

AstraZeneca Sues HHS over Drug Pricing Program Advisory Opinion Regarding Contract Pharmacies

On January 12, 2021, AstraZeneca Pharmaceuticals LP filed a complaint in Delaware federal court against the Department of Health and Human Services (HHS) for issuing an invalid Advisory Opinion.

The 340B Drug Pricing Program, 42 U.S.C. § 256b (Section 340B), requires drug manufacturers to discount thousands of medications for hospitals serving under-resourced populations. The program plays an essential role in supporting the health care community. By helping health care providers stretch scarce federal resources to allow for access to lower cost medications, eligible entities participating in the program are able to expand the type and volume of care they provide to the most vulnerable patients and communities.

In 2010, the Health Resources and Services Administration, the agency within the HHS that administers Section 340B, issued a guidance saying that contracting pharmacies with 340B-covered health facilities could receive those same discounts. According to AstraZeneca's complaint, since 2010, use of contract pharmacies has grown exponentially.

Despite the guidance, AstraZeneca restricted the amount of contractor relationships it would recognize. On October 1, 2020, AstraZeneca announced it would only recognize one arrangement per covered hospital that does not maintain an on-site pharmacy. In response to AstraZeneca and other major pharmaceutical groups halting their drug discounts, the American Hospital Association and four other hospital organizations sued HHS for failing to enforce the 340B Drug Pricing Program requirements.

In December 2020, HHS issued an advisory opinion mandating drug manufacturers to give the same substantial discounts to contracting pharmacies as they do to the hospitals themselves. HHS believes this will help to target and assist vulnerable population.

While AstraZeneca recognizes the good intentions of the 1990s program, the pharmaceutical company argues that it only benefits hospitals and contract pharmacies rather than transferring 340B discounts to patients in need. Moreover, AstraZeneca maintains that the use of contract pharmacies stretches the 340B program beyond its original purpose. Under the new advisory opinion, AstraZeneca claims it risks severe civil monetary penalties, potential revocation of its ability to participate in Medicare and Medicaid, and penalties under the False Claims Act. The bottom line is that for drug manufacturers, the impact of this ruling will affect their revenue. As a larger number of drug sales become eligible for 340B discounts, drug manufacturers will incur greater revenue losses.

AstraZeneca requests for the court to declare the advisory opinion invalid and that AstraZeneca is not required to offer 340B discounts to contract pharmacies.



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