# THE 340B COALITION

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## SAFETY-NET PROVIDERS URGE HHS TO CURB DRUGMAKER OVERCHARGES

Washington, D.C., May 22, 2018—The 340B Coalition, representing safety-net providers from across the country, today urged the Trump administration to stop delaying implementation of rules designed to prevent pharmaceutical manufacturers from overcharging. The rules, ordered by Congress in 2010, have been delayed four times in the last 16 months and the administration has proposed delaying them again until July 2019.

In a letter commenting on that proposal, the Coalition says the rules should be put in place immediately, without further delay. The U.S. Department of Health and Human Services (HHS) "has already spent eight years considering and responding to four separate rounds of public comments. Any further delay is contrary to federal law," the group's letter says.

Congress enacted the 340B program to enable hospitals, clinics, and health systems to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." By lowering drug costs for these providers, the 340B program supports care for low-income and rural patients.

Congress required HHS to issue regulations to establish civil monetary penalties for manufacturers that "knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug." HHS published a proposed rule in June 2015 and a final rule in January 2017 that was to take effect in April 2017. The new Trump administration delayed the effective date shortly after it took office and has extended that delay more three times. It is due to take effect July 1, but HHS has proposed an additional one-year postponement.

In its letter, the Coalition noted that the HHS Office of the Inspector General has reported numerous findings of manufacturer overcharges, and that, under a recent settlement, Mylan agreed to pay $19.3 million plus interest to 340B covered entities to resolve allegations that the company overcharged entities for the drug EpiPen.

The Coalition noted a parallel issue that is also stymieing efforts to ensure manufacturers do not overcharge 340B providers. Congress mandated in 2010 that HHS create an online ceiling price database accessible to covered providers so they can know how much they should pay for drugs. HHS has delayed posting that information while the regulation is still pending.

"The [340B] program cannot function as intended if covered entities cannot determine whether manufacturers charge prices in compliance with the law," the Coalition letter says, "340B covered entities require this basic information so that they can be assured that they are being charged appropriately."

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*Members of the 340B Coalition include the Children's Hospital Association, America's Essential Hospitals, 340B Health, the Hemophilia Alliance, the National Association of Community Health Centers, the National Alliance of State and Territorial AIDS Directors, the National Rural Health Association, the National Family Planning & Reproductive Health Association, the National Coalition of STD Directors, Planned Parenthood Federation of America, the National Association of Counties, the HIV Medicine Association, and the National Health Care for the Homeless Council.*