Hepatitis and HIV Groups Protest 340B Restrictions to Low-Cost Drugs

Several makers of hepatitis C drugs are limiting health care providers' access to the 340B Drug Pricing Program's discounts.

April 21, 2022 By Trent Straube

A number of advocacy groups representing the HIV and viral hepatitis communities are "gravely concerned" that manufacturers of hepatitis C meds are limiting access to low-cost meds available through the federal 340B Drug Pricing Program. Specifically, the drugmakers are requiring health care providers—notably community centers and clinics that serve low-income populations—to submit extra claims data from contract pharmacies in order to receive the hepatitis C meds at reduced costs.

"These actions by manufacturers impose an administrative burden on covered entities while diverting scarce resources away from patient care, disincentivize covered entities from developing comprehensive hepatitis C programs to serve patients with complex medical and social needs, and impede our ability to address health inequities and eliminate hepatitis C," wrote advocates in a joint statement from AIDS United, National Alliance of State & Territorial AIDS Directors, National Viral Hepatitis Roundtable, Ryan White Clinics for 340B Access, The AIDS Institute and Treatment Action Group (TAG).

> Joint statement from TAG and other viral hepatitis and HIV/AIDS advocates: we are gravely concerned by pharma companies' efforts to impose administrative burdens on community health providers in the 340B program, undermining access for critical populationshttps://t.co/vcOM6BoByl

— Treatment Action Group (TAG) (@TAGTeam_Tweets)

April 20, 2022

“We are gravely concerned by pharma companies’ efforts to impose administrative burdens on community health providers in the 340B program, undermining access for critical populations,” TAG tweeted.

Administered by the federal Health Resources and Services Administration, the 340B Program requires drugmakers that participate in Medicaid to sell drugs at a reduced cost to safety net health care providers, including hospitals, clinics and community centers that serve low-income, underserved and Indigenous populations. The idea is that the savings and refunds help pay for the various services their clients couldn’t afford to access otherwise.

“While we appreciate the commitment to using the 340B Program for the benefit of its intended communities, unilateral actions by manufacturers without commensurate measures to support the safety net undermine the shared goals of health equity and viral hepatitis elimination,” reads the joint statement. “The 340B Program enables these covered entities to support and tailor care models that address health disparities among underserved populations identified in the [federal] Viral Hepatitis National Strategic Plan. The Strategic Plan documents stark disparities in hepatitis C prevalence among African Americans, people living with both HIV and hepatitis C, and people with histories of substance use disorder, as well as hepatitis C-related mortality among Native Americans, African Americans, and people born before 1965.”

AIDS Healthcare Foundation (AHF) is also decrying the restrictions to 340B Program discounts. The California-based AHF recently organized a protest against drug manufacturer Gilead Sciences for its move to undermine safety net providers’ access to 340B program benefits. According to AHF, Gilead is the 15th drugmaker to place limits on the 340B contract pharmacy programs.*

“The 340B statute gives providers the undeniable legal right to access discounted drugs for their patients. Drug manufacturers have absolutely no right to place conditions on this access—but they are constantly trying to devise new ways to do so,” explained Laura Boudreau, AHF’s chief of operations/risk management and quality improvement, in an AHF press statement about the protest. “This latest move hurts safety net providers who do not have their own in-house pharmacy but instead rely on outside pharmacies to make drugs available to their patients. Gilead will only provide these providers access to discounts if they turn over sensitive data about the providers’ patients. Providers who don’t submit this data are shut out—contrary to the letter and spirit of the 340B program.”

Similarly, Ryan White Clinics for 340B Access released a statement last month about drugmakers’ policies to “no longer honor contract pharmacy arrangements with covered entities, including grantees, unless the covered entity submits 340B contract pharmacy claims through the 340B ESP

platform or qualifies for an exception." For more, see "Gilead to Restrict Access to 340B Prices at Contract Pharmacies for Branded Hep C Drugs; AbbVie Adds Imbruvica to Restrictive Contract Pharmacy Policy."

In related news, advocates have also expressed concerns about future funding of the 340B Program. For example, HIV clinics that rely on 340B support could lose over $100 million each year—notably those serving Black, brown, queer and Southern communities. For more about that, see "PrEP Programs Face Devastating Loss of Funding for HIV Prevention."

And for more insight on the importance of the 340B Program, read this POZ blog post by AIDS United's 340B Working Group, a collection of safety-net providers who work to advance health equity.

*Editor's note: An earlier version of this article stated that Gilead Sciences' 340B restrictions applied not only to hep C meds but also to HIV treatments. A Gilead spokesperson clarified that the drugmaker's Contract Pharmacy Integrity Initiative applies only to branded hepatitis C products.

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