

### **Protecting the 340B Drug Pricing Program**

The 340B Drug Pricing Program (340B Program) is an essential way to receive discounted outpatient drugs for many rural hospitals serving vulnerable populations who may lack insurance or be low income. Recently, unlawful attacks on the 340B program by drug manufacturers have created challenges for safety-net hospitals trying to obtain discounts provided by the program.<sup>i</sup>

#### **Policy Recommendations:**

Policy makers must take legislative action to protect the 340B Drug Pricing Program, including to:

- Support and increase hospital access to contract pharmacies while protecting providers as covered entities.
- Put an end to burdensome data reporting requirements for providers.
- Ensure that drug manufacturers cannot impose unlawful requirements on 340B covered entities.
- Include new Rural Emergency Hospital model as a covered entity eligible to participate in the 340B program.
- Continue application of the Administrative Dispute Resolution (ADR) process for covered entities to petition manufacturers violations, pending legislation.
- Pursue administrative enforcements such as issuing civil monetary penalties against manufacturers referred by HRSA and enforcing the pharmaceutical pricing agreement between HHS and each pharmaceutical manufacturer participating in Medicaid.

#### **Recommended Action**

A starting point to enforcing the 340B drug pricing program is [H.R. 4390 PROTECT 340B Act of 2021](#), however more action is needed to uphold this essential program. The PROTECT 340B Act prohibits health insurers and Pharmacy Benefit Managers (PBM) from discriminating against 340B providers or their contract pharmacy on the basis of their 340B status. Additional legislative action is needed from Congress to address data restrictions and ensure covered entities are able to continue utilizing the contract pharmacies they rely on. Reigning in further attacks on the 340B program is necessary so that it remains a lifeline for safety-net hospitals and the patients they serve.

#### **Overview**

Established in 1992, 340B is required for pharmaceutical manufacturers who have drugs that are covered on an outpatient basis by Medicaid and Medicare Part B.<sup>ii</sup> The manufacturers agree to offer front-end drug discounts to safety-net providers serving vulnerable populations, including many rural providers such as critical access hospitals (CAH), sole community hospitals (SCH) and rural referral centers (RRC) and disproportionate share hospitals (DSH).<sup>ii, iii</sup>

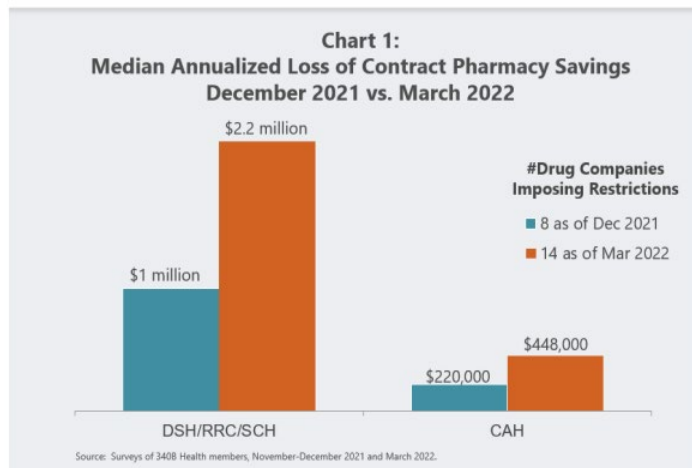
For many rural safety-net hospitals that are operating on thin financial margins, 340B is a way “to stretch scarce Federal resources as far as possible.”<sup>i, iv</sup> Savings from 340B programs are used to provide services and health programs within the communities the hospital serves.<sup>i</sup> The Government Accountability Office (GAO) reported in 2015 that entities participating in the 340B program save an estimated 20-50% off standard drug prices.<sup>ii</sup> These savings directly translate to essential funding for rural hospitals to support life-saving work. For example, a rural hospital in Kansas stated that 340B savings has allowed the hospital to, “add a full-time position for case management, increase staffing hours, develop after-school programs and open clinics in impoverished towns that lacked health care.”<sup>v</sup> The 340B program also promotes health equity by

expanding access to patients in underserved communities by creating savings to address social determinants of health like transportation, food insecurity, life skills training, and social support services.

Starting in July of 2020, an increasing number of pharmaceutical manufacturers have unlawfully implemented restrictions on 340B.<sup>i</sup> Restrictions have included increased data requirements, requirements for in-house or contract pharmacies, and increasing prices for 340B discount drugs above the rate of inflation.<sup>i</sup> Importantly, the Health Resources and Services Administration (HRSA), which oversees 340B, does not have the statutory authority to uphold the program that is currently under attack. HRSA has issued violation letters to pharmaceutical manufacturers in violation of the statute, with some manufacturers filing lawsuits.<sup>i, iv</sup> In a recent statement from HRSA, two of three U.S. District Court opinions have sided with HRSA that pharmaceutical manufacturers unlawfully restricted access to 340B drugs, and they are considering options for the dissenting opinion.<sup>iv</sup>

Further, the 340B program has faced mounting threats recently from pharmacy benefit managers (PBMs). For years, PBMs have taken advantage of the lack of federal oversight on their participation in the 340B program through discriminatory contracting practices, which transfers 340B savings away from the rural provider through unpredictable fees, restrictive contracting terms, and aggressive auditing tactics to lower reimbursement. Starting in August 2020, pharmaceutical manufacturers launched an aggressive attack against 340B covered entities by refusing to ship 340B-priced medications to contract pharmacies, unless they turned over claims data.<sup>vi</sup>

**Annualized losses due to contract pharmacy restrictions have doubled since the end of 2021.**



While HRSA, PBMs, and manufacturers are pursuing legal options, the lack of 340B savings is impacting safety-net hospitals. A study conducted by 340B Health found that the loss of contract pharmacy savings doubled for CAH from \$220,000 to \$448,000 and for DSH, RRC, and SCH from \$1 million to \$2.2 million during the short span of December 2021 to March 2022.<sup>i</sup> Because of the restrictions, safety-net hospitals are reporting that they will need to make cuts to existing programs that are funded by 340B savings, ultimately impacting patient care and the ability for patients to receive vital medications.<sup>i</sup>

- i. [https://www.340bhealth.org/files/Contract\\_Pharmacy\\_Survey\\_Report\\_FINAL\\_05-05-2022.pdf](https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf)
- ii. <https://www.340bhealth.org/members/340b-program/overview/>
- iii. <https://www.aha.org/system/files/media/file/2019/03/fact-sheet-340b-drug-pricing-program-0119.pdf>
- iv. <https://www.hrsa.gov/opa/index.html>
- v. <https://khn.org/news/article/340b-big-pharma-hospitals-battle-over-drug-discounts-patients-miss-out-on-millions-in-benefits/>
- vi. <https://www.nachc.org/report-340b-a-critical-program-for-health-centers/>