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State Options for Managing 340B Drug Pricing Programs

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Recent headlines discussing various implications of the federal 340B Drug Pricing Program (340B) have spurred legislators' interest. But what is 340B?

At its core, the intent of 340B is to increase prescription drug access to underserved populations by "stretching scarce federal resources." The roots of 340B can be traced to the implementation of the Medicaid Drug Rebate Program. As a condition of the program, manufacturers who choose to have their drugs covered by Medicaid must agree to provide substantial rebates to state Medicaid programs. In fact, Medicaid must receive the largest discount or rebate offered to private purchasers—known as the "best price." Manufacturers are also required to provide an additional rebate if prices rise faster than inflation.

Before the Medicaid Drug Rebate Program, many manufacturers already offered considerable discounts to safety-net providers. Soon after program implementation, some drug companies canceled their safety-net provider contracts to avoid triggering a new Medicaid "best price." To counter these actions, the federal 340B Drug Pricing Program (340B) was created to ensure safety-net providers had access to discounts on outpatient drugs without impacting rebates paid in Medicaid.

Organizations that qualify for 340B are known as covered entities (CEs) and are certified by the Health Resources and Services Administration (HRSA). CEs include some disease-specific providers (e.g., hemophilia, HIV and black lung), certain categories of hospitals—such as children's hospitals and rural referral centers—federally qualified health centers and more. CEs receive average discounts of 20-50% off list prices and can generate revenue by charging insurers (except Medicaid) the market price rather than the lower 340B acquisition cost. Some CEs are federally required to reinvest 340B revenue to improve patient services and access to care, while others have no restrictions.

Between 2000 and 2020 the number of CEs increased from 8,100 to 50,000 and purchases through the program climbed from $5.3 billion in 2010 to $38 billion in 2020. In addition to dispensing drugs through in-house pharmacies, CEs may contract with non-affiliated retail pharmacies, known as contract pharmacies, to dispense drugs to 340B-eligible patients on their behalf. Contract pharmacies have also experienced exponential growth—over 4,000% from 2010-2020. Although a person may receive their prescriptions through a contract phar-

Did You Know?

- At least 19 state legislatures considered 340B-related bills as of July 2022.
- The 340B Drug Pricing Program serves more than 10 million people in all 50 states, Washington, D.C. and the territories.
- According to a 2019 report, at least 16 states have contracts with covered entities to care for and administer certain specialty medicines to people who are incarcerated.

macy, they must be a patient of a CE with a medical record on site.

The rise in the number of CEs, contract pharmacies and drug purchases has drawn both praise and criticism. Advocates of 340B claim these increases are illustrative of CEs expanding the type and volume of care they provide to safety-net patient populations. Others say the savings generated by 340B are not being used to help the populations they are intended to serve. They also take issue with the number and type of CEs that qualify for 340B. For example, in one analysis almost 60% of contract pharmacies are located in an area with a higher median income than the affiliated hospital.

Manufacturers and covered entities are both subject to audits from HRSA to ensure program compliance. Importantly, manufacturers are not required to pay rebates under the Medicaid Drug Rebate Program on drugs purchased through the 340B program. In other words, CEs are prohibited from collecting duplicate discounts for drugs dispensed to Medicaid beneficiaries.

The responsibility of ensuring that drugs are not receiving duplicate discounts rests with state agencies. State Medicaid programs, whether administered through a fee-for-service payment model or managed care organization, must identify and choose which drugs will be covered under Medicaid and which will be covered under 340B. When drugs for a Medicaid patient are covered under 340B, CEs receive the discounted 340B price and the state cannot receive federal rebates. If a Medicaid beneficiary's drugs are not covered under 340B, CEs do not receive 340B discounts and the state can claim the rebate through Medicaid.

A 50-state Kaiser Family Foundation survey of Medicaid pharmacy directors revealed that avoiding duplicate discounts has been costly as well as administratively burdensome for some states. To help states avoid duplicate discounts, HRSA established the Medicaid Exclusion File that requires CEs to report which products will be included under 340B. Guidance from the Centers for Medicare & Medicaid Services also outlines seven strategies states might implement to circumvent duplicate discounts.

Even with these protections in place, some manufacturers have limited 340B discounts to some contract pharmacies to ensure duplicate discounts do not occur. As of June 2022, 17 pharmaceutical companies have put restriction policies in place.

State Actions

States have pursued a variety of activities to manage the 340B program. For example, at least 38 states use the Medicaid Exclusion File to avoid duplicate discounts. At least 10 states prohibit pharmacy benefit managers (PBMs) and other payers from denying 340B pricing to CEs or a contract pharmacy acting on their behalf.

Another strategy lawmakers may consider is to enforce 340B billing by monitoring provider network contracts. This approach would ensure 340B entities are billing state programs at 340B acquisition cost.

States may also leverage 340B discounts for state departments of correction by entering into agreements with 340B providers to administer certain high-cost medications (e.g. hepatitis C or HIV anti-virals) to their inmate populations. Texas was the first state to implement this type of partnership by arranging for individuals living in correctional facilities in the state's eastern region to see providers from the University of Texas Medical Branch. Several other states—including California, Connecticut, Georgia, Illinois, New Jersey, North Carolina, Virginia and Washington—also have partnerships between correctional facilities and 340B hospitals.

Federal Actions

In response to manufacturers restricting 340B discounts to contract pharmacies, the federal Department of Health and Human Services (HHS) issued an advisory opinion in December 2020 stating that drugmakers must honor 340B pricing to both CEs and contract pharmacies. HHS followed this by sending notifications to several manufacturers claiming they were in violation of the 340B statute and could face fines.

HHS withdrew the guidance but some manufacturers still challenged the violation notices in court. Three federal district courts have issued rulings. Courts in Indiana and New Jersey ruled in favor of HHS while findings in a Washington, D.C., court fell in favor of drugmakers. A fourth case in Delaware is still pending. HHS has appealed the D.C. district court decision and the case is still pending.

Additional Resources

- NCSL, 340B Drug Pricing Program and States
- Health Resources and Services Administration, 340B Drug Pricing Program
- Apexus, 340B Prime Vendor Program

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