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August 28, 2026

The Honorable Bill Cassidy
United States Senator
Chair, Committee on Health, Education, Labor, and Pensions

Dear Chairman Cassidy,

The Academy of Managed Care Pharmacy (AMCP) thanks you for the opportunity to provide comments in response to the 340B Drug Pricing Integrity and Affordability for Patients Act (340B for Patients Act) discussion draft.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 300 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.[1]

Congress created the 340B Drug Pricing Program in 1992 to help hospitals and clinics treating large numbers of underserved patients stretch scarce federal dollars and offer more comprehensive care. Under the program, drug manufacturers participating in Medicaid are required to sell outpatient drugs to eligible healthcare organizations at steep discounts. Qualifying providers buy outpatient prescription drugs at steep discounts and bill at their normal rate.[2] These savings would, in theory, get reinvested in patient services—expanded pharmacy operations, specialty clinics, and community health programs. Many rural hospitals and community health centers depend on 340B margin as a lifeline to maintain operations and expand services in medically underserved areas where other healthcare options are scarce.

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[1] Academy of Managed Care Pharmacy. *About AMCP.* Available at https://www.amcp.org/about,
[2] Mulligan, K. The 340B drug pricing program: Background, ongoing challenges and recent developments (Oct. 14, 2021). Available at: https://schaeffer.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/.

The 340B program has evolved into the second-largest federal drug pricing program in the United States. Changes in federal policy and drug market dynamics have contributed to the program's rapid growth over the past two decades. Prescription drugs are the fastest-growing component of health care spending in the US, driven by increased prices for and utilization of specialty drugs.[3] However, the 340B program is growing much faster than drug prices and may even inflate drug prices. In 2010, Congress expanded eligibility to include a broader set of hospitals, while HRSA removed restrictions on the number of pharmacies that covered entities may use to dispense 340B drugs to their patients. The number of entities participating in the program has grown by over 600%, driven largely by increased participation by pharmacies and child sites.[4] Recent court rulings have forced the Health Resources and Services Administration (HRSA), the agency that oversees the 340B program, to roll back guardrails on patient eligibility and covered entities' use of contract pharmacies and child sites. According to HRSA data, discounted purchases grew by 23% in 2025, to over $100 billion.[5] Estimated net revenue for covered entities has ballooned to nearly $80 billion, with larger hospitals claiming more than 80% of all discounts.[6] Covered entities are not required to report how they allocate net 340B revenue, which raises doubts about whether the 340B program's mission is achieved. Meanwhile, mandatory discounts raise drug prices and out-of-pocket costs for consumers, employers, and state Medicaid programs.[7,8]

Our members represent stakeholders on all sides of the 340B program, including healthcare payers, Medicaid pharmacy directors, and safety net provider networks. AMCP believes that Congress should make evidence-based improvements to the 340B program that enhance transparency and accountability while protecting access for patients who depend on safety-net healthcare services. AMCP supports many of the proposals in the

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[3] Niu S, Happe LE, Abuloha S, Svensson M. Concentration of spending and share of specialty drug spending in Medicare Part D over a 10-year period. J Manag Care Spec Pharm. 2024 Dec;30(12):1355-1363. Available at: https://doi.org/10.18553/jmcp.2024.30.12.1355..

[4] Halleman, S. (Jul. 16, 2026). 340B spending ballooned to $100B in 2025, federal data shows. Healthcare Dive. Available at: https://www.healthcaredive.com/news/340b-spending-ballooned-100-billion-2025-federal-data-shows/825395/.

[5] Health Resources & Services Administration. 2025 340B covered entity purchases. (2026). Available at: https://www.hrsa.gov/opa/updates/2025-340b-covered-entity-purchases.

[6] Fein, A. (Jul. 15, 2026). The 340B program hit $100 billion in 2025: Has it become too big to reform? Drug Channels Institute. Available at: https://www.drugchannels.net/2026/07/the-340b-program-hit-100-billion-in.html.

[7] Masia, N., Motyka, J., Westrich, K., and Campbell, J. (May 2025). The 340B drug purchasing program and commercial insurance premiums. Health Capital Group. Available at: https://www.healthcapitalgroup.com/340b-state-insurance-premiums.

[8] Sun, C., Zeng, S., and Martin, R. (2025). The cost of 340B to states. IQVIA. Available at: https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-to-states.

340B for Patients Act, including establishing a reasonable patient definition, improving transparency, enhancing oversight of child sites and contract pharmacy arrangements, and promoting patient affordability.

Rebate Conditions

AMCP supports the proposal to establish standardized claims data that covered entities must submit to claim discounts or rebates. This data will help prevent duplication or diversion of discounts by covered entities, state Medicaid programs, and manufacturers with drugs selected under the Medicare Drug Price Negotiation Program. See the Preventing Duplicate Discounts and National Clearinghouse sections for additional considerations on this topic. AMCP is concerned that allowing participating manufacturers to adopt a rebate model may impose a financial burden on smaller covered entities that rely on 340B discounts to fund vital services. AMCP urges Sen. Cassidy to limit this provision to hospital covered entities with high net patient revenue—or delay implementation for non-hospital covered entities—to ensure that lower-resourced entities do not bear the cost of operationalizing this new system.

Patient Definition

AMCP believes that Congress must adopt safeguards to ensure that 340B covered entities only receive discounts for drugs dispensed to eligible patients. We support the patient definition established under Section 4 of the 340B for Patients Act, which establishes that eligible patients must have 1) received an outpatient health care service at the covered entity within the past 2 years, 2) maintain auditable medical records that demonstrate an ongoing patient relationship, and 3) receive the prescription or order for the covered outpatient drug (COD) from a practitioner as a result of an outpatient health care service or referral.

AMCP suggests two changes to strengthen the patient definition offered in the 340B for Patients Act. First, the bill should define the term "referral" as used in Section 340B(b)(3)(iii). AMCP believes that referral capture should be limited to care coordination activities where a patient is referred by their primary care provider to receive medical services not offered by the covered entity. The covered entity should remain responsible for the individual's overall care and maintain records of the referral and any services provided or diagnoses made by the referred specialist. Second, the bill should clarify the role of telemedicine in establishing an ongoing patient relationship. AMCP believes that covered entities should be able to claim 340B discounts on drugs dispensed in connection with outpatient health care

services provided in-person or virtually. However, televisits should not be the sole basis for establishing a patient relationship.

Contract Pharmacies

AMCP agrees with the crux of the bill's contract pharmacy provisions—namely, increasing oversight of such arrangements to ensure that covered entities receive discounts only for eligible patients and ensuring that contract pharmacies comply with standards that apply to covered entities. AMCP also supports the standards for contract pharmacy and third-party administrator remuneration.

AMCP believes that establishing a workable patient definition and improving oversight of contract pharmacy arrangements may address many stakeholders' concerns regarding overexpansion of the program. Other restrictions on the use of contract pharmacies—limiting them to the covered entity's service area, limiting hospital covered entities to 5 pharmacy agreements, and restricting the use of mail order—are reasonable but may not be necessary if other reforms proposed in the discussion draft are implemented. AMCP appreciates that these restrictions are progressive, but stresses that imposing overlapping reporting requirements and restrictions on covered entities may increase program administration costs and undermine the core goal of reinvesting savings from drug discounts to improve care for low-income communities.

If the limits on contract pharmacy agreements involving mail-order pharmacies remain in the bill, AMCP suggests that the bill adopt an alternative measure to determine which communities face limited access to pharmacies. The Metropolitan Statistical Area measure should not be used to determine certain hospital covered entities' ability to use mail-order pharmacies to reach patients. The Metropolitan Statistical Area measure does not factor in pharmacy distance or density. In 2022, Congress found that, "[c]ore-based statistical area delineations…are not intended for any public or private sector non-statistical uses such as program administration or service delivery."[9] AMCP encourages Congress to consider measures that more accurately identify communities that face difficulty accessing health care services, particularly pharmacy services. Congress established a definition of "essential retail pharmacy" (ERP) in the Consolidated Appropriations Act of 2026. Under the law, ERPs are defined as unaffiliated pharmacies located in a rural area with no other retail pharmacy within 10 miles, a suburban area with no other pharmacy within 2 miles, or an urban area

[9] Metropolitan Areas Protection and Standardization (MAPS) Act of 2021 (P.L. 117-219), Sec. 2(2). Available at: https://www.congress.gov/bill/117th-congress/senate-bill/1941/text.

with no other pharmacy within 1 mile.[10] This section could be further tailored to target rural communities with pharmacy access challenges by limiting mail-order contract pharmacy arrangements to areas with rural ERPs. While the ERP measure is not perfect, as it only considers distance and ignores other factors that contribute to lack of pharmacy access, ERP is a better fit to deliver services to communities in pharmacy deserts.[11]

Covered Entity Transparency

AMCP supports the disclosure requirements included in Section 6 of the 340B for Patients Act. AMCP seeks clarity on certain components of the transparency provisions in Section 6. AMCP supports requiring Disproportionate Share Hospitals (DSHs), and other entities as determined by the Secretary, to report information on the margin generated from CODs. This provision will promote greater understanding of the value of 340B discounts to hospitals that make up the lion's share of discounted purchases under the program. The bill adjusts the level of detail required for disclosure based on annual net patient revenue, ensuring that smaller entities do not face excessive burdens. However, the bill limits reporting on charity care activities to DSHs with annual net patient revenue exceeding $1 billion. Hospital covered entities have drawn scrutiny for providing less charity care than their peers that do not participate in the 340B program.[12] Given that expanding community benefit was a core motivator of the 340B program, AMCP believes that the charity care disclosure requirement should be applied to a larger set of hospital covered entities. The bill should also clarify that entities should report charity care based on actual costs, rather than the hospital's usual and customary prices, to reflect the true value of services rendered.

Another component of the 340B for Patients Act transparency framework that warrants attention is the reports on categories of expenditures. This provision will enable HHS and the public to better understand how covered entities invest 340B margin to offer comprehensive health care services to the communities they serve. However, the reporting on expenditure categories is limited to non-hospital covered entities with net patient revenue over $200 million. AMCP believes the bill should apply to all covered entities with net patient revenue exceeding $200 million, including DSHs and other hospital categories.

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[10] Consolidated Appropriations Act of 2026 (P.L. 119-75), Sec. 6223(b)(2). Available at: https://www.congress.gov/bill/119th-congress/house-bill/7148/text#yb3c7f97b-6fca-11f1-9f1f-75bc427816d3-intro-1.

[11] Gravlee, E., Ramachandran, S., and Qato, D. (Dec. 19, 2025). Critical access pharmacy designations could strengthen access. Health Affairs Forefront. Available at: https://www.healthaffairs.org/do/10.1377/forefront.20251216.325474.

[12] Popovian, R., Sydor, A., Czubaruk, K., Walker, M., and Smith, W. (Feb. 17, 2026). Financial outcomes and community benefit in the 340B program: Comparing 340B and non-340B hospitals. MedRxiv. Available at: https://doi.org/10.64898/2026.02.12.26346191.

Ensuring Affordability

AMCP supports expanding the financial assistance that 340B covered entities must provide to their patients. However, the sliding fee scale could create operational challenges, particularly for contract pharmacies and federally qualified health centers. Unlike a hospital, patients don't fill out intake forms before having their prescriptions filled at a pharmacy. Contract pharmacies would have to establish new systems to verify whether a patient is eligible, including patient-submitted information about their household income. The bill should specify that covered entities must communicate whether patients qualify for assistance, or direct HHS to develop standards for how contract pharmacies may comply with this section. Health centers are already required to implement patient assistance programs under the terms of their applicable grants. While the bill simply requires these entities to comply with the terms of their grants, AMCP stresses that the bill should be tailored to not place additional burdens on safety net providers. For instance, the bill could reduce or remove monetary penalties for non-hospital entities that violate this section, provided they implement a corrective action plan approved by HRSA.

The patient assistance program described here could raise premiums, particularly high-deductible health plans where patients typically have larger out-of-pocket obligations. Under the bill, covered entities are required to make up the difference between an applicable patient's out-of-pocket obligation and the amount owed under the sliding fee scale. Covered entities will likely respond by increasing the billed amount for CODs to maintain the same margin after accounting for payments made under the assistance program. To prevent inflating insurance premiums, the bill should limit patient assistance to patients without health coverage.

Preventing Duplicate Discounts

The 340B statute prevents manufacturers from paying duplicate discounts on a COD. Covered entities are required to have mechanisms in place to prevent duplicate discounts. HRSA requires covered entities to disclose whether they will use 340B drugs for their Medicaid fee-for-service patients (carve-in) or purchase drugs for those patients through other mechanisms (carve-out), and this information is reported in the Medicaid Exclusion File. There remains significant ambiguity about who is responsible for preventing duplicate discounts under managed Medicaid. In 2024, CMS finalized a rule requiring Medicaid MCOs to use unique, Medicaid-specific codes and group numbers on beneficiary insurance cards, which was intended to make it easier to identify Medicaid MCO claims and enable stakeholders to develop systems to include (or exclude) such claims as 340B drugs. The

rule does not dictate how states, Medicaid MCOs, or covered entities should use the information. There remains significant variation across states in their requirements for MCOs and covered entities, undermining the integrity of both the 340B program and the Medicaid Drug Rebate Program.

AMCP believes that Congress must establish a sustainable solution that enables covered entities to comply with their statutory obligations and reduces uncertainty for participating manufacturers, state Medicaid programs, and their MCO partners. Congress should build on prior reforms to increase transparency into pharmacy-level data that can identify Medicaid MCO and 340B claims. Covered entities, as well as their child sites and contract pharmacies, should be required to use existing National Council for Prescription Drug Program (NCPDP) data elements to identify 340B drugs.[13] HRSA should direct 340B entities to use 340B claims identifiers, and work with NCPDP to include these data elements in the SCRIPT standards for electronic prescribing. Identifying 340B drugs at the point of sale would facilitate the exclusion of CODs purchased under the 340B program, avoiding costly disputes between states and participating manufacturers.

National Clearinghouse

Federal drug pricing programs, including the Medicare Drug Price Negotiation Program, Medicare Inflationary Rebate Program, and the Medicaid Drug Rebate Program, exempt 340B purchases from the discounts manufacturers owe to public payers. The lack of claims-level transparency and uncertainty around which patients are eligible for 340B discounts creates confusion for payers, pharmacy benefit managers, community pharmacies, and manufacturers. These stakeholders have responded by establishing additional validation requirements before supplying or reimbursing 340B drugs, increasing administrative complexity for covered entities. Implementing AMCP's recommendation to require 340B entities to use 340B claims identifiers would address some of these concerns. Congress could provide further transparency into 340B claims by establishing a national clearinghouse. Under this model, HHS would contract with a third-party vendor to review claims-level data submitted by covered entities, Medicaid MCOs, and PDP/MA-PD sponsors, as well as rebate files maintained by state Medicaid agencies. The selected vendor would validate whether a claim is eligible for 340B discounts and share data with the manufacturer to ensure the manufacturer does not pay duplicate discounts. Congress should not restrict payers' and pharmacy benefit managers' ability to manage their

[13] National Council for Prescription Drug Programs. (2019). 340B information exchange. Available at: https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.

pharmacy networks and verify that contract pharmacies are filling claims appropriately. Information submitted to the national clearinghouse must remain confidential to avoid impacting business arrangements between pharmacies, manufacturers, and payers.

Conclusion

AMCP thanks Sen. Cassidy for the opportunity to provide feedback on the 340B for Patients Act. We look forward to working together to increase transparency in the 340B program and promote prescription drug affordability for patients. If you have any questions regarding AMCP's comments or would like further information, please contact me at acolborn@amcp.org or (703) 684-2627.

Sincerely,

Adam Colborn, JD
Vice President, Government Affairs