Maryland

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# AbbVie Comments on the Board's 340B Program Study and Recommendations for Report Scope

**Fitzpatrick, Helen** <hfitzpatrick@abbvie.com> Mon, Jun 15, 2026 at 2:24 PM
To: "data.pdab@maryland.gov" <data.pdab@maryland.gov>
Cc: "Stone, Patrick" <patrick.stone@abbvie.com>

Good afternoon Dr. York,

Thank you for the opportunity to submit AbbVie's comments regarding the Board's study of the federal 340B Program. AbbVie recognizes that the 340B Program is an exclusively federal program, and that states do not have independent authority to regulate or investigate 340B Program compliance. Recent decisions in the 4th circuit have reinforced this preemption by ruling against the states of Maryland and West Virginia.

States do, however, retain plenary authority over their Medicaid programs — including claims adjudication, provider participation, and reimbursement policy. In that lane, Abbvie recently submitted the enclosed letter to Deputy Secretary Briskin regarding Medicaid program integrity and addressing the impact of the 340B program on Medicaid spending and rebates. We submit that as our comment letter and encourage the board to align the report with Medicaid department goals while acknowledging the states lack of an authority to regulate the program.

Additionally, AbbVie respectfully recommends that the Board's report reflect the following:

1. Assess the impact of 340B program growth on the state employee health plan and Medicaid, particularly through increased costs and the potential loss of manufacturer rebates.
2. Evaluate the impact of 340B program growth and spread pricing by the covered entities on private health plans, including the extent they are paying the full price/WAC for the drug while the covered entities keep the spread and what portion they are paying PBMs and their Third Party Administrators (TPAs).
3. Examine how nonprofit covered entities are using their 340B revenue, including the extent to which those funds are directed to patient care, charity care, and community benefit. The review should also assess whether any Maryland covered entities retain 340B-related revenue in offshore accounts and evaluate their overall levels of charity care and related financial assistance.
4. Examine the extent to which contract pharmacies have driven 340B program growth and better understand how much PBMs and their TPAs are retaining from 340B revenue. This recent Drug Channels analysis may be a useful resource on the scale of the contract pharmacy market. We also would suggest researching the work of Sayeh Nikpay, PhD (Member of the Minnesota Prescription Drug Affordability Board), given her research on how PBMs and TPAs continue to take a greater share in 340B revenue generated by covered entities.
5. Study whether financial incentives in the 340B program may encourage prescribing of higher-cost medicines, including in situations where lower-cost generics or biosimilars are available.
6. Review the recent Fourth Circuit decision in the Maryland case, as it may provide important legal context for the state's consideration of 340B contract pharmacy policy.

Thank you for your consideration of these recommendations. Please reach out to AbbVie if we can assist you in this matter.

Sincerely,

Helen Fitzpatrick

**HELEN KIM FITZPATRICK**

Vice President, State Government Affairs

abbvie

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[redacted]

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**2 attachments**

**AbbVie-v.-Brown-04.14.2026.pdf**
167K

**AbbVie_340B_SMD_Maryland.pdf**
95K

abbvie

May 28, 2026
Perrie T. Briskin
Deputy Secretary and Medicaid Director
Maryland Department of Health
201 W. Preston Street
Baltimore, MD 21201

**Strengthening Medicaid Program Integrity in Maryland — Addressing the Impact of 340B-Acquired Drug Claims on Medicaid Spending and Rebates**

Dear Perrie T. Briskin:

AbbVie writes to support Maryland's commitment to Medicaid program integrity. AbbVie recognizes that the 340B Program is an exclusively federal program, and that states do not have independent authority to regulate or investigate 340B Program compliance. States do, however, retain plenary authority over their Medicaid programs — including claims adjudication, provider participation, and reimbursement policy. This letter accordingly addresses the intersection of the 340B Program and Medicaid, and the impact that 340B acquisition dynamics have on Maryland's Medicaid spending and rebate revenue. As Maryland revalidates Medicaid providers as suggested by CMS Administrator Oz's April 23 letter, we encourage Maryland to examine how Medicaid claims involving drugs acquired through the 340B Program affect Medicaid spending and rebate revenue. CMS Administrator Oz's April 23 letter to all governors made clear that program dollars must serve the patients they were designed to reach. We believe that the same principle should apply to Medicaid claims where the intersection of the 340B Program and Medicaid can create misaligned incentives affecting prescribing and spending that are not fully captured in existing federal reporting.

AbbVie sees an opportunity for Maryland to strengthen its Medicaid program and ensure that every dollar invested in the safety net reaches the patients and communities it is intended to serve. Maryland may be forgoing Medicaid Drug Rebate Program (MDRP) rebates on a growing volume of 340B claims. These rebates would otherwise flow to the state under fee-for-service and managed care arrangements for any Medicaid 340B patient. Under federal law, states cannot collect MDRP rebates on drugs acquired at the 340B discount price. As 340B utilization by hospital covered entities has grown nationally, so has the volume of Medicaid claims which receive no rebate. AbbVie encourages Maryland to examine whether excluding 340B-acquired drugs from Medicaid reimbursement, effectively requiring covered entities to dispense non-340B units to Medicaid enrollees, would restore a meaningful source of rebate revenue to the state program. AbbVie's Maryland -specific data, detailed below, provides a starting point for estimating the magnitude of that foregone revenue.

**What AbbVie's Data Shows**

- **Rapid program growth from a single manufacturer perspective.** In 2025, AbbVie provided $85 million in 340B Program discounts to Maryland covered entities — a 22.2% increase over 2024.
- **Discounts are concentrated in large hospital settings rather than safety-net grantees.** 93.3% of AbbVie's discounts in Maryland went to hospitals; 6.7% went to grantee safety-net providers (FQHCs, Ryan White clinics).
- **Prescribing diverges from the broader market.** Since 2023, ten Humira biosimilars have entered the market. Some biosimilars are priced more than 85% off the branded list price and biosimilar uptake has accelerated rapidly in commercial and Medicare settings nationally. Hospitals and clinics participating in 340B have not consistently followed the same trajectory. Across therapeutic categories, 340B Program hospitals dispense approximately 23% fewer Humira biosimilars than non-340B hospitals.

The economic dynamics are driven, in large part, by 340B program mechanics. As is common for branded products, the spread between the deeply discounted 340B acquisition cost on branded Humira and the reimbursement collected from commercial payers, Medicare, or Medicaid managed care is substantially larger than the spread available on a biosimilar. Even though the biosimilar costs the patient and the payer meaningfully less, the 340B spread incentivizes the covered entity to use the branded product instead of the biosimilar, with the resulting margin being retained by the covered entity, rather than directly reducing costs for patients or payers at the point of sale.

**Reducing Medicaid Spending Inefficiencies Arising from Claims Involving 340B Acquired Drugs in Maryland**

To support alignment with Medicaid program integrity goals, we respectfully suggest that Maryland enhance its oversight of Medicaid claims involving 340B-acquired drugs. The data described above suggests that the intersection of the 340B Program and Medicaid may be contributing to higher drug costs and reduced rebate revenue for the state. The following measures, each grounded in Maryland's existing authority over Medicaid claims adjudication and provider participation, would help Maryland better understand and address these dynamics.

1. **Enhanced Medicaid claims transparency for 340B acquired drugs.** Require that, for any Medicaid claim involving a drug acquired at the 340B discount price, the submitting provider report the acquisition cost, the reimbursement received. Several states — including Minnesota, Maine, and Oregon — have enacted reporting frameworks addressing claims involving 340B-acquired drugs; Maryland can build on that precedent using its existing authority over Medicaid drug benefit claims and provider reporting.
2. **Medicaid provider audit and oversight for claims involving 340B acquired drugs.** Apply Maryland's existing Medicaid provider audit and termination authority to claims where a 340B-acquired drug is dispensed to a Medicaid beneficiary, with particular attention to duplicate discount avoidance, appropriate identification of 340B-acquired claims to prevent excessive loss of Medicaid rebates, and adequate documentation of the acquisition basis. While the 340B program is an exclusively federal program administered by HRSA, Maryland has independent authority over Medicaid claim adjudication, reimbursement policy, and a provider's continued Medicaid participation.

3. **Medicaid reimbursement policy for 340B-acquired drugs.** As a matter of Medicaid reimbursement policy, require covered entities to identify, at the point of claim submission, whether a drug dispensed to a Medicaid beneficiary was acquired at the 340B price. Where a 340B-acquired drug is billed to Medicaid, Maryland should deny reimbursement or require the covered entity to substitute a non-340B-acquired unit. This structural change would restore MDRP rebates on claims currently exempt from rebate liability under the duplicate discount prohibition and allow the rebate to flow directly to the state and federal governments.

AbbVie is prepared to share additional Maryland-specific data with your team and welcome the opportunity to discuss these considerations in greater detail. We would welcome the opportunity to engage at your convenience.

Thank you for your leadership and consideration.

Sincerely,

Patrick Stone
Director, State Government Affairs
AbbVie Inc.

**UNPUBLISHED**

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

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**No. 24-1939**

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ABBVIE, INC., (a Delaware corporation); ALLERGAN, INC., (a Delaware corporation); DURATA THERAPEUTICS, INC., (a Delaware corporation); ABBVIE PRODUCTS LLC, (a Georgia limited liability company); APTALIS PHARMA US, INC., (a Delaware corporation); PHARMACYCLICS LLC; ALLERGAN SALES, LLC, (a Delaware limited liability company),

Plaintiffs – Appellants,

and

NOVARTIS PHARMACEUTICALS CORPORATION; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

ANTHONY G. BROWN, in his official capacity as Attorney General of the State of Maryland; KRISTOPHER RUSINKO, in his official capacity as Board President of the Maryland Board of Pharmacy; DAPHANIE ROBINSON, in her official capacity as a member of the Maryland Board of Pharmacy; ADETORO ORIAIFO, in his official capacity as a member of the Maryland Board of Pharmacy; KRISTEN FINK, in her official capacity as a member of the Maryland Board of Pharmacy; KAREN SLAGLE, in her official capacity as a member of the Maryland Board of Pharmacy; BRENDA OLIVER, in her official capacity as a member of the Maryland Board of Pharmacy; KARLA EVANS, in her official capacity as a member of the Maryland Board of Pharmacy; JAVIER VAZQUEZ, in his official capacity as a member of the Maryland Board of Pharmacy; AKESH PATEL, in his official capacity as a member of the Maryland Board of Pharmacy; KEVIN MORGAN, in his official capacity as a member of the Maryland Board of Pharmacy; JENNIFER HARDESTY, in her official capacity as a member of the Maryland Board of Pharmacy; PEGGY GLASCOE GEIGHER, in her official capacity as a member of the Maryland Board of Pharmacy; NEIL LEIKACH, in his

official capacity as a member of the Maryland Board of Pharmacy; MARYLAND BOARD OF PHARMACY/PRESIDENT,

Defendants – Appellees.

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AMERICAN HOSPITAL ASSOCIATION; MARYLAND HOSPITAL ASSOCIATION; MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS; 340B HEALTH; AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS,

Amici Supporting Appellees.

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**No. 24-1949**

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NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff – Appellant,

and

ABBVIE, INC., (a Delaware corporation); ALLERGAN, INC., (a Delaware corporation); DURATA THERAPEUTICS, INC., (a Delaware corporation); ABBVIE PRODUCTS LLC, (a Georgia limited liability company); APTALIS PHARMA US, INC., (a Delaware corporation); PHARMACYCLICS LLC; ALLERGAN SALES, LLC, (a Delaware limited liability company); PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

ANTHONY G. BROWN, in his official capacity as Attorney General of the State of Maryland; KRISTOPHER RUSINKO, in his official capacity as Board President of the Maryland Board of Pharmacy; DAPHANIE ROBINSON, in her official capacity as a member of the Maryland Board of Pharmacy; ADETORO ORIAIFO, in his official capacity as a member of the Maryland Board of Pharmacy; KRISTEN FINK, in her official capacity as a member of the Maryland Board of Pharmacy; KAREN SLAGLE, in her official capacity as a member of the Maryland Board of

Pharmacy; BRENDA OLIVER, in her official capacity as a member of the Maryland Board of Pharmacy; KARLA EVANS, in her official capacity as a member of the Maryland Board of Pharmacy; JAVIER VAZQUEZ, in his official capacity as a member of the Maryland Board of Pharmacy; AKESH PATEL, in his official capacity as a member of the Maryland Board of Pharmacy; KEVIN MORGAN, in his official capacity as a member of the Maryland Board of Pharmacy; JENNIFER HARDESTY, in her official capacity as a member of the Maryland Board of Pharmacy; PEGGY GLASCOE GEIGHER, in her official capacity as a member of the Maryland Board of Pharmacy; NEIL LEIKACH, in his official capacity as a member of the Maryland Board of Pharmacy; MARYLAND BOARD OF PHARMACY/PRESIDENT,

Defendants – Appellees.

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AMERICAN HOSPITAL ASSOCIATION; MARYLAND HOSPITAL ASSOCIATION; MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS; 340B HEALTH; AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS,

Amici Supporting Appellees.

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**No. 24-1978**

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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff – Appellant,

and

ABBVIE, INC., (a Delaware corporation); ALLERGAN, INC., (a Delaware corporation); DURATA THERAPEUTICS, INC., (a Delaware corporation); ABBVIE PRODUCTS LLC, (a Georgia limited liability company); APTALIS PHARMA US, INC., (a Delaware corporation); PHARMACYCLICS LLC; ALLERGAN SALES, LLC, (a Delaware limited liability company); NOVARTIS PHARMACEUTICALS CORPORATION; ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs

v.

ANTHONY G. BROWN, in his official capacity as Attorney General of the State of Maryland; KRISTOPHER RUSINKO, in his official capacity as Board President of the Maryland Board of Pharmacy; DAPHANIE ROBINSON, in her official capacity as a member of the Maryland Board of Pharmacy; ADETORO ORIAIFO, in his official capacity as a member of the Maryland Board of Pharmacy; KRISTEN FINK, in her official capacity as a member of the Maryland Board of Pharmacy; KAREN SLAGLE, in her official capacity as a member of the Maryland Board of Pharmacy; BRENDA OLIVER, in her official capacity as a member of the Maryland Board of Pharmacy; KARLA EVANS, in her official capacity as a member of the Maryland Board of Pharmacy; JAVIER VAZQUEZ, in his official capacity as a member of the Maryland Board of Pharmacy; AKESH PATEL, in his official capacity as a member of the Maryland Board of Pharmacy; KEVIN MORGAN, in his official capacity as a member of the Maryland Board of Pharmacy; JENNIFER HARDESTY, in her official capacity as a member of the Maryland Board of Pharmacy; PEGGY GLASCOE GEIGHER, in her official capacity as a member of the Maryland Board of Pharmacy; NEIL LEIKACH, in his official capacity as a member of the Maryland Board of Pharmacy; MARYLAND BOARD OF PHARMACY/PRESIDENT,

Defendants – Appellees.

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AMERICAN HOSPITAL ASSOCIATION; MARYLAND HOSPITAL ASSOCIATION; MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS; 340B HEALTH; AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS,

Amici Supporting Appellees.

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Appeals from the United States District Court for the District of Maryland, at Baltimore. Matthew James Maddox, District Judge. (1:24-cv-01557-MJM)

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Argued: September 9, 2025 Decided: April 14, 2026

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Before RICHARDSON, RUSHING, and BENJAMIN, Circuit Judges.

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Vacated and remanded by unpublished opinion. Judge Richardson wrote the opinion, in which Judge Rushing joined. Judge Benjamin wrote a dissenting opinion.

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**ARGUED:** Matthew Scott Owen, KIRKLAND & ELLIS, LLP, Washington, D.C.; Philip J. Perry, LATHAM & WATKINS, LLP, Washington, D.C.; Jessica Lynn Ellsworth, HOGAN LOVELLS US LLP, Washington, D.C., for Appellants. Ryan Robert Dietrich, OFFICE OF THE ATTORNEY GENERAL OF MARYLAND, Baltimore, Maryland, for Appellees. **ON BRIEF:** Ashley C. Parrish, John D. Shakow, Washington, D.C., Nicole Bronniman, KING & SPALDING LLP, Houston, Texas; Meredith M. Pohl, Lucas H. Funk, KIRKLAND & ELLIS, Washington, D.C.; Timothy Maloney, JOSEPH GREENWALD LAAKE, Greenbelt, Maryland, for Appellants AbbVie, Inc.; Allergan, Inc.; Durata, Therapeutics, Inc.; AbbVie Products LLC; Aptalis Pharma US, Inc.; Pharmacyclics LLC; and Allergan Sales, LLC. Catherine E. Stetson, Susan M. Cook, Marlan Golden, HOGAN LOVELLS US LLP, Washington, D.C., for Appellant Novartis Pharmaceuticals Corporation. Andrew D. Prins, Abid R. Qureshi, LATHAM & WATKINS LLP, Washington, D.C., for Appellant Pharmaceutical Research and Manufacturers of America. Anthony G. Brown, Attorney General, Joshua R. Chazen, Assistant Attorney General, Howard R. Feldman, Assistant Attorney General, OFFICE OF THE ATTORNEY GENERAL OF MARYLAND, for Appellees. William B. Schultz, Margaret M. Dotzel, Alyssa Howard Card, ZUCKERMAN SPAEDER LLP, Washington, D.C., for Amici Curiae.

RICHARDSON, Circuit Judge:

In 2024, Maryland enacted H.B. 1056, which imposes restrictions on drug manufacturers participating in the federal 340B program.* Md. Code § 12-6C-09.1. Specifically, the Maryland statute prohibits a "340B manufacturer" from "directly or indirectly . . . limit[ing]" the distribution of "a 340B drug to" a "pharmacy that is under contract with . . . a covered entity," unless required by federal law or regulation. Md. Code § 12-6C-09.1(c)(1). The state law defines "340B manufacturer," "340B drug," and "covered entity" by reference to 42 U.S.C. § 256b, which establishes the 340B program. *Id.* § 12-6C-09.1(a). In short, H.B. 1056 imposes obligations on drug manufacturers solely by virtue of their participation in the federal 340B program and does not regulate manufacturers outside that program.

Plaintiffs—drug manufacturers and an industry trade association—sued to enjoin H.B. 1056's enforcement on several grounds, including that it was preempted by the federal statute. The district court found that the plaintiffs were unlikely to succeed on the merits and denied the preliminary injunction. This appeal followed.

Maryland was not the only state to pass a law that targeted 340B program participants. West Virginia passed a materially similar statute, *see* W. Va. Code § 60A-8-

* The 340B program is a spending-power bargain between Congress and drug manufacturers. *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, No. 25-1054, slip op. at 5 (4th Cir. March 31,2026) [*PhRMA*]; 42 U.S.C. § 256b. Manufacturers that "opt into" the 340B program must provide price discounts on drugs sold to specified health-care providers. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). In turn, these manufacturers gain access to payment under Medicaid for covered drugs. *Id.* at 114–15; *see also PhRMA*, slip op. at 7–8.

6a, which this Court recently held is likely preempted. *PhRMA*, slip op. at 30–31. We also held that the remaining injunction factors supported granting a preliminary injunction. *Id.* at 29; *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). In light of this Court's decision in *PhRMA*, we hold that the district court erred as a matter of law. *See United States v. Schooner Peggy*, 5 U.S. (1 Cranch) 103, 110 (1801); *Thorpe v. Housing Auth. of Durham*, 393 U.S. 268, 281–82 (1969). We leave it to the district court to determine in the first instance, applying the principles set forth in *PhRMA*, the propriety of preliminary relief.

Accordingly, we vacate the district court's order and remand for further proceedings consistent with *PhRMA*.

*VACATED AND REMANDED*

DEANDREA GIST BENJAMIN, Circuit Judge, dissenting:

When Congress established the 340B program, its "goal was simple: stretch scarce healthcare dollars and expand access to essential medications for vulnerable communities." *AbbVie, Inc. v. Murrill*, 166 F.4th 528, 534 (5th Cir. 2026). The 340B program requires drug manufacturers—as a condition of coverage of their products under Medicaid and Medicare Part B—to agree to offer certain drugs to covered entities that serve uninsured and low-income individuals at discounted prices. 42 U.S.C. § 256b. Many covered entities lack the resources to operate in-house pharmacies, so they partner with outside pharmacies to dispense the discounted drugs. In recent years, drug manufacturers have imposed restrictive policies that constrain covered entities' use of contract pharmacies. States around the country responded by enacting statutes to combat such policies and preserve access to necessary drugs for the people Congress sought to protect. Drug manufacturers, in turn, have mounted a wave of litigation contending that the 340B program preempts these state measures.

We heard oral argument on the constitutionality of two such state statutes: Maryland's H.B. 1056 and West Virginia's S.B. 325. Md. Code § 12-6C-09.1; W. Va. Code § 60A-8-6a. In the West Virginia case, the majority departed from the unanimous view of the circuit courts[1] and the overwhelming consensus view of the district courts[2] and held

[1] *AbbVie, Inc. v. Murrill*, 166 F.4th 528, 538–42 (5th Cir. 2026); *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 648 (5th Cir. 2025); *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024).

[2] Since my dissent in *Pharmaceutical Research & Manufacturers of America v. McCuskey*, No. 25-1054, 2026 WL 898259, at *16 nn.2–3 (4th Cir. Mar. 31, 2026)

that West Virginia's S.B. 325 is likely preempted by the 340B program. *See Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, No. 25-1054, 2026 WL 898259, at *8–12 (4th Cir. Mar. 31, 2026). There, I dissented because no binding or persuasive authority sets out or requires a

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(Benjamin, J., dissenting), I have identified additional relevant decisions. At least 11 district courts have refused to enter preliminary injunctions on comparable state statutes. *Pharm. Rsch. & Mfrs. of Am. v. Weiser*, 2026 WL 763970 (D. Colo. Mar. 18, 2026); *AstraZeneca Pharms. LP v. Lopez*, 2026 WL 497141 (D. Haw. Feb. 23, 2026); *Pharm. Rsch. & Mfrs. of Am. v. Frey*, 2026 WL 184504 (D. Me. Jan. 23, 2026); *Novartis Pharm. Corp. v. Frey*, 2025 WL 2813787 (D. Me. Sept. 23, 2025); *Astrazeneca Pharms. LP v. Weiser*, 2025 WL 3653161 (D. Colo. Dec. 17, 2025); *AbbVie, Inc. v. Weiser*, 811 F. Supp. 3d 1264 (D. Colo. 2025); *AbbVie Inc. v. Neronha*, 1:25-cv-00388-JJM-AEM (D.R.I. Sept. 30, 2025); *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657 (S.D. Miss. 2024); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. 2024); *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271 (M.D. Tenn. June 30, 2025); *AbbVie, Inc. v. Brown*, 1:24-cv-01557-MJM (D. Md. Sept. 10, 2024).

And at least five district courts have dismissed a drug manufacturer's preemption arguments on a motion to dismiss or motion for summary judgment. *Pharm. Rsch. and Mfrs. of Am. v. Skrmetti*, 2026 WL 803261, at *11–15 (M.D. Tenn. Mar. 23, 2026) (dismissing manufacturers' claim that Tennessee law was preempted); *AbbVie Inc. v. Skrmetti*, 2026 WL 542712, at *10–12 (M.D. Tenn. Feb. 26, 2026) (same); *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 645 F. Supp. 3d 890, 902 (E.D. Ark. 2022) (granting summary judgment for state on manufacturers' claim that Arkansas law was preempted), *aff'd*, 95 F.4th 1136 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768, (2024); *Astrazenca Pharms. LP v. Bailey*, 2025 WL 644285, at *3 (W.D. Mo. Feb. 27, 2025) (dismissing manufacturers' claim that Missouri law was preempted); *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, 2024 WL 4361597, at *8–9 (W.D. La. Sept. 30, 2024) (granting summary judgment for state on manufacturers' claim that Louisiana law was preempted).

So, that totals to 16 district courts that have rejected or dismissed a drug manufacturer's preemption arguments, compared to the two district courts that have found otherwise. *See Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439 (S.D. W. Va. 2024); *see also AbbVie, Inc. v. Drummond*, 2025 WL 3048929 (W.D. Okla. Oct. 31, 2025).

heightened preemption analysis for laws passed under the Spending Clause.[3] *See McCuskey*, 2026 WL 898259, at *21–24 (Benjamin, J., dissenting).

Because the majority vacated and remanded the district court's order consistent with its *McCuskey* decision, I dissent here for the same reasons I did in *McCuskey*. Maryland did not overstep its bounds by enacting H.B. 1056. I would have affirmed the district court's denial of a preliminary injunction.

[3] After we heard oral argument, it seems as if drug manufacturers have astutely taken note of the majority's interest in Congress' spending power and have begun advancing those arguments in their latest challenges to state delivery statutes. Yet two district courts (which, so far as I am aware, are the only two district courts to consider the argument) have already found the Spending Clause arguments unlikely to succeed. *See Weiser*, 2026 WL 763970, at *4; *see also Lopez*, 2026 WL 497141, at *14.

Maryland
Hospital Association

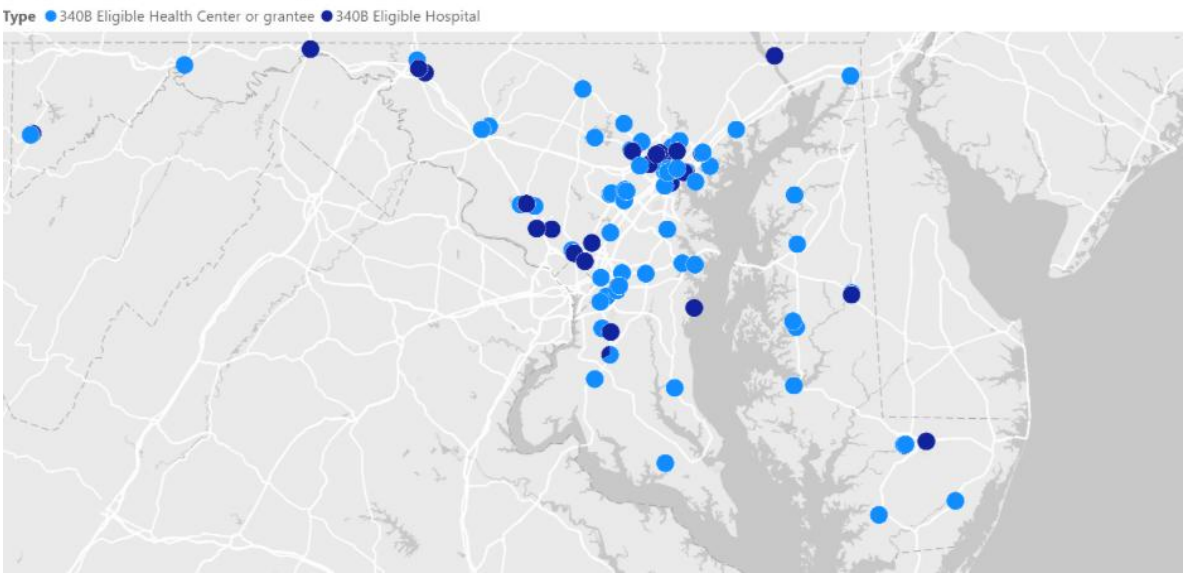
**June 15, 2026**

**Maryland Hospital Association Response to the Prescription Drug Affordability Board's 340B Drug Pricing Program Data Request**

The Maryland Hospital Association is pleased to respond to the Board's request for information about the 340B Drug Pricing Program on behalf of its member hospitals and health systems. Congressionally enacted in 1992, the federal statute requires drug manufacturers to sell covered outpatient drugs to qualified safety net hospitals and clinics at a discount as a condition of having their drugs covered under Medicaid.

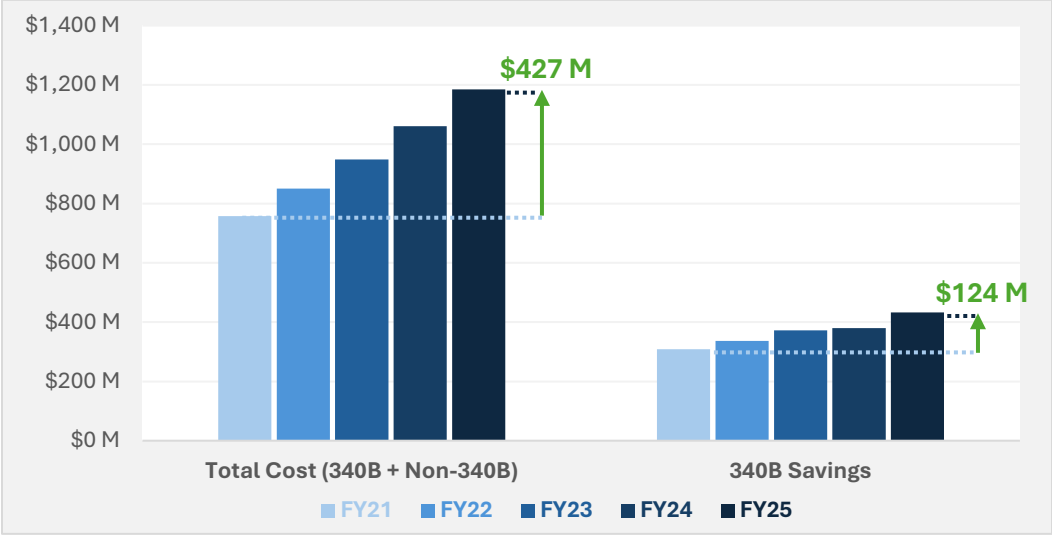
The program has stringent eligibility standards based on the complexity of the patients that covered entities serve. 340B-eligible hospitals must serve a disproportionately high percentage of low-income patients (Disproportionate Share Hospital, as defined in Section 1886(d)(1)(B) of the Social Security Act (Act)), specialize in pediatric care (Children's Hospital, as defined in Section 1886(d)(1)(B)(iii) of the Act), or be a rural hospital (Critical Access Hospital, as defined in Section 1820(c)(2) of the Act, or Rural Referral Center, as defined in Section 1886(d)(5)(C)(i) of the Act). Community health centers are also eligible for the 340B program (such as a Federally Qualified Health Center), providing care for underserved populations through such programs as the Ryan White HIV/AIDS clinics, hemophilia treatment centers, and others. Together, these 340B-eligible entities make up the health care safety net for Maryland's most vulnerable patients (see Figure 1). These programs expand access to critical care and generate incalculable savings for the State in avoidable health expenses due to preventive and supportive care provided by these entities at no cost to the taxpayers.

**Figure 1: 340B Covered Entities in Maryland**



Maryland 340B-eligible hospital margins are constrained by the unique all-payer rate-setting system in the State. The average annual margin of a 340B-eligible hospital in Maryland is about 2% to 3%. At the same time, Maryland hospitals face sharp increases in the cost of prescription drugs. Data from six hospitals across two Maryland hospital systems shows that total drug costs have grown substantially faster than 340B savings. In fact, 340B savings account for less than 30% of the overall drug spending, underscoring that these savings are critical to hospitals' ability to keep pace with rapidly rising drug costs (see Figure 2).

**Figure 2: Increases in Prescription Drug Costs Far Outpace Increases in 340B Savings**




Source: Pharmacy data submitted represents six Maryland hospitals

### 340B Growth Reflects Rising Health Care Costs

The growth in 340B savings largely reflects broader trends affecting hospitals and the health care system, nationwide and in Maryland. Rising patient complexity, increasing drug prices, and growing demand for prescription therapies have significantly increased hospital spending on pharmaceuticals. Because the 340B discount represents a proportionate discount of the average price of a drug, 340B savings naturally increase as the underlying cost of the drug increases. Growth in 340B savings should therefore be understood as a response to escalating drug costs

Increased medical complexity. Hospitals are caring for increasingly complex patients as the prevalence of chronic disease grows and Maryland's population ages. Hospitals also face rapidly rising costs for labor, supplies, equipment, and prescription drugs. Industry benchmark data from Strata Decision Technology, LLC, shows that hospital expenses increased 7.5% in 2025, more than twice the rate of hospital price growth (3.3%). Drug expenses rose even faster, increasing 13.6%, or more than four times higher than the growth in hospital prices. As a result, hospitals must deliver more resource-intensive care in an environment where the cost of providing care continues to outpace growth in hospital prices.

Increased drug costs. By leveraging access to discounted outpatient drugs through the 340B program, covered entities are better able to defray the double-digit inflation rates and rapidly rising cost of drugs each year. The growth in hospital drug expenses reflects rising costs of medications and adoption of newer, expensive therapies like oncology and other specialty drugs.

Academic medical centers, in particular, depend on some of the most expensive drugs to treat some of the most complex patients. Price increases have been above general inflation for hundreds of drugs. A recent report found that drug prices increased for nearly 900 drugs in just the first two weeks of 2026.[1] Additionally, the median annual list price for new drugs, including those that treat conditions like hemophilia, cancer, muscular dystrophy, and rare diseases increased 23% from 2023 to 2024. Hospitals absorb these increases while managing drug supply chain instability and maintaining high quality patient care.

Increased demand for drugs. Demand for drugs is also increasing dramatically as new drug therapies more frequently replace surgery and other clinical interventions. For example, new chemotherapies are taking the place of cancer surgeries. GLP-1 drugs are increasingly taking the place of other medical interventions to treat obesity and obesity-related chronic conditions and demonstrate the compounded impact of rising demand and drug costs. GLP-1 utilization increased by 700% from 2019 to 2024. During the same period, GLP-1 prices grew approximately 4% to 5% annually. The combined impact is a 500% increase in spending on GLP-1 drugs.

Growth in the 340B program has been driven by broader health system trends described above, including rising drug prices, increased demand, and increasing use of specialty medications, all of which contribute to massive increases to pharmaceutical manufacturer bottom lines.

**Hospitals Reinvest 340B Savings**

The Maryland Hospital Association (MHA) collected FY 2025 data requested by PDAB from 16 hospitals, and 2 affiliated on-campus 340B-eligible clinics which reported a combined $607 million in 340B savings. Table 1 provides total 340B savings estimates by requested categories.

[1] Pharma Companies Raise List Prices, Including 16 That Had Agreements to Lower Prices with Trump Administration: Report, PharmExec (Jan. 19, 2026), https://www.pharmexec.com/view/companies-raise-list-prices-16-agreements-lower-prices-trump-administration-report ("According to a new analysis from 46brooklyn, drug companies have hiked up the price of 872 different name brand medications, ranging from covid vaccine shots, treatments for cancer, Type 2 diabetes, cardiovascular disease, and more[2] over the first two weeks of 2026." (citing Brand Drug list Price Change Box Score, 46brooklyn Research, https://www.46brooklyn.com/branddrug-boxscore).

**Table 1: Prescription Drug Affordability Board Data Request**

| 340B Categories | Total Savings FY2025 |
|---|---|
| Mixed Use | $245M |
| Retail-Owned/In-House | $261M |
| Contract Pharmacies (Internal and External) | $101 M |
| **Total 340B Savings** | **$607M** |

Hospitals use these 340B savings to support community programs and services that address local health needs and improve access to care.

In addition to helping offset the costs of caring for underserved patients, the 340B Drug Pricing Program provides eligible hospitals with the flexibility needed to invest in tailored solutions that address the unique needs of their communities. If the program were eliminated or scaled back, many safety net hospitals would struggle to maintain long-standing vital community partnerships and services that patients rely on.

Hospitals use 340B savings to support a wide range of services that address barriers to care and improve health outcomes. Examples include home visits and transportation assistance, diabetes management and smoking cessation programs, housing initiatives, and services for individuals experiencing homelessness. Hospitals also use 340B savings to maintain outpatient specialty clinics, expand behavioral health services, and provide preventative services such as free health screenings. These investments directly support early intervention, improve continuity of care, and prevent avoidable hospitalizations and emergency department visits.

**Increased Administrative Burden**

Hospitals also face increasing administrative costs due to manufacturer policies that require 340B covered entities to spend considerable time and resources on procurement, compliance, and financial analysis. These policies often require hospitals to navigate multiple manufacturer-specific platforms, manually submit claims and invoice documentation, reconcile rebate and purchasing discrepancies, and continuously monitor evolving contract pharmacy restrictions and eligibility requirements. As a result, hospitals must maintain complex internal tracking processes, audit-ready documentation, and ongoing financial analyses to support compliance and validate 340B eligibility determinations. The lack of standardized processes across manufacturers creates operational inefficiencies, increases the risk of payment disputes and compliance exposure, and requires hospitals to invest additional personnel and technology resources simply to maintain access to 340B savings and preserve program integrity.

| Cost Category | Examples / Responsibilities |
|---|---|
| **Program Stewardship, Compliance & Governance** | • Annual external audits and internal corrective action oversight<br>• Continuous regulatory monitoring and audit readiness activities<br>• Diversion prevention and duplicate discount oversight<br>• Duplicate discount prevention monitoring and claims reconciliation (Medicaid fee-for-service (FFS), managed Medicaid, and multi-payer claims)<br>• Diversion monitoring and compliance investigations, including eligibility validation, provider relationship review, encounter qualification analysis, prescription review, corrective actions, and auditing<br>• Contract pharmacy oversight, replenishment review, claims auditing, reversal/rebill review, and diversion risk investigations<br>• Multidisciplinary compliance review involving pharmacy operations, split-billing oversight, compliance, revenue cycle, finance, legal, and IT<br>• Internal and external reporting requirements (Health Resources and Services Administration, HSCRC, manufacturers, state reporting, etc.)<br>• Subscription platforms and industry resources<br>• Stakeholder coordination across pharmacy, compliance, finance, legal, supply chain, and clinical operations |
| **Operations & Clinical Support** | • Program management staffing<br>• Policy and procedure development and maintenance<br>• Patient care and clinical resources associated with medication dispensing and management<br>• Contract pharmacy administration and dispensing fees<br>• Eligibility review, manual claim validation, and exception management<br>• Provider, pharmacy, and clinic education<br>• Annual conferences, continuing education, and regulatory training |
| **Supply Chain & Inventory Management** | • Inventory, accumulator, and split-billing management<br>• PHS account, wholesaler, and supplier account management |

| | |
|---|---|
| | • Purchasing reconciliation and replenishment oversight<br>• NDC crosswalk maintenance and data mapping activities<br>• Ongoing inventory monitoring and discrepancy resolution |
| **Finance & Revenue Integrity** | • Duplicate discount, rebate, and Inflation Reduction Act (IRA) eligibility reconciliation<br>• Medicaid FFS claim monitoring and duplicate discount prevention activities, including carve-in/carve-out oversight, BIN/PCN maintenance, claims reconciliation, reversal/rebill review, and payer analysis<br>• IRA rebate reconciliation, validation, dispute management, and appeals<br>• Good Faith Inquiry (GFI) review, supporting documentation preparation, disputed claim investigation, audit trail development, and manufacturer response coordination<br>• Revenue cycle management (RCM) and billing modifier oversight<br>• Financial analytics, savings analysis, and reimbursement review<br>• Accounting, reporting, payment reconciliation, and manufacturer rebate tracking |
| **Legal & Contract Administration** | • Contract pharmacy and vendor contract management<br>• Regulatory review and legal analysis<br>• Manufacturer policy review and compliance guidance |
| **Technology & Data Infrastructure** | • Third-Party Administrator (TPA) software and system support<br>• Manufacturer-specific reporting and claims submission platforms (340B ESP, Beacon, Truzo, CMS Medicare Transaction Facilitator, etc.)<br>• Automated reversal/rebill monitoring and duplicate discount detection tools<br>• Claims-level audit trail preservation, compliance reporting, and audit-support infrastructure<br>• Data integrations between TPAs, wholesalers, EHRs, billing systems, and manufacturers<br>• SQL databases, dashboards, automation tools, reporting systems, analytics infrastructure, audit documentation systems, and data retention platforms |

Maryland
Hospital Association

**Why Maryland Enacted Contract Pharmacy Protections**

Beginning in 2020, some drug manufacturers imposed restrictions on sales to 340B covered entities that utilize contract pharmacy arrangements. These actions threatened patient access to prescription medications and undermined a key mechanism through which hospitals and other covered entities serve their communities.

In response, Maryland lawmakers passed House Bill (HB) 1056, which took effect in 2024 and is codified at Md. Code, Health Occupations § 12-6C-09.1. Like 21 other states, Maryland acted to protect access to prescription drugs for low-income, uninsured, and underinsured patients by prohibiting manufacturers from restricting the acquisition or delivery of 340B drugs through authorized contract pharmacy arrangements.

Contract pharmacy arrangements allow 340B covered entities to partner with local and specialty pharmacies so that 340B covered entity patients can obtain needed prescriptions close to home, or can access specialty medications used to treat chronic, serious, or life-threatening conditions, improving medication adherence and health outcomes.

This is especially important for working families, seniors, and patients facing transportation barriers, who may not be able to travel to a qualifying hospital. As one witness testified: "It is not feasible to expect patients to go to one particular pharmacy to access affordable medications—not the busy new mom being treated for postpartum depression or the diabetes patient who needs insulin. When essential medications are not accessible and affordable, patients suffer."

Under Maryland law, drug manufacturers are subject to specified enforcement actions and penalties under the Maryland Consumer Protection Act (MCPA), including a civil fine of up to $5,000 per violation, if drug manufacturers "directly or indirectly deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with or otherwise authorized by a covered entity to receive 340B drugs on behalf of the covered entity."

Unfortunately, today, at least 12 drug manufacturers are imposing some form of 340B contract pharmacy restrictions in our state.[2] Without the protections of HB 1056, drug manufacturers could impose additional discriminatory practices that may further restrict access to care and strain covered entities, threatening the loss of vital services. That view still stands. If struck down, drug manufacturers' restrictive policies would undermine the very goals the 340B

[2] As of June 10, 2026, the following drug manufacturers are still preventing access to 340B pricing for contract pharmacies located in Maryland: AstraZeneca, Boehringer Ingelheim, EMD Serono, Exelixis, Incyte Corp., Jazz Pharmaceuticals, Karyopharm Therapeutics, Mallinckrodt Pharmaceuticals, Merck, Inc., Novo Nordisk, Pfizer, and United Therapeutics.

program was designed to protect and could limit Marylanders' access to affordable, high-quality health care.

**The Impact of 340B Funds on Community and Care Investments**

The following responses were submitted by Maryland hospitals describing how 340B savings support patient care, community programs, workforce investments, and access to services.

**Hospital 1: "**As a multi-jurisdictional, nonprofit covered entity serving the broader DMV region, we are deeply invested in our expanding presence across Maryland, where we continue to increase access to care for Maryland residents."

Key investments supported by 340B savings include:

- Established 25 clinics across Maryland, spanning primary care and specialized services
- Employ over 5,000 Maryland residents across hospital and clinic locations
- Partner with the state of Maryland to support care delivery in schools and community settings

The hospital noted that increasing manufacturer audits, "good faith inquiries," rebate model proposals, and other pressures on the 340B program threaten its ability to sustain and expand these investments and services for vulnerable populations in Maryland.

**Hospital 2:** The hospital reported that growing administrative burdens and changes to the 340B program would reduce its ability to reinvest savings into patient care and community support services.

Potential impacts identified by the hospital include:

- Reduced funding for patient support services and hospital-based care programs
- Impacts to pharmacy staffing, discharge medication assistance, and infusion center operations
- Reduced financial support for case management, social work, and other patient assistance programs
- Potential reductions in community services, forcing patients to travel farther or experience gaps in care
- Challenges maintaining access to specialty medications and services for patients with HIV, cancer, and immunocompromising conditions due to high drug acquisition costs and reimbursement uncertainty

**Hospital 3:** The hospital reported using 340B savings to support affordable medications, patient assistance programs, transitional care, transportation, behavioral health coordination, housing support, workforce development, and maternal wellness initiatives.

The hospital has participated in the 340B program since 2016 and has used savings to expand services, including:

- Lyft transportation programs
- Peer recovery programs
- Social determinants of health screenings
- Congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and oncology clinics

The hospital also described significant health and socioeconomic challenges within its service area, including limited access to primary care, high rates of chronic illness, behavioral health conditions, and substance use disorders.

One example shared by the hospital involved a patient recovering from a leg amputation who faced barriers accessing rehabilitation services. Through the hospital's transportation support program, the patient was able to complete therapy, receive a prosthesis, return to work, and regain independence.

**Conclusion**

The 340B program plays a critical role in expanding access to care for vulnerable patients across Maryland. Although administering the program requires significant resources, its benefits to patients and the communities hospitals serve far outweigh those costs. As prescription drug acquisition costs have risen dramatically, the 340B program has enabled hospitals to offset a modest share of those increases and reinvest the savings in community-based clinical care. MHA appreciates PDAB's engagement on this issue and supports its efforts to preserve the integrity and long-term sustainability of this vital program.

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