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Fact Sheet - 340B Drug Pricing Program: Fact vs. Fiction

Key Takeaway

The 340B Drug Pricing Program is a small program with big benefits for underserved patients and communities. It allows eligible hospitals to stretch scarce federal resources to maintain, improve and expand access to support a variety of patient services and programs that are improving the health and well-being of patients and communities across the country. Given the increasingly high cost of prescription drugs, the 340B program remains a critical resource to creating healthier communities.

Background

For over 30 years, the 340B Drug Pricing Program has been a crucial lifeline for eligible hospitals to manage rising prescription drug costs and ensure the patients and communities they serve have access to the health care services they need. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers who choose to participate in Medicaid to sell certain outpatient drugs at discounted prices to eligible health care organizations, including those providing care for underserved populations such as children, patients living with cancer, and those living in rural communities.

Eligible hospitals can generate savings by purchasing outpatient drugs at a discounted price instead of the higher price they would have paid for the drug outside of the 340B program. The savings allow 340B hospitals to stretch limited federal resources to improve access to vital patient programs and services, which in many cases includes providing drugs to patients at a little or no cost. As the cost of drugs continue to rise rapidly, the 340B program is more important now than ever before to preserve access to care.

Despite the program's proven track record, drug companies have consistently tried to reduce the program's benefits to patients and communities. Drug companies and other stakeholders continue to spread inaccuracies about the program, putting their profits ahead of the needs of patients and providers. This document highlights some of this misinformation and sets the record straight on the 340B program.

Fact vs. Fiction

Fiction: Growth in the 340B program is out of control.

Fact: Though the 340B program has grown over time, it remains a small program that delivers big benefits to patients and communities. In 2010, Congress expanded the benefits of the 340B program to other hospitals to improve health care access to more low income and uninsured patients. Those hospitals included critical access hospitals (CAHs), rural referral centers, sole community hospitals and free-standing cancer hospitals. While Congress has expanded the program to these safety-net hospitals, the drugs used by these hospitals account for only a small fraction of drugs sold under the 340B program. Other factors that contribute to the program's growth include Centers for Medicare & Medicaid Services' policy changes resulting in a growing shift from inpatient to outpatient care and the increased development and use of high-cost specialty drugs to treat complex medical conditions.

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Fiction: The 340B program has lost its way from its original intent.

Fact: The 340B program continues to enable participating providers to expand access to care for vulnerable communities just as Congress intended when it established the program in 1992. Congress stated the purpose of the program was to permit providers that care for a high number of low income and uninsured patients "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." This includes, but is not limited to, improved access to outpatient prescribed pharmaceuticals. Hospitals have used savings from the 340B program to establish and support a variety of programs that are improving access and quality of care for not only low income and uninsured patients, but also the entire community the hospital serves.

Fiction: 340B hospitals do not pass along the savings they receive from the program to their patients.

Fact: The 340B program generates valuable savings for eligible hospitals to reinvest in programs that enhance patient services and access to care. Every hospital cares for a unique patient population with a unique set of needs. Each 340B hospital uses its savings based on the needs of their patients. For example, some 340B hospitals use their savings to support opioid treatment services for their patients, which include providing free naloxone, especially in areas where the opioid epidemic is rampant. Other 340B hospitals have used their savings to provide free care to the local homeless population.

Fiction: There is no transparency in the 340B program.

Fact: 340B hospitals have continuously demonstrated and reported on their commitment to using their savings to provide important services and programs to vulnerable communities that they otherwise would not be able to provide. 340B hospitals report a number of data on how much they invest in resources to benefit the community. These data are reported both through the IRS tax form 990 submitted by all non-profit hospitals. These data show that in 2020 alone, 340B hospitals provided nearly $85 billion in community benefits, a nearly 25% increase from the prior year. Additionally, many 340B hospitals have publicly disclosed that they use their savings to support important patient services such as medication management programs, diabetes education programs and mental health services. In 2018, the AHA established the 340B Good Steward Principles to demonstrate 340B hospitals' commitment to transparency to ensure that the program meets the congressional objective: "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Many 340B hospitals have proactively committed to these principles and are actively communicating their annual 340B savings and how they use those savings to benefit their communities.

Fiction: A 340B rebate model would have no impact on 340B hospitals or their patients.

Fact: Operationalizing the 340B program as a rebate model would jeopardize patients' access to drugs, create enormous operational burdens for 340B hospitals, and exacerbate financial challenges for hospitals. Since the start of the program, the Health Resources and Services Administration (HRSA) has operationalized access to the 340B price as an upfront discount. Changing this process to require hospitals to purchase 340B drugs at full price (e.g., wholesale acquisition cost), submit claims data to drug companies, and then wait for a rebate for the price difference will create significant financial

challenges for hospitals. The upfront costs hospitals will be forced to incur in purchasing drugs at full price will be impossible for many hospitals and will leave them unable to stock certain medications, leaving patients unable to access these medications. In addition, hospitals will be forced to incur significant costs to develop the systems and processes required to provide the necessary data elements to drug companies in order to access the rebate.

Fiction: 340B hospitals do not provide significant levels of charity care.

Fact: 340B hospitals provide substantial community benefit, and charity care tells just one small piece of the story. Charity care is only indicative of the amount of care provided to patients who qualify for the hospital's financial assistance policy and is therefore provided to the patient free of cost. It does not account for costs that hospitals incurred for services where payment was expected but not received (bad debt) or payment shortfalls from public payers like Medicaid (underpayments). Therefore, it is more accurate to look at a hospital's total uncompensated care (bad debt and charity care) and their total community benefits, which among other costs includes uncompensated care costs as well as payment shortfalls. Hospitals provided nearly $43 billion in uncompensated care in 2020 alone, of which 340B hospitals roughly made up 68%. In addition, in 2020, 340B hospitals provided nearly $85 billion in total community benefits. 340B hospitals are providing these high levels of uncompensated care and community benefits despite many of these hospitals operating on razor-thin margins.

Fiction: The 340B program lacks any meaningful oversight.

Fact: Hospitals that participate in the 340B program are subject to rigorous oversight and must meet numerous program integrity requirements.

Hospitals must:

- Recertify annually their eligibility to participate in the program and attest to meeting all the program requirements.
- Participate in audits conducted by HRSA, which oversees the program, and drug manufacturers.
- Maintain auditable records and inventories of all 340B and non-340B prescription drugs.

In addition, many 340B hospitals conduct their own self-audits to ensure compliance with 340B program guidelines. The AHA and its 340B hospital members support program integrity efforts to help ensure that all covered entities are compliant with the program requirements.

Fiction: 340B is a primary driver of consolidation.

Fact: This is simply untrue. Many legitimate factors exist that drive physician offices to consolidate with hospitals. As costs of caring for patients has increased dramatically, in large part due to the exorbitant growth in drug prices, physician offices have increasingly found it difficult to maintain their operations. In addition, the significant administrative burden that exists with insurance companies through unnecessary prior authorizations and claim denials have hampered physician offices' ability to operate effectively. Hospitals also are strengthening ties to each other and to physicians in an effort to respond to new payment systems, quality improvement efforts, implementation of electronic medical records and coordinated care across the entire health care continuum. For example, some oncology practices have found that close partnerships with 340B hospitals improve their ability to

deliver chemotherapy and cancer care to their patients. Unlike independent oncology practices, hospitals care for all patients who seek care, regardless of their insurance status or ability to pay. They also treat patients who are sicker and require more complex services than those treated by private practice oncology clinics.

Fiction: Contract pharmacy arrangements don't benefit patients.

Fact: In order to expand the reach of the 340B program, HRSA allows 340B participants to contract with outside pharmacies to dispense drugs to their eligible patients. Contract pharmacies are an extension of the 340B covered entities and provide patients access to their prescribed drug treatments at their local community pharmacy or through the mail (e.g., a specialty 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.