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**Contact: Amy Simmons Farber**  
**202 309 0338**  
**[Asimmons@nachc.org](mailto:Asimmons@nachc.org)**

## **NACH Lawsuit Against HHS to Defend the 340b Drug Discount Program from Prescription Drug Manufacturer Attacks**

### ***Key Points***

The National Association of Community Health Centers (NACHC) has filed suit to take action in response to recent moves by drug manufacturers to severely limit the ability of health centers to fully utilize the federal 340B drug discount program.

The NACHC suit seeks to compel the Department of Health and Human Services (HHS) to implement a long-delayed dispute resolution process that will help health centers contend with drug companies that are violating the 340B statute and/or their binding pharmaceutical pricing agreements. The most recent example of these violations is the abrupt decision by several of the most profitable drug manufacturers to stop shipping discounted drugs to health centers' contracted pharmacies.

After decades of shipping 340B priced drugs to health center contract pharmacies, drug manufacturers have suddenly decided to stop -- in the midst of a historic global pandemic -- a move that NACHC describes in the suit as "callous" and "a clear violation of 340B statutory requirements and the binding pharmaceutical pricing agreements manufacturers have with HHS."

NACHC estimates that 10 million low-income patients will suffer reduced access to health center services and affordable medicine unless HHS acts now. Many of these health center patients live in poverty, suffer from multiple chronic diseases, and are uninsured or rely on public insurance. Twelve percent have tested positive for COVID.

Bipartisan Members of Congress have also sounded the alarm to HHS, calling the drugmakers' actions "a dangerous precedent."

While the HHS General Counsel signaled "significant concerns" with the actions of at least one of these pharmaceutical manufacturers, no action has been taken to ensure these manufacturers are making their covered outpatient drugs available at 340B discount prices to covered entities for dispensing at their contract pharmacies.

### **Impact**

Across the country, millions of patients' lives are at stake and health center operations and budgets face possible devastation in the midst of an overwhelming public health pandemic.

The significant, irreparable harm these patients have suffered and will suffer is both direct and indirect. Direct harm to health center patients has included, and will include, drastic increases in the price of life-sustaining medications for chronic conditions like diabetes, respiratory diseases, cardiovascular disease, HIV/AIDS, and substance use disorder.

NACHC has fielded endless numbers of complaints from health centers in the past few weeks about high drug prices that low income patients will be forced to pay. For instance:

- A health center patient may now pay up to \$600 for a 30 day supply of insulin that used to cost \$17.
- The price of preventive inhaler for asthma may rise from \$17-18 to \$350 or more per month.

Patients' geographic, transportation, and time-availability barriers also hinder how they can receive medications, even in cases where a health center's existing in-house pharmacy or pharmacies could theoretically make such medications available.

There are adverse and, at times, even fatal health consequences when a patient faces a delay in receiving medication. Likewise, a shift to a similar, but not identical, clinical alternative medication – assuming one exists – may not be well-tolerated or be as effective for patients.

### **The Argument for Protecting 340B**

The 340B program's objective is to reduce drug costs and "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Any savings the program generates for health centers is derived directly from the statutorily mandated discount pricing scheme which costs taxpayers nothing.

Health centers use the savings they generate through the 340B program to provide additional services in their service area. For example, savings are used to cover the cost of medication for uninsured or underinsured patients who cannot afford it. Savings are also used to expand access to necessary medical and crucial enabling services, which can include medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services, and transportation assistance.

Section 330 expressly authorizes each health center to provide services, including pharmaceutical services, through its own staff or through "contracts or cooperative agreements" with other entities, or a combination thereof.

Health centers are subject to rigorous oversight and accountability. They are subject to audits by both HHS and manufacturers to ensure compliance and many, if not most, health centers perform their own internal auditing functions to ensure compliance.



Health centers across the nation have proven to be excellent stewards of tax dollars and 340B savings. They are nonprofits, accountable by law and audit, and driven by mission – not money.