PUBLICATION

Overserved: Drug Manufacturers Attempt to Cut Off Contract Pharmacies' Access to 340B Program

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Recent litigation between the federal government and drug manufacturers will surely impact how covered entities and contract pharmacies under the 340B Drug Discount Program (the 340B Program) operate going forward. A federal appeal is underway over drug manufacturers' ability to add conditions and, in some cases, cut off sales to contract pharmacies operating under the 340B Program. While litigation continues, the Health Resources and Services Administration (HRSA) and the United States Congress may have to confront gaps pointed out under select provisions within the 340B Program – the long-term effect of which will most certainly affect how drug manufacturers, covered entities, and contract pharmacies interact going forward.

Evolution of Contract Pharmacies

In March 2010, HRSA released expanded guidance relating to the role of contract pharmacies. Under this expanded guidance, covered entities under the 340B Program were allowed to establish contract pharmacy arrangements with an unlimited number of pharmacies – going from allowing "a single point for pharmacy services, either an in-house pharmacy or an individual contract pharmacy" to now allowing covered entities to "use multiple pharmacy arrangements as long as they complied with guidelines developed to help ensure against diversion and duplicative discounts." HRSA hoped that the expansive use of contract pharmacies would allow covered entities to "more effectively utilize the 340B Program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies, and patients served." As part of this expansion, for-profit retail pharmacies were provided an opportunity to dispense 340B medicines.

Over the next ten years, the effects of this expansion were mesmerizing. Since 2010, contract pharmacies, including retail pharmacies and other third parties, have profited substantially – the average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent compared with a margin of 22 percent for non-340B medicines dispensed through independent pharmacies. In addition, 340B-covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018 (which represents more than 25 percent of pharmacies' and providers' total profits from dispensing or administering brand medicines). Between April 2010 and April 2020, contract pharmacy participation grew a staggering 4,228 percent. While the intention from HRSA with this expanded guidance was to provide low-income and rural patients more access to 340B medicines, there is no clear evidence that this expansion improved the care of these patients. Substantial, overwhelming evidence exists, though, to demonstrate that contract pharmacies have most definitely benefitted.

Drug Manufacturer Issues with Expanded Use of Contract Pharmacies and Subsequent Litigation

Beginning in the summer of 2020, drug manufacturers began to cut off sales of 340B products to covered entities' contract pharmacies and, in addition, impose conditions and restrictions on the continued sale of 340B drugs to covered entities' contract pharmacies. For example, drug manufacturer, Novartis, implemented a new policy that now only honors "(1) all covered pharmacy arrangements in which 'the contract pharmacy is located within a 40-mile radius of the covered entity' and (2) all contract pharmacies of 'federal grantee covered entities.'" So far, 12 drug companies – including Eli Lilly, Novartis, Novo Nordisk, United Therapeutics, AstraZeneca and Sanofi – have announced similar 340B changes citing concerns over whether patients are

actually benefitting from the discount and a desire to avoid duplicative discounts with Medicaid. Concerns over fraud and diversion of 340B medication were also cited by drug manufacturers in influencing their decision to implement changes to their 340B drug policies. The six above mentioned manufacturers had been fined by HRSA in 2021, with five of those manufacturers suing HRSA in three separate lawsuits charging that the federal government did not have the authority under 340B to impose fines in response to the restrictions the manufacturers have laid out.

While judges in two of the lawsuits held that drug manufacturers could not unilaterally impose restrictions on covered entities' access to 340B discounts, both cited desires for Congress to step in and clear up the ambiguities found within the statute. In the third suit brought by Novartis and United Therapeutics, the court went in an opposite direction – finding that both Novartis' and United Therapeutics' 340B policies did not violate Section 340B. While the court ruled in favor of Novartis and United Therapeutics, the court also expressed a desire for Congressional action – cabining its ruling to state that Section 340B does not:

"prohibit drug manufacturers from attaching conditions to the sales of covered drugs through contract pharmacies. Nor do they permit all conditions. Accordingly, any future enforcement action must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue here."

More than 800 hospitals have urged the Biden administration to appeal this ruling – fearing the potential negative downstream effects such new 340B policies set by drug manufacturers may have on the ability for hospitals under this program to care for low-income patients and those living in rural communities. On December 28, 2021, the U.S. Department of Justice filed an appeal to the lawsuit brought by Novartis and United Therapeutics.

While the appeal plays out in 2022, Congress may nevertheless consider heeding to the calls of the federal judges involved in these three lawsuits and clear up the legal questions created by these various drug manufacturers. Whatever the eventual result, the 340B Drug Pricing Program may be due for changes.

With all these challenges to the 340B Drug Program, covered entities should focus on ways to optimize their program. The best way to stay up to date with changes is a heightened emphasis on compliance resources, both external and internal, to provide program oversight and education. By focusing on program compliance requirements, covered entities will ensure they are prepared to address HRSA, state, and manufacturer audits that will increase under the evolving landscape of the 340B Drug Program.

Baker Donelson will monitor future developments. Baker Donelson professionals provide legal services, as well as policy and advocacy assistance, on behalf of hospitals and other health care providers participating in the 340B program and vendors that support them. For more information, contact your Baker Donelson Health Law attorney.