at program qualifications and enforcement.

The number of hospitals availing themselves of 340B savings has increased exponentially in the last 10 years; and the value of 340B drug purchases has grown from $4 billion to $24 billion during that same timeframe. Since 2009, the number of hospitals has tripled, and more than two-thirds are private, non-profit hospitals. The government is now looking for ways to stem the tide but is finding little help in the regulations (or the enforcement thereof).

The original intent of the program was to provide better services and access for low-income, medically underserved individuals, which hospitals may find easier due to the savings they are afforded under the program. Participating hospitals realize savings under the program by purchasing pharmaceuticals at 340B prices and billing for them at regular rates. Given the cost savings, the volume of drugs sold under the 340B program continually increases. Even though nothing in the program directly combats this growth, it does not sit well with the government or the pharmaceutical companies who are the ones who, in the long run, take the hit.

The 340B program was designed in such a way that the government really has no skin in the game but, nonetheless, assumes the bulk of the oversight responsibility. The pharmaceutical companies are required to sell drugs to participating hospitals at deeply discounted rates but have little ability to monitor consumption. The Health Resources and Services Administration (HRSA) is responsible for screening applicants to ensure they meet the participation requirements and for monitoring application of the discounts for

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drug purchases.

The participation requirements are, however, not exceptionally burdensome – nor well-written. A nongovernmental hospital need only qualify as a non-profit disproportionate share hospital (DSH) and have in place a contract with a governmental agency requiring provision of services to low-income patients. The regulations fail to define "contract" or "low-income" and include no details about the type, frequency, extent or monetary value of the services required (or proof that they were actually provided). HRSA reviews only 20 percent of new applicants to confirm that the contract has been fully executed and does not expire before the hospital's 340B participation begins. Otherwise, HRSA simply trusts that the hospital has been truthful in its representations of eligibility to participate, for both initial registration and annual recertification.

In August 2015, HRSA attempted to curb the growth of 340B by proposing new standards, referred to as "Mega Guidance." But HRSA was forced to withdraw the intended revisions in January 2017 amid comments and federal court opinions that HRSA lacked authority to promulgate such drastic changes in the regulations. The guidance would have significantly impacted hospital 340B participation and savings by altering the eligibility requirements for both patients and hospitals. With the withdrawal of the Mega Guidance, the 1998 regulations remain intact and provide insufficient clarity to support the government's efforts to control the continued expansion of the program, though efforts continue.

Most recently, in December 2019, the U.S. Government Accountability Office (GAO) issued a report titled *Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*. The report is based on a study of hospital compliance with eligibility requirements and enforcement of those requirements by HRSA. GAO found the regulations and enforcement thereof woefully inadequate while, at the same time, recognizing that there is not much to work with when it comes to meaningful rules.

But the real problem is not that ineligible hospitals may have been permitted to participate – it is that the program design is such that no one has any ability to control how hospitals use their 340B

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savings. There is no requirement that a hospital somehow prove that it spent the money on the needy. Nor is there any easy way to add a requirement of that sort to the regulations.

Bottom line . . . it is not hospitals' fault that the 340B program was poorly designed and pretty much ignored by HRSA for more than 20 years – or that the hospitals, squeezed by lower reimbursements, attempt to realize as much savings as possible from the program. Nothing legally prevents them from doing so. But as the program continues to grow, legislators are taking more and more heat from the pharmaceutical lobby to do something to rein in the expansion of the 340B program. Unfortunately, their hands are basically tied by poorly written rules.

Sadly, the current regulations may not be fixable, and the 340B program may become a casualty of poor legislation. But it is, nonetheless, important for 340B-covered entities to be on the lookout for any attempts by HRSA to change the rules – or enforce them in a manner inconsistent with the regulations. Desperate times call for desperate measures, and HRSA is determined to change the course of 340B.

For a more in-depth discussion of the 304B program, you can contact Rhonda Frey, Chad Eckhardt, Brian Higgins or any other member of Frost Brown Todd's Health Care Innovation Team.

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