

PUBLICATION

Lawmakers Call on HHS to Stop Drug Companies from Denying 340B Drug Pricing

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Members of Congress of both parties are requesting that the Department of Health and Human Services (HHS) take action to ensure that providers participating in the 340B drug pricing program can continue to receive discounted drug prices through the program. On September 17, 2020, a bipartisan group of 28 Senators wrote to HHS requesting action, following a similar request on September 14, 2020 from a bipartisan group of 243 members of the U.S. House of Representatives and a September 3, 2020 letter from House Democratic leaders of the Energy and Commerce Committee. Senator Joe Manchin (D-WV) sent a separate letter on September 15, 2020.

The letters are in response to recent actions by drug manufacturers to stop offering 340B-discounted prices for drugs dispensed through pharmacies under contract with 340B providers. The letters urge HHS to require manufacturers to continue offering 340B pricing, including for drugs dispensed through contract pharmacies.

A group of 22 Senate Democrats also [wrote](#) to the Pharmaceutical Research and Manufacturers of America (PhRMA) on September 15, 2020, asking what the industry is doing to stop denials of 340B pricing to program participants.

Background on 340B Contract Pharmacies

340B providers include public and non-profit hospitals that serve high volumes of low-income patients or are located in rural areas, as well as providers that receive federal grant funding, such as Federally Qualified Health Centers (FQHCs), Ryan White HIV/AIDS clinics, and recipients of funding to treat and prevent sexually transmitted diseases, among others. 340B providers can access program savings through the use of 340B-discounted drugs in several settings, depending on the provider type: 1) hospital outpatient clinic areas, 2) provider-owned retail pharmacies, and 3) external pharmacies under contract with the provider to dispense 340B drugs purchased by the provider to the provider's patients (340B contract pharmacies).

Providers have used 340B drugs through the contract pharmacy model since the program's early years in the 1990s. The Health Resources and Services Administration (HRSA) has issued guidance recognizing that the 340B statute requires drug manufacturers to offer 340B pricing to program participants, including when the drugs are to be dispensed through contract pharmacies.

Recent Drug Company Actions

In recent months, several drug manufacturers have announced they will no longer provide 340B pricing for drugs dispensed through contract pharmacies. Others have indicated they will require providers to submit contract pharmacy claims data to be reviewed by manufacturers and will deny 340B pricing for use in contract pharmacies if providers do not share the data or will take other actions that could make program participation more difficult.

Some drug companies appear to be taking the position that the 340B statute does not require manufacturers to offer 340B pricing to providers for drugs dispensed through contract pharmacies, so long as manufacturers make 340B prices available directly to providers for use in their in-house pharmacies. Several manufacturers

have pointed to the fact that HRSA policy outlining contract pharmacy use is articulated through guidance, not regulations. HHS has [indicated](#) that sub-regulatory guidance documents "do not have the force and effect of law and are not meant to bind the public in any way."

Response from Lawmakers and 340B Providers

Supporters of the 340B program have indicated that it is the 340B statute, not HRSA guidance, that requires drug manufacturers to offer 340B pricing, and this obligation extends to drugs dispensed through contract pharmacies. HRSA guidance reiterates manufacturer obligations under the statute, and the statute does not allow manufacturers to pick and choose when to offer 340B prices.

The group of 28 Senators calling for HHS action included 12 Republicans, one independent, and 15 Democrats, including the ranking members of the Health Education, Labor, and Pensions (HELP) and Finance Committees. The Senators shared their belief that recent manufacturer actions "run counter to the statute."

The bipartisan letter from 243 members of the House, led by Representatives David McKinley (R-WV), Diana DeGette (D-CO), Greg Gianforte (R-MT), Dusty Johnson (R-SD), Doris Matsui (D-CA), and Peter Welch (D-VT) indicated, "There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts."

A September 3, 2020 letter from House Democratic leaders of the Energy and Commerce Committee highlighted the actions HHS could take to stop drug company denials of 340B pricing. The letter specified, "Congress has provided you with tools, including manufacturer auditing rights and civil monetary penalties, to enforce [the 340B statute]." The letter was sent by Committee Chair Representative Frank Pallone (D-NJ), Chair of the Subcommittee on Health Representative Anna Eshoo (D-CA), and Representative DeGette, Chair of the Subcommittee on Oversight and Investigations.

Senator Richard Blumenthal (D-CT) led a letter with 21 other Senate Democrats sent to PhRMA on September 15, 2020 requesting that the trade association provide information to the Senators by September 29, 2020 on what steps the drug industry is taking to stop manufacturers from denying 340B pricing for use in contract pharmacies and end demands for claims data.

340B providers have made similar requests of HHS. More than 1,100 of the 340B hospitals sent a [letter](#) to HHS on September 10, 2020, asking that HHS take action to stop manufacturers from denying 340B pricing. The 340B Coalition, which includes groups representing all providers in 340B, wrote to HHS on July 16, 2020, calling for action. Seven hospital groups sent a [joint letter](#) on August 26, 2020.

Implications for 340B Providers

Providers have expressed concern that, absent action from HHS, more manufacturers could cease offering 340B pricing for drugs dispensed through contract pharmacies. For some providers, the 340B benefit generated through contract pharmacies amounts to a significant share of their overall 340B benefit. This can be especially true for rural hospitals and community health centers, which often do not have in-house pharmacies. For many providers, ensuring access to 340B pricing for use in contract pharmacies may be critical to maintaining the benefit of the 340B program moving forward.

We will continue to monitor developments regarding the 340B program and share new information as we learn of it.