

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for patients in vulnerable communities. These organizations include public and nonprofit disproportionate share hospitals, children’s hospitals, critical access hospitals, sole community hospitals, rural referral centers, community health centers, and hemophilia treatment centers that serve the needy.

The program allows eligible hospitals to stretch limited federal resources to provide more affordable and more expansive health services to the patients and communities they serve. Hospitals use 340B savings to provide free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement, for example, medication management and community health programs, among other services and programs.

In order to expand the reach of the 340B program, the Health Resources and Services Administration (HRSA) allows 340B participants (also known as “covered entities”) to contract with outside pharmacies to dispense drugs to eligible patients. Contract pharmacies serve as an extension of the 340B provider and provide patients access to prescription drugs outside of the four walls of the hospital or community clinic. For hospitals, these arrangements allow them to better serve their vulnerable communities by increasing access to more affordable health care services. A number of drug companies have taken unprecedented actions, beyond the scope of the statute, to limit the distribution of certain 340B drugs to hospitals and health systems. These unlawful actions range from limiting the distribution of certain 340B drugs to demanding superfluous, detailed reporting of 340B drug claims distributed through hospitals’ contract pharmacies. Despite calls from the Department of Health and Human Services (HHS) stop these practices, drug manufacturers continue to violate the statute by knowingly overcharging for 340B drugs.

AHA Position

- The drug companies’ abusive tactics will negatively impact 340B hospitals’ ability to stretch their scarce resources to provide more affordable access to care and must be ended immediately.
- The 340B statute is clear – drug manufacturers must provide 340B pricing to eligible hospitals for any drug. The manner in which the drug is dispensed is irrelevant.
- HRSA, in its oversight of the 340B program, established and then expanded the use of contract pharmacies to improve access to 340B drugs for vulnerable communities served by the 340B program.
- Contract pharmacies are particularly important in rural areas. Nearly half of all eligible 340B hospitals are in rural areas that often lack adequate access to health care services. More than 80% of rural 340B hospitals, use contract pharmacies to ensure their patients have access to needed outpatient drugs, as well as other essential services.
- Through contract pharmacy arrangements, 340B hospitals expand access to affordable health care services for everyone in these vulnerable communities, and the financial relief the program provides to rural hospitals from the exorbitant prices they would otherwise pay helps keep their doors open to everyone in the community.
- HRSA conducts annual audits of covered entities to ensure they are complying with 340B rules and regulations. This includes auditing for the duplicate discounts and diversion the drug companies claim without foundation are attributable to 340B contract pharmacies. In addition, many covered entities conduct periodic self-audits of their programs to ensure they are in compliance with the rules.

- HRSA should use its authority to stop any drug manufacturer from employing these pernicious tactics and to ensure that 340B drugs are available and accessible to vulnerable communities.

Key Facts

- **Access to 340B drugs is more important than ever.** Hospitals are responding to the immense financial and operational challenges posed by the COVID-19 public health emergency. Instead of supporting the hospitals caring for communities ravaged by the public health crisis or working to address the inadequacies of the fractured pharmaceutical supply chain unearthed by this pandemic, these drug companies have decided to decimate a program that is actively working to help patients and communities in an effort to increase the drug companies' already excessive profits. These actions will undoubtedly force hospitals to divert critical resources away from caring for patients during the pandemic.
- **HHS states drug companies must provide 340B discounts to contract pharmacies.** In December 2020, HHS' General Counsel advised drug companies that they must provide 340B discount prices to pharmacies that contract with covered entities, noting "This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be purchased by a covered entity."
 - **HHS must enforce program requirements and halt drug company actions that undermine the program.** Despite the strong words of support for contract pharmacies, HHS has yet to penalize drug companies violating the statute.
 - **HHS issued a final rule in late 2020 to put in place a statutorily-required alternative dispute resolution (ADR) process to allow 340B covered entities to challenge drug manufacturers.** HHS claimed the ADR process would be an avenue for 340B covered entities to address disputes with drug manufacturers' contract pharmacy restrictions. Some of the major manufacturers immediately moved to challenge HHS for issuing the ADR final rule. The court process is expected to continue through the first half of 2021. The AHA has weighed in to support HHS' efforts to implement the ADR process.
 - The AHA, other national hospital groups and an organization of hospital pharmacists filed a federal lawsuit against the HHS over the department's failure to enforce program requirements. In February 2021, a federal judge dismissed the case without prejudice stating that HHS is still contemplating what action it might take and that in light of the transition to a new Administration it couldn't yet be said to have abdicated its responsibility to enforce the 340B statute against the drug companies. The lawsuit may be refiled if the new Administration fails to do something tangible to hold drug companies accountable for withholding 340B discounts within a reasonable amount of time.