Fact Sheet: 340B Drug Pricing Program — Contract Pharmacy Arrangements

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, called "covered entities," include public and nonprofit disproportionate share hospitals, children's hospitals, critical access hospitals, sole community hospitals, rural referral centers, and federal grantee programs.

The program allows eligible hospitals to stretch limited federal resources to provide more affordable and comprehensive health care services and expand its reach to serve more patients and communities. Hospitals use 340B savings in many ways based on the unique needs of the populations they serve. Some examples include providing free care for uninsured patients, offering free or discounted drugs, providing behavioral health services, and implementing, for example, medication management and community health programs, among other community-focused services and programs.

In light of the mission of the 340B program to ensure more patients have access to care, the Health Resources and Services Administration (HRSA) allows covered entities the ability to contract with community and specialty pharmacies to dispense drugs on their behalf to their eligible patients. Contract pharmacies serve as an extension of the 340B provider and allow patients access to their prescribed drug treatments in the convenience of their local community pharmacy or through the mail (i.e., mail-order pharmacy). For hospitals, these arrangements allow them to ensure that their patients can access the drugs they need when they need it, especially as patients rely more heavily on specialty drugs many of which are in limited distribution. For patients, these arrangements make it easier to access their needed drugs without having to travel to the hospital to receive the drug. The 340B savings generated from these arrangements allow the hospital to better serve their vulnerable communities by increasing access to more affordable health care services. Despite these benefits to patients and providers, several drug companies have taken unprecedented and unlawful actions to limit or deny access to 340B pricing through these contract arrangements with community and specialty pharmacies. The Department of Health and Human Services (HHS) has referred several companies to the Office of the Inspector General for violating the law, for which the drug companies have litigated and is currently pending resolution in the Federal Appeals Court. Meanwhile, several states have introduced or passed legislation that would prohibit drug companies from denying 340B discounts through contract pharmacy arrangements.

Key Facts

- The drug companies' abusive tactics are negatively impacting 340B hospitals' ability to stretch their scarce resources to provide more affordable access to care and must end immediately. A recent AHA survey found that these actions are resulting in over $500 thousand in average annual losses to critical access hospitals, while DSH hospitals are losing an average of nearly $3 million every year. As more drug companies impose more restrictions, these losses are exponentially increasing, with many reporting tens of millions in losses.
- The 340B statute is clear – drug manufacturers must provide 340B pricing to eligible hospitals for any covered outpatient drug regardless of where or how that drug is dispensed, as long as that drug is dispensed to an eligible patient.
- HRSA, in its oversight of the 340B program, established and then expanded the use of contract pharmacies, recognizing the value of contract pharmacies to improve access to 340B drugs for vulnerable patients and communities.
- Contract pharmacies are particularly important in rural hospitals, many of which do not have their own in-house pharmacies, and therefore solely rely on a network of contracted community and specialty pharmacies to ensure their patients have access to the drugs they need. Approximately half of all eligible 340B hospitals are located 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.
- Contract pharmacies allow all hospitals to ensure access to a wide range of 340B drugs for their patients. For hospitals that do have their own in-house pharmacy, they are unable to stock every drug that a patient could possibly need, especially since many specialty drugs are in limited distribution and unavailable to keep in continuous inventory. Having these contractual relationships with external pharmacies allows the hospital to provide the patient with a needed drug, even if the hospital's pharmacy does not inventory that drug. Not only does the patient benefit in such an instance, but allowing access to the drug in a more convenient manner to the patient at their local community pharmacy helps ensure better compliance with prescribed treatments.
- HRSA conducts 200 annual audits of covered entities, a great majority of which are for hospitals, to ensure they are complying with 340B rules and regulations. These rigorous audits ensure that 340B drugs are being given only to eligible patients (diversion), and that covered entities are not receiving both a 340B discount and a Medicaid rebate for the same

drug (duplicate discount). In addition, many covered entities conduct periodic self-audits of their programs to ensure they are in compliance with program rules.

AHA Position

- **HHS must use all available tools to halt drug company actions that undermine the program.** 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." We encourage HHS to use the full extent of their authority to penalize drug companies for violating the statute.
- **Access to the 340B program is more important than ever.** Hospitals are facing significant financial challenges due to a confluence of factors from historic inflationary cost pressures and critical workforce shortages. Of particular concern is a dramatic rise in drug costs which have increased approximately 20% between 2019 and 2022. Hospitals need access to the 340B program to ensure that they can maintain access to healthcare services for their patients in the face of these challenges.
- **HHS should finalize the 340B administrative dispute resolution (ADR) proposed rule.** In November 2022, the Biden Administration issued a proposed rule that sets up a revised ADR process that is "less trial-like" and more administrative. We appreciate the agency making the process more provider-friendly and for removing certain barriers that will allow more 340B providers to seek relief for claims at issue. However, HHS should explicitly include language that would allow 340B providers to bring contract pharmacy claims where 340B pricing was denied before the ADR process. The agency should also spell out a timeline for decisions to be made by the ADR panel so that hospitals are not left with an indefinite time period for resolution to their cases. HHS should expeditiously finalize the rule with these recommended changes to provide hospitals an avenue to address drug manufacturers actions.