North Dakota Legislative Council

Prepared for the Health Care Committee
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PRESCRIPTION DRUG TRANSPARENCY REPORTING STUDY - BACKGROUND MEMORANDUM

INTRODUCTION

Section 1 of Senate Bill No. 2370 (2025) (appendix) directs the Legislative Management to study reporting requirements for covered entities in North Dakota which participate in the federal drug discount program under 42 U.S.C. § 256(b) and how reported data could be used to develop public policy that benefits patients in North Dakota. The study must include:

- Consideration of the various entities participating in the federal drug discount program which should be required to report data to this state, including health care facilities, contract pharmacies, federally qualified health centers, drug manufacturers, pharmacy benefits managers, and health insurers;
- Consideration of the specific data elements that each entity should be required to report;
- Exploration of methods of reporting, compiling, and sharing the compiled data which provide the greatest benefit to patients in North Dakota;
- Analysis of issues relating to the confidentiality and disclosure of the data; and
- Consideration of reporting enforcement mechanisms, including civil penalties for failing to report.

The study also must include input and consultation with a variety of stakeholders.

BACKGROUND

In 1992, Congress enacted section 340B of the Public Health Service Act, which created the federal 340B Drug Pricing Program. The program requires drug manufacturers participating in Medicare or Medicaid to offer outpatient drugs at discount prices to certain covered entities. *See* 42 U.S.C. § 256b; *see also* 42 CFR pt. 10. In 2010, through the Patient Protection and Affordable Care Act, Congress expanded the list of covered entities eligible to participate in the program and added provisions regarding compliance. Pub. L. No. 111-148, tit. VII. B, §§ 7101-02, 124 Stat. 119, 821-27. Covered entities include federally qualified health centers, tribal and urban Indian health centers, children's hospitals, critical access hospitals, rural referral centers, and other providers that care for rural and underserved populations. 42 U.S.C. § 256b(a)(4).

The 340B Drug Pricing Program is administered by the Health Resources and Services Administration (HRSA), a division of the United States Department of Health and Human Services (HHS). For fiscal year 2023, the HRSA estimated program sales constituted 7.2 percent of the United States drug market, and in 2020, the total reported 340B program sales were approximately $38 billion. The HRSA estimates covered entities save between 25 to 50 percent on the cost of covered outpatient drugs through the program.[1]

[1] United States Department of Health and Human Services, Health Resources and Services Administration, *Justification of Estimates for Appropriations Committee Fiscal Year 2023*.

340B DRUG PRICING PROGRAM REQUIREMENTS

Pricing

Section 340B requires a manufacturer to enter an agreement with the United States Secretary of HHS which prohibits the manufacturer from charging an amount in excess of the ceiling price for covered outpatient drugs purchased by a covered entity. 42 U.S.C. § 256b(a)(1). Section 340B provides each agreement "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id*.

The 340B ceiling price is the maximum statutory price a drug manufacturer may charge a covered entity for the purchase of a covered outpatient drug. The ceiling price is fixed by formula and is equal to the average manufacturer price from the preceding calendar quarter for the smallest unit of measure minus the unit rebate amount. *See* 42 U.S.C. § 256b(a)(2); *see also* 42 U.S.C. § 1396r-8(c); 42 CFR § 10.10. Manufacturers may not charge covered entities more than the ceiling price if they sell the drug to any other entity at any lower price. Covered entities may pass the drug discounts on to patients; however, federal law does not mandate covered entities to do so.

There are several requirements covered entities must meet to purchase drugs at 340B prices. Section 340B prohibits "diversion," which occurs when covered entities "resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). An individual is not considered a "patient" of the covered entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration of the drugs at home.[2] Additionally, Section 340B prohibits covered entities from receiving the program discount on drugs also subject to a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A)(i).

Compliance

Section 340B requires HRSA to ensure both covered entities and manufacturers comply with program requirements. *See* 42 U.S.C. § 256b(d). Federal law allows both HRSA and manufacturers to audit covered entities to ensure they meet the requirements for 340B pricing. *See* 42 U.S.C. § 256b(a)(5)(C). The covered entities must participate in the audit and maintain auditable records and inventories of all 340B and non-340B prescription drugs.[3] Audits may include review of compliance with eligibility requirements, duplicate discounts, diversion, and group purchasing prohibition requirements. The review also may include testing of drug transaction records. After completing an audit, the HRSA issues a final report and, if applicable, issues a request for a corrective action plan. If the covered entity disagrees with the findings, the entity has 30 days to provide appropriate supporting documentation. If an entity fails to submit a required corrective action plan, the entity is removed from the program.

Manufacturers also are subject to selective audits by HRSA. 42 U.S.C. § 256b(d)(1)(B)(v). These audits may include a review of eligibility status and compliance with ceiling prices. Manufacturers have the same process for responding to a final report and completing a corrective action plan as covered entities. However, HRSA posts public notices if a manufacturer is found in violation of program requirements and may require the manufacturer to identify all affected covered entities, contact each covered entity, and discuss a method for possible repayment.

Participants in the program who are noncompliant also may be subject to civil monetary penalties. 42 CFR § 10.10. Drug manufacturers and covered entities may be fined, and covered entities may be removed from the program or referred to other federal agencies for consideration of appropriate action under federal law. 42 U.S.C. § 256b(d)(1)(B)(vi), (d)(2)(B)(v)(I)–(III). Covered entities also must annually recertify their eligibility to participate and attest to complying with all program requirements.[4]

[2] *See* 72 Fed. Reg. 1543 (Jan. 12, 2007).
[3] *See* 80 Fed. Reg. 52300 (Aug. 28, 2015).
[4] 80 Fed. Reg. 52300 (Aug. 28, 2015).

The HRSA also promulgates regulations governing alternative dispute resolution proceedings with manufacturers and covered entities. Manufacturers and covered entities may use these proceedings to resolve disputes related to pricing overcharges and covered entity eligibility.

LITIGATION

Federal

In 2010, HHS issued new guidance expanding the number of pharmacies a covered entity may contract with to distribute 340B drugs to patients from one pharmacy to an unlimited number of pharmacies, provided the covered entity complies with federal guidance intended to prevent diversion and duplicate discounts.[5] After the issuance of this guidance, the number of contract pharmacies increased from approximately 1,300 in 2010, to 20,000 in 2017.[6]

In 2020, HHS released an advisory opinion requiring drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies.[7] The United States District Court for the District of Delaware held the advisory opinion was arbitrary, but while the court was considering what relief to afford, HHS withdrew the opinion.[8] *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58–62 (D. Del. 2021). During this period, HRSA sent violation letters to drug manufacturers directing them to honor all contract pharmacy relationships. Thereafter, several drug manufacturers filed lawsuits seeking vacatur of the enforcement letters, declaratory judgments, and injunctions. Both the Third Circuit Court of Appeals and the District of Columbia Circuit Court of Appeals found in favor of pharmaceutical manufacturers and determined federal law did not require manufacturers to deliver discounted drugs to unlimited numbers of pharmacies. *See Novartis Pharms. Corp. v. Johnson,* 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023).

State

Several states have enacted laws prohibiting manufacturers from placing conditions on covered entities' use of contract pharmacies. Arkansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, and West Virginia have been involved in litigation over their respective laws.[9]

In Arkansas, state law prohibits a manufacturer from limiting a covered entity's ability to contract with an outside pharmacy. After the law was enacted, pharmaceutical manufacturers brought suit, arguing the statute was pre-empted by federal law. *Pharmaceutical Research and Manufacturers of America v. McClain*, 95 F.4th 1136, 1141 (8th Cir.). In upholding the Arkansas state law, the Eighth Circuit Court of Appeals held that federal law does not pre-empt the state statute. The court found that covered entities retain legal title to the 340B drugs and reasoned that shipping the drugs to pharmacies does not extend discounted pricing to ineligible entities. Instead, the pharmacy acts as an agent of the covered entity in dispensing the drugs. *Id*. at 1142.

In 2025, the North Dakota Legislative Assembly passed House Bill No. 1473, codified as North Dakota Century Code Section 43-15.3-08(3), which makes it a Class B misdemeanor for a drug manufacturer or agent of a manufacturer to take certain actions that may interfere with a contract pharmacy's or covered entity's ability to access or dispense of a drug purchased by the covered entity under Section 340B. Pharmaceutical manufacturers recently filed a lawsuit against the state concerning this law. *See Astrazeneca Pharmaceuticals LP v. Wrigley*, 1:25-cv-00182 (D.N.D. Aug 01, 2025).

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[5] 75 Fed. Reg. 10272 (Mar. 5, 2010).

[6] United States Government Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement.*

[7] HHS Office of General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020).

[8] HHS Office of General Counsel, *Withdrawing Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (June 18, 2021).

[9] See Arkansas Code § 23-92-604(c); La. R.S. 40:2881-2886 ("Act 358"); Md. Code Health Occ. §§ 12-6C-09.1 through 12-6C-13; Minn. Stat. Ann. § 62J.96; Miss. Code Ann. §§ 41-149-1 through 41-149-11; Mo. Ann. Stat. § 376.414; and W. Va. Code Ann. § 60A-8-6a.

STUDY APPROACH

As provided in Section 1 of Senate Bill No. 2370, the study must include input from and consultation with the following stakeholders:

- Professional associations representing hospitals, pharmacies, federally qualified health centers, rural health, and pharmaceutical manufacturers;
- The Insurance and Securities Department;
- The Department of Health and Human Services;
- The North Dakota Board of Pharmacy;
- Hospitals participating in the federal drug discount program;
- Federally qualified health centers;
- Pharmacies that have contracts with covered entities participating in the program; and
- Health insurers.