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AN OVERVIEW OF THE FEDERAL 340B DRUG PRICING PROGRAM

The federal 340B Drug Pricing Program (Program) allows certain entities that serve low-income patients to receive discounted outpatient drugs from manufacturers that participate in Medicaid and Medicare. Manufacturers must sell covered drugs at Program prices for Medicaid to cover the drugs. The Program is intended to enable covered entities to use federal resources to improve accessibility and provide more comprehensive services, but federal statutes do not restrict how covered entities can use revenue from the Program.

Program Overview

Section 602 of the Veterans Health Care Act of 1992 added section 340B of the Public Health Service Act. Under the Program, entities receive a 20 to 50 percent discount on the average manufacturer price of outpatient prescription drugs.[1] The covered entities may generate revenue under the Program if patients' insurance reimbursements exceed the 340B price. According to the Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), which administers the Program, Program discounts enable covered entities "to stretch scarce federal resources as far as possible" and to fund safety-net care. According to the U.S. Government Accountability Office (GAO), the Program grew from about 9,700 covered entities in 2010 to about 12,700 in 2020.[2]

States cannot order "duplicate discounts" on prescription drugs, whereby states earn a rebate through the 340B Program and the Medicaid Drug Rebate Program.

Eligible Entities

Section 340B(a)(4) of the Public Health Service Act specifies the entities that are eligible to participate in the Program. Eligible entities include certain federal grantees (*e.g.,* family planning clinics or Ryan White HIV/AIDS Program entities), nonprofit hospitals that treat those who are medically underserved, and institutions owned by a state or local government. Entities are not allowed to divert drugs purchased at the Program price to an individual who is not a patient of the entity.

1 While manufacturers report drug price data to HRSA, ceiling prices are propriety and are not disclosed to covered entities.

2 A covered entity could have multiple sites of operation. According to the GAO, about 75 percent of the 37,500 covered entity sites in the Program are affiliated with hospitals.

About 20 percent of covered entities are hospitals, which include critical access hospitals, rural referral centers, sole community hospitals, children's hospitals, free-standing cancer hospitals, and disproportionate share hospitals (DSHs). DSH facilities are general acute care hospitals that serve a disproportionate number of low-income patients and automatically qualify for the 340B program annually if they provide enough inpatient services to Medicaid and low-income Medicare beneficiaries.[3] The remaining 80 percent of covered entities could be affiliated with a hospital or other federal grantee, such as a federally qualified health center (FQHC) or Ryan White HIV/AIDS Program grantee.

While the statute does not restrict how covered entities can use revenue generated by the Program and HRSA does not have the authority to track how revenue is used, a survey by a group representing safety-net hospitals showed that covered entities use the revenue to reduce patients' drug costs, provide uncompensated care, and maintain broader hospital operations, among other things.[4] HRSA's Bureau of Primary Health Care, however, requires a FQHC to use Program discounts for community benefits to fulfill grant requirements and remain a covered entity.

Some covered entities enter into agreements with non-affiliated retail pharmacies, known as contract pharmacies, to provide services to patients. These entities are not included in the federal 340B enacting statute. However, in 2001, HRSA created Alternative Methods Demonstration Projects (AMDP), which allow certain covered entities to contract with retail pharmacies. This allowed entities without in-house pharmacies to dispense medications under the Program. In 2010, HRSA expanded the program to allow covered entities to contract with multiple pharmacies without going through the AMDP process.

HHS Opinion on Contract Pharmacies

In July 2020, six pharmaceutical manufacturers announced they would stop selling drugs at the Program ceiling price to contract pharmacies.[5] In response to the companies' decision, the American Hospital Association sued the federal government for its failure to enforce Program price requirements.

On December 3, 2020, HHS issued Advisory Opinion 20-06, which stated, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." According to HRSA, any drug manufacturer that charges a covered entity more than the ceiling price may be subject to a fine. The manufacturer AstraZeneca sued HHS over the opinion, asserting the department did not have the statutory authority to issue the opinion. HHS filed a motion to dismiss the lawsuit, arguing the opinion expressed a standard federal rule. The U.S. District Court for the District of Delaware denied the motion.

In May 2021, HRSA sent letters to the six manufacturers stating the companies were violating federal law by restricting the covered entities' access to Program drug prices. The letters called on manufacturers to "immediately begin offering its covered outpatient drugs at the

3 In contrast, the 340B program covers only outpatient drugs.

4 Medicare Payment Advisory Commission, "Report to the Congress: Overview of the 340B Drug Pricing Program," May 2015.

5 The six manufacturers are AstraZeneca, Eli Lilly, Novartis, Novo Nordisk, Sanofi, and United Therapeutics.

340B ceiling prices to covered entities through their contract pharmacy arrangements." In response, Eli Lilly, one of the manufacturers that received a letter, asked the U.S. District Court for the Southern District of Indiana for a preliminary injunction to stop the federal government from imposing penalties.

On June 18, 2021, HHS withdrew the 2020 advisory opinion. HRSA, however, has not withdrawn the letters to the six manufacturers.

Kansas Legislative Action

At the December 9, 2020 meeting of the Robert G. (Bob) Bethell Joint Committee on Home and Community Based Services and KanCare Oversight, several conferees discussed concerns with the Program. A representative of the Community Care Network of Kansas stated that pharmacy benefit managers (PBMs) are attempting to secure contracts that treat health centers differently because they are 340B-covered entities and advocated for legislation that prevents such activity. PBMs manage prescription drug benefits for health insurers by negotiating with drug manufacturers and pharmacies.

2021 HB 2260 and SB 128, with nearly identical content as introduced, would prohibit disparate treatment by PBMs of certain pharmacies or pharmaceutical services providers based on those entities' 340B status. The bills would prohibit PBMs from setting disparate terms between 340B entities and other pharmacies or discriminating against a 340B entity. The bills also would include contract pharmacies in the definition of "340B covered entity."

Supreme Court Decisions

On December 10, 2020, the Supreme Court of the United States (Court) ruled in *Rutledge v. Pharmaceutical Care Management Association* that the federal Employee Retirement Income Security Act (ERISA) did not preempt an Arkansas law that requires PBMs to pay pharmacies the cost of acquiring prescription drugs. A 1974 law that established minimum standards for employee pension plans, ERISA traditionally preempts state laws that "relate to" employee health benefits. However, the Court ruled in 1995 that ERISA preemption did not apply to a New York law regulating hospital billing rates because the law had an "indirect economic influence" on employee health plans.[6] ***Rutledge*** expanded the Court's 1995 ruling to exempt from ERISA preemption state regulations of administrative contractors, namely PBMs. According to the Court, state regulation of intermediary contractors does not "directly regulate health benefit plans at all."

6 *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co*., 514 U.S. 645 (1995).