

A Breakdown of Recent 340B Program Changes

Learn How 340B Drug Discount Program Changes Could Negatively Impact Providers' Bottom Lines



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If you've been following the trade press, it sure seems the 340B Drug Discount Program is about to have a "come to Jesus" moment, doesn't it? Following explosive growth, harsh accusations of program abuse, Congressional inquiries, a lawsuit, an interpretive rule and forthcoming mega-rule, this relatively small program seems to be getting a lot of attention. So what's all the fuss about? There are a lot of moving parts, but as a hospital general counsel, this could represent millions to your institution's bottom line. Here are all the reasons to make sure you're not caught off-guard.

Let's start with the basics. The 340B Program was established in 1992 to help hospitals providing care to the indigent and uninsured by requiring drug manufacturers to provide discounts (typically between 20-50 percent) to covered entities on outpatient drugs. According to the Health Resources and Services Administration (HRSA), the agency that administers the program, "the 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

The list of covered entities has grown over time, with the latest additions coming from the Affordable Care Act (ACA), and includes disproportionate share hospitals, certain children's hospitals, PPS-exempt cancer centers, sole community hospitals, rural referral centers, critical access hospitals and a host of eligible clinics. HRSA provides guidance on how to define eligible patients, registration and program integrity requirements. Generally speaking, HRSA has allowed a fair amount of flexibility, which now seems poised for change.

In recent years, the program sparked Congressional attention, with Senator Charles Grassley (R-IA) taking a particularly keen interest. There was some question of non-profit hospitals making a profit from 340B, and Sen. Grassley wanted to know if the program was working as intended. In his mind, the "intent and design of the program is to help lower outpatient drug prices for the uninsured." Sen. Grassley also questioned whether

HRSA's perceived lack of oversight of the program allowed for such abuses. He wasn't alone- the U.S. Government Accountability Office (GAO) also found that the program lacked adequate oversight in 2011. In 2013, Sen. Grassley continued his investigation, and turned his attention to the contract pharmacy market and revenue as a result of HRSA program guidance allowing covered entities to work with in-house as well as contract pharmacies (Walgreens, for example, currently holds about 75 percent of the market).

To add to the ongoing turbulence, HRSA issued regulations in 2013 implementing a key provision in the ACA that limited the application of the 340B program for newly-covered entities. HRSA's controversial orphan drug rule essentially states that orphan drugs would be excluded from the discount program when prescribed for their Federal Food, Drug and Cosmetic Act (FFDCA) designated condition or rare disease, but the exclusion would *not* apply to orphan drugs prescribed for other conditions. Drug manufacturers sued... and prevailed. The U.S. District Court for the District of Columbia found that HRSA exceeded its rulemaking authority, and struck down the implementing rule. In response, however, HRSA announced it would be moving forward with the rule despite the decision.

So what's next? The long-anticipated 340B "mega-rule." In response to growing concerns regarding lack of oversight, potential program abuse and calls for enhanced transparency, HRSA submitted a rule to the Office of Management and Budget (OMB) in for review in April. The anticipated release date was June, which slipped to July, and then to August, and now September.

When the rule *is* released, there are a number of issues that could be addressed, all of which have significant implications for the future of the program and participating entities. This includes:

1. **Definition of Eligible Patient:** HRSA currently defines eligible patients as those who "receive health care services other than drugs from the 340B covered entity." There is no timeline to determine how long a patient should qualify for a discount, which is currently indefinite. Other sites affiliated with covered entities are also eligible for discounts, but some believe this definition has gone too far to include hospital-affiliated physicians that receive discounts for patients in private practice.
2. **Definition of Covered Entity:** In particular, some questions have arisen about which hospitals and off-site facilities are eligible to receive discounts.
3. **Diversion:** It is currently unclear whether discounted drugs are transferred to eligible patients or patients

covered by Medicare or private insurance, and there is currently nothing to prevent entities from doing just that. Critics are harsh on diversion, particularly when the discounted drug is reimbursed by private insurance or Medicare, with hospitals keeping the difference.

4. **Contract Pharmacy Compliance:** The rule is likely to expand reporting requirements to prevent duplicate discounts, as well as oversight of a market that is perceived to allow for more opportunity for diversion than in-house pharmacies.
5. **Limits on use of 340B Revenue:** The rule could include guidance on how hospitals can use revenue from the program.
6. **Focus Shift to Patient:** There is spirited debate over the original intent of 340B, and whether the program was supposed to support safety net hospitals or patients. The rule could include guidance that ultimately shifts the current focus on entities to patients, and more closely align the discounted drug to eligible patients.

There's a potential hiccup, however: does HRSA even have the authority to promulgate regulations? The Agency believes so, as authorized under HRSA's general authority under the 340B program to promulgate regulations. But the court found in *PhRMA v. Department of Health and Human Services* that HRSA exceeded its rulemaking authority, and found no general authority to carry out rulemaking under Section 340B.

HRSA does, however, have audit authority despite taking a relatively lax position on oversight with relatively few audits initiated over the last few years. Congressional oversight is also expected to continue, with the potential for additional letters to hospitals requesting site-specific information on their use of the program.

The bottom line is this: safety net hospitals are currently struggling with ACA implementation, tight state budgets, and delivery system reform, all the while providing critical health services to millions of vulnerable Americans. Ongoing 340B issues and anticipated program changes promise to be another complicating factor with strong potential to restrict the program and the millions of dollars in savings hospitals and clinics are currently receiving. That's reason enough to make sure you are prepared.