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VIA EMAIL: Bipartisan340BRFI@email.senate.gov

The Honorable John Thune
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Washington, DC 20510

The Honorable Debbie Stabenow
731 Hart Senate Office Building
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The Honorable Shelley Moore Capito
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The Honorable Tammy Baldwin
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The Honorable Jerry Moran
521 Dirksen Senate Office Building
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The Honorable Benjamin Cardin
509 Hart Senate Office Building
Washington, DC 20510

Re: Senate Request for Information on the 340B Drug Pricing Program

Dear Senators:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide feedback on this bipartisan request for information (RFI) on policy solutions to "ensure the 340B program has the stability and oversight needed to continue to achieve the original intention of serving eligible patients."[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone.

PhRMA supports the goals of the 340B drug pricing program (340B program), which Congress enacted more than three decades ago to help expand access to discounted medicines for low-income and otherwise vulnerable patients. PhRMA is committed to working with Congress and other stakeholders to ensure the program serves the interests of these patients and true safety-net providers that care for them. That is why we have joined with other 340B stakeholders to urge Congress to enact comprehensive legislative reforms that realign the 340B program to achieve these important ends. PhRMA is a member of the Alliance to Save America's 340B Program (ASAP 340B) and the Alliance for Integrity & Reform of 340B (AIR340B), both of which also submitted comments in response to the RFI. We urge Congress to carefully consider the comments these organizations submitted and the comments PhRMA submits here.

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[1] Senate Request for Information on the 340B Drug Pricing Program, Jun. 16, 2023, https://www.thune.senate.gov/public/_cache/files/ae0dd1da-964e-4153-9b5c-2ef9e026b5f0/AE52FC84E091EEA333D8732365A665DC.ss340b.pdf.

Executive Summary

Today's 340B program is plagued by misaligned incentives that leave vulnerable patients behind.

Congress created the 340B program in 1992, in part, to address unintended consequences of the Medicaid drug rebate statute enacted as part of the Omnibus Budget Reconciliation Act of 1990. In creating the 340B program, Congress acknowledged the "best price" provision in the Medicaid drug rebate statute created a "disincentive" that "discourage[s] manufacturers from providing substantial voluntary or negotiated discounts" they had historically offered to certain safety-net clinics and hospitals because those discounts could trigger higher Medicaid rebates nationwide.[2] As a result, the 340B program arose because of the Medicaid statute's unanticipated impact on voluntary manufacturer discounts to true safety-net clinics and hospitals caring for large shares of vulnerable patients.[3]

The statute and its legislative history reflect an express congressional intent to create a program with a very important and targeted purpose. Congress did not create the 340B program to benefit hospitals that do not serve as safety-net providers for large numbers of low-income and uninsured patients.[4] Moreover, the 340B program was not designed to create a separate and unaccountable revenue stream to fund hospital spending that does not more directly benefit these patients.[5] PhRMA believes the large discounts biopharmaceutical manufacturers provide to covered entities under the 340B program should help low-income, uninsured, and other vulnerable patients obtain the outpatient medicines they need—and true safety-net hospitals qualifying for the program should be accountable for using the program's benefits properly and not engaging in predatory practices that saddle patients with medical debt.

The 340B program of today is unrecognizable in both character and size when compared to the targeted program Congress originally created. Currently, the average discount on 340B medicines is nearly 60%,[6] and at $44 billion in annual discounted sales, the size of the 340B program has surpassed that of Medicaid and Medicare Part B and is now the country's second largest federal prescription drug program, behind only Medicare Part D.[7] While the program was initially built to support grantees and other frontline safety-net providers, hospital use of 340B has become vastly concentrated among disproportionate share hospitals (DSHs), which comprise 80% of all 340B purchases.[8] Despite the program's dramatic growth, there is no guarantee patients benefit from the significant discounts manufacturers provide on medicines. A combination of factors has contributed to the program's explosive growth and its resulting distortions across the health care marketplace, including:

- lax program eligibility standards and requirements that have not kept pace with rapidly evolving market trends, including vertical alignment among providers (*e.g.*, large health systems) and payers (*e.g.*, insurance companies with affiliated chain pharmacies and pharmacy benefit managers (PBMs));
- covered entities' use of an increasingly complex web of arrangements with for-profit consultants, chain pharmacies and PBMs to generate significant profits through the program;
- weak enforcement by the Health Resources & Services Administration (HRSA) of covered entities' program compliance obligations; and
- a lack of transparency regarding covered entities' accumulation and use of 340B profits.

These factors show the program is clearly serving the interests of large hospitals—many of which have dismal track records in meeting their charitable obligation to care for the most vulnerable patients in their communities, as described

[2] H.R. Rep. No. 102-384(II), at 10-12 (1992).
[3] Id. at 12 (stating that the 340B statute is intended to apply "to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans").
[4] Id. at 10, 12.
[5] Id.; see also id. at 14 ("The Committee does not intend to extend "covered entity" status to a private nonprofit hospital that has a minor contract to provide indigent care which represents an insignificant portion of its operating revenues.").
[6] Berkeley Research Group, 340B Program at a Glance, Dec. 2022, https://media.thinkbrg.com/wp-content/uploads/2022/12/06082105/340B-Program-at-a-Glance-2022_clean.pdf.
[7] HRSA, 2021 340B Covered Entity Purchases, https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases.
[8] HRSA, 2021 340B Covered Entity Purchases, https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases.

below.[9,10] These factors also show the program is clearly working for profit-seeking PBM and pharmacy conglomerates—which are among the largest corporations in the United States.[11] Notably missing, however, is strong evidence the 340B program is expanding access to affordable medicines for low-income and otherwise vulnerable patients.

In fact, there is little data to suggest the 340B program has provided meaningful benefits to patients. Rather, a growing body of evidence from nonpartisan, independent sources, including *The New England Journal of Medicine (NEJM)*, *Journal of the American Medical Association (JAMA)*, *The New York Times, The Wall Street Journal,* the Government Accountability Office (GAO), the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and others has shown how the program has failed to achieve Congress' objective. Below are highlights from research demonstrating the 340B program's failure to meet the needs of patients:

1. **The 340B program creates and fuels market-distorting incentives that affect prices patients pay for medicines, accelerate hospital acquisitions of physician practices, and put care for vulnerable patients further out of reach by shifting access points to costlier hospital settings that tend to be in wealthier areas**. Many hospitals have leveraged the 340B program by buying community-based physician practices to generate even greater 340B profits.[12] These acquisitions are driving consolidation in provider markets, leading to higher prices for payers because commercial reimbursement for hospital-owned practices is typically higher due to their market power.[13,14] Hospitals' acquisition of physician practices can also leave patients with fewer community-based options to access care and push patients into higher cost hospital-based settings further from their homes.[15] These shifts in site of treatment undermine health equity.[16]

   The 340B program's impact on health equity is not just theoretical or academic conjecture—it is occurring right now in underserved neighborhoods across the country. The incentives for gaming driven by ineffective program standards, including HRSA's existing 340B hospital "child site" policy, were laid bare in a September 2022 story published by *The New York Times*. The story profiled how Bon Secours Mercy Health leveraged the 340B status of Richmond Community Hospital, located in an historically underserved area of Richmond, Virginia, to expand access to patients in higher income areas while leaving vulnerable patients in Richmond Community's service area without critical health services:

   > "Ringed by public housing projects, Richmond Community consists of little more than a strapped emergency room and a psychiatric ward. It does not have kidney or lung specialists, or a maternity ward…. Yet the hollowed-out hospital—owned by Bon Secours Mercy Health, one of the largest nonprofit health care chains in the country—has the highest profit margins of any hospital in Virginia, generating as much as $100 million a year …. [a] former doctor in Richmond Community's emergency department

[9] This Nonprofit Health System Cuts off Patients with Medical Debt, The New York Times, Jun. 2022, https://www.nytimes.com/2023/06/01/business/allina-health-hospital-debt.html.
[10] Lown Institute Hospitals Index, 2023 Fair Share Spending Report, https://lownhospitalsindex.org/2023-fair-share-spending/.
[11] Drug Channels, For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving Contract Pharmacy Market, Jul. 2023, https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html.
[12] S. Desai and J.M. McWilliams, Consequences of the 340B Drug Pricing Program, New England Journal of Medicine, Feb. 2018, https://www.nejm.org/doi/full/10.1056/nejmsa1706475#:~:text=In%20conclusion%2C%20the%20340B%20Drug,mortality%20among%20low%2Dincome%20patients.
[13] Parente S, Ramlet M., Unprecedented Growth, Questionable Policy: The 340B Drug Program, Carlson School of Management at University of Minnesota, https://carlsonschool.umn.edu/sites/carlsonschool.umn.edu/files/inline-files/340BMinnesotaWhitePaper%20%281%29.pdf.
[14] Testimony of Zach Cooper, Senate Finance Committee Hearing: "Consolidation and Corporate Ownership in Health Care," Jun. 8, 2023, https://www.finance.senate.gov/imo/media/doc/20230605_sfc_testimony.pdf.
[15] Testimony of Martin Gaynor, Senate Judiciary Committee Subcommittee on Competition Policy, Antitrust, and Consumer Rights Hearing: "Antitrust Applied: Hospital Consolidation and Solutions," May 19, 2021, https://www.judiciary.senate.gov/download/martin-gaynor-testimony?download=1.
[16] Isaiah E, et al., 340B Hospital Child Sites and Contract Pharmacy Demographics, Avalere, Apr. 2022, https://avalere.com/insights/340b-hospital-child-sites-and-contract-pharmacy-demographics.

> [said] … 'Bon Secours was basically laundering money through this poor hospital to its wealthy outposts.'"[17]

2. **With no requirement for 340B hospitals to help low-income patients, growth in non-profit hospital participation in the 340B program has not translated to higher rates of charity care or improved health outcomes in vulnerable communities**. Despite their valuable tax exemptions, many non-profit hospitals' charity care levels do not appear to be aligned with their obligations as charitable organizations.[18] Generally, non-profit hospitals are required as a matter of federal law to have written and widely publicized financial assistance policies describing the free or discounted care available for eligible patients.[19] Unfortunately, these non-profit hospitals often make that aid difficult to access[20,21] and, according to Kaiser Health News, nearly half of non-profit hospitals are routinely sending medical bills to patients whose incomes are low enough to qualify for charity care.[22] While non-profit status is required for a non-governmental hospital to participate in the 340B program, evidence shows a significant share of hospitals participating in the program provide less charity care than non-340B hospitals. In fact, two-thirds of DSHs that participate in 340B provide below-national-average levels of free and reduced-cost treatments to uninsured or low-income patients, when compared to all hospitals.[23] At the same time, participation in the 340B program does not appear to have increased care or improved outcomes for patients in underserved areas. An Agency for Healthcare Research and Quality (AHRQ)-funded study concluded, "financial gains for [340B] hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients."[24]

3. **Purchasing dynamics create perverse incentives to prescribe more expensive medicines, driving up costs for patients and payers**. While hospitals receive large discounts on 340B medicines, they may still be reimbursed by payers at the same rates as non-340B providers, creating financial incentives for 340B hospitals to prescribe more and/or more expensive medicines to capture a greater "spread."[25,26] According to Harvard researchers, "the most insidious effect of 340B...is the incentive it gives clinics to prescribe high-cost medications, even when effective and far cheaper options exist."[27] To this point, there is also evidence demonstrating the 340B program incentivizes use of more expensive medicines when a lower-cost biosimilar may be available.[28] As a result, several reports and studies have found higher drug spending at 340B facilities for Medicare and commercially-insured patients

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[17] Thomas K, Silver-Greenberg J., How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits, *The New York Times*, Sept. 27, 2022. https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html.
[18] Bai, Ge, et al., Analysis Suggests Government And Nonprofit Hospitals' Charity Care Is Not Aligned With Their Favorable Tax Treatment, Health Affairs, Apr. 5, 2021, https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01627.
[19] See 26 U.S.C. § 501(r).
[20] Levey, Noam, Hundreds of Hospitals Sue Patients or Threaten Their Credit, a KHN Investigation Finds. Does Yours?, KFF Health News, Dec. 21 2022. https://kffhealthnews.org/news/article/medical-debt-hospitals-sue-patients-threaten-credit-khn-investigation/.
[21] Temple University Beasley School of Law, Patient Affordability and Debt Collection Policies at 340B Program Hospitals, May 2022, https://phlr.org/sites/default/files/uploaded_images/PatientAffordability340B_PolicyBrief_May2022.pdf (An analysis of patient financial assistance policies at 75 340B Hospitals found that only 13 of the 75 hospitals' policies include information to help low-income patients access their prescription medicines).
[22] Rau, Jordan, Patients Eligible for Charity Care Instead get Big Bills, KFF Health News, Oct. 19, 2019, https://kffhealthnews.org/news/patients-eligible-for-charity-care-instead-get-big-bills/.
[23] Alliance for Integrity and Reform of 340B, Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Drug Pricing Program, Feb. 2022, https://340breform.org/wp-content/uploads/2022/02/AIR340B_LeftBehind_2022.pdf.
[24] Desai, Sunita, and J. Michael McWilliams, Consequences of the 340B Drug Pricing Program, New England Journal of Medicine, Feb. 8, 2018, https://www.nejm.org/doi/full/10.1056/nejmsa1706475#:~:text=In%20conclusion%2C%20the%20340B%20Drug,mortality%20among%20low%2Dincome%20patients.
[25] Conti, Rena M., and Peter B. Bach., Cost Consequences of the 340B Drug Discount Program, Journal of the American Medical Association, May 15, 2013, https://jamanetwork.com/journals/jama/article-abstract/1680369.
[26] Desai, Sunita, and J. Michael McWilliams, Consequences of the 340B Drug Pricing Program, New England Journal of Medicine, Feb. 8, 2018, https://www.nejm.org/doi/full/10.1056/nejmsa1706475#:~:text=In%20conclusion%2C%20the%20340B%20Drug,mortality%20among%20low%2Dincome%20patients.
[27] Marcus JL, et al., Perverse Incentives — HIV Prevention and the 340B Drug Pricing Program, New England Journal of Medicine, Jun 2, 2022, https://www.nejm.org/doi/full/10.1056/NEJMp2200601.
[28] Bond, Amelia M., Emma B. Dean, and Sunita M. Desai, The Role Of Financial Incentives In Biosimilar Uptake In Medicare: Evidence From The 340B Program, Health Affairs May 1, 2023, https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00812.

compared to non-340B sites of care.[29,30] MedPAC has also noted that, although 340B hospitals are able to purchase outpatient medicines at a steep discount, beneficiary cost-sharing in Medicare Part B is based off the default payment rate (typically, average sales price plus 6%), which leaves seniors paying higher out-of-pocket costs than they would face if Medicare paid less for 340B-discounted medicines.[31]

Legislative improvements to the 340B program are urgently needed to realign the program to ensure it is helping vulnerable patients.

Multiple independent government reports from GAO, OIG, and MedPAC have recommended policy changes to strengthen the 340B program (as noted in the Appendix). These recommendations are far reaching and underscore the need for fundamental, comprehensive reforms to the program—not piecemeal changes, such as simply codifying a role for contract pharmacies.[32] In order to put the 340B program on a sustainable path with a focus on patients and true safety-net providers, Congress must address all aspects of the program that have contributed to health inequities, fueled greater consolidation, increased health care costs and left vulnerable patients behind.

PhRMA appreciates the bipartisan interest in seeking policy solutions to achieve stability and accountability in the 340B program. The 340B program is complex and drives a multitude of incentives for stakeholders. Changes to only one aspect of the program without consideration of downstream impacts and incentives could exacerbate the trends we see today. We strongly encourage Congress to carefully consider the full range of policy shortcomings that have taken the 340B program off course. It is time for Congress to enact comprehensive legislative reforms to realign the 340B program to support vulnerable patients and true safety-net providers and ensure appropriate oversight and accountability.

Below is a summary of key policies PhRMA urges Congress to enact as part of comprehensive legislation to reform the 340B program. A more detailed discussion of these policies is set forth in the next section of this letter.

1. **Patient Definition**. To ensure the 340B program delivers fully on its promise for patients, Congress should clarify in the statute who qualifies as an eligible "patient" of a covered entity to whom benefits must be delivered.
2. **Patient Affordability**. To ensure low-income and uninsured patients benefit from the program, all covered entities (including their child sites) and contract pharmacies should be required to pass through 340B discounts to reduce out-of-pocket costs of medicines for these patients based on their ability to pay.
3. **Contract Pharmacy**. Any new policy that contemplates a role for contract pharmacies in the 340B program should come with reasonable limits, including limits on how contract pharmacies are able to profit (if at all) from the program, and should only be enacted as part of comprehensive reform that must address patient affordability and program accountability and integrity, including a requirement to provide claims level data.
4. **Hospital Eligibility Standards**. Program eligibility requirements for hospitals should be updated to ensure they reflect the safety-net mission of the program. This includes requiring 340B hospitals to provide charity care to uninsured, low-income, and other vulnerable patients, and prohibiting 340B hospitals from engaging in aggressive medical debt collection with respect to these patients.

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[29] GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, Jun. 2015, https://www.gao.gov/products/gao-15-442.

[30] Hunter MT, et al., Analysis of 2020 Commercial Outpatient Drug Spend at 340B Participating Hospitals, Milliman, Sept. 2022, https://www.milliman.com/-/media/milliman/pdfs/2022-articles/9-13-22_phrma-340b-commercial-analysis.ashx.

[31] MedPAC, Report to Congress: Medicare and the Health Care Delivery System, Jun. 2015, https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-chapter-3-part-b-drug-payment-policy-issues-june-2015-report-pdf/.

[32] GAO, 340 Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, Jan. 2020, https://www.gao.gov/products/gao-20-212; GAO, Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, Dec. 2019, https://www.gao.gov/assets/710/705854.pdf; GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, Jun. 2018, https://www.gao.gov/products/gao-18-480; OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, Jun. 2016, https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf; GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, Jun. 2015, https://www.gao.gov/products/gao-15-442; MedPAC, Report to Congress: Medicare and the Health Care Delivery System, Jun. 2015, https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-chapter-3-part-b-drug-payment-policy-issues-june-2015-report-pdf/; OIG, Contract Pharmacy Arrangements in the 340B Program, Feb. 2014, https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf; GAO, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, Sept. 2011, https://www.gao.gov/products/gao-11-836.

5. **Hospital Child Sites**. A hospital child site should be subject to the same requirements applied to the parent hospital with which it is associated. For example, each child site should be required to serve low-income and vulnerable patients, provide a meaningful range of clinically relevant services (not just furnishing a medicine), and follow the parent hospital's sliding fee scale discount policy to share 340B discounts with eligible patients.
6. **Claims Clearinghouse**. Congress should require HHS to create a neutral third-party 340B claims clearinghouse to facilitate improved identification and verification of 340B claims and to avoid prohibited duplicate discounts.
7. **For-Profit Entities**. To ensure program discounts are reaching patients, Congress should limit the nature and amount of fees pharmacies and other for-profit entities charge to perform 340B-related services on behalf of covered entities.
8. **Transparency**. Congress should require covered entities to publicly report basic information so stakeholders and policymakers can ensure the 340B program is working as intended.
9. **HRSA Oversight**. To ensure HRSA has adequate resources to oversee the 340B program, Congress should provide HRSA with ongoing funding dedicated to this purpose. In the absence of clear and meaningful program requirements, Congress should step in to clarify covered entities' statutory compliance obligations. In doing so, Congress should clearly state that the 340B program is a federal program governed exclusively by federal law and that states are not permitted to grant additional rights or impose additional obligations related to the program.
10. **Manufacturer Audits**. Congress should require HRSA to update manufacturer audit guidelines and establish stronger financial penalties that promote covered entity compliance.

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Detailed Responses to Requests for Information

As described above, PhRMA urges Congress to enact a comprehensive set of reforms to the 340B program. Piecemeal reforms are not sufficient on their own to address the fundamentally misaligned incentives that have taken the program off course and left vulnerable patients behind. Piecemeal changes, including policies that authorize the use of contract pharmacies, risk exacerbating the problematic trends highlighted above and—more importantly—would do nothing to expand access to affordable medicines for patients who need it most. PhRMA urges Congress to meet this moment and enact comprehensive reforms patients deserve.

PhRMA's detailed responses to the questions set forth in the RFI follow below.

1. What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

To ensure HRSA has adequate resources to oversee the 340B program, Congress should provide HRSA with ongoing funding dedicated to this purpose.

According to the Government Accountability Office (GAO), as of September 2020, HRSA issued over 1,500 findings of non-compliance in finalized covered entity audits conducted between fiscal years 2012 through 2019.[33] These findings included violations of the 340B statute and HRSA guidance in the areas of covered entity eligibility, diversion, and duplicate discounts.[34] Final results for audits conducted in fiscal year 2021 showed similarly troubling findings: more than 60% of audited covered entities had at least one finding of non-compliance, and nearly 30% had two or more such findings.[35]

Despite significant growth in the program and persistent levels of covered entity non-compliance reported in HRSA's annual audit findings, HRSA still audits just 200 covered entities per year. This level of covered entity oversight is not adequate to address known and widespread program integrity risks identified in HRSA's audits and in numerous GAO and OIG reports.

Policy Recommendation. Congress should provide HRSA with ongoing, dedicated funding that is sufficient to support the agency's oversight of covered entities through audits and other activities targeted at known program integrity risks. In addition to increased congressional appropriations to support this oversight, lawmakers could consider a cost recovery fee or "user fee" mechanism. Under a fee-based model, covered entities would pay fees to HRSA (or a contractor) based on a very small percentage of their annual 340B-eligible medicine purchases. Fees incurred by any single covered entity would likely pale in comparison to the significant fees they readily pay to for-profit third-party administrators and chain pharmacies (*i.e.*, PBMs) providing contract pharmacy services.[36,37,38] Similar proposals to support covered entity oversight have been included in HRSA budget requests under Republican and Democratic presidential administrations[39] and in proposed legislation.[40]

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[33] GAO, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, Dec. 2020, https://www.gao.gov/products/gao-21-107.
[34] Id.
[35] ADVI, Analysis of FY 2021 HRSA 340B Covered Entity Audits, Feb. 23, 2023, https://www.advi.com/insight/analysis-of-fy-2021-hrsa-340b-covered-entity-audits/#HRSA-footer-eleven. The most common sanction imposed on these covered entities was a requirement to repay affected manufacturers' discounts for which the covered entities were not eligible. Covered entities were not required to pay penalties, nor did HRSA terminate any covered entities from the 340B program as a result of non-compliance identified during these audits. Id.
[36] GAO, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, Appendix I, July 2018, https://www.gao.gov/products/gao-18-480.
[37] Drug Channels, 340B and PBMs, Benefit Design Problems, Overworked Pharmacists, Hospitals Keep Grabbing Physicians, and New Patent Games, May 2021, https://www.drugchannels.net/2021/05/drug-channels-news-roundup-may-2021.html
[38] Complaint, Brandywine Hospital v. CVS Health Corp. et al., No. 2:23-cv-01458 (E.D. Pa. Apr. 17, 2023) (noting that CVS retained 40% of the covered entity's 340B "savings" because CVS provided both TPA services and dispensed medications to patients); Complaint, New York v. CVS Health Corp., No. 452197/2022 (N.Y. 2022) (noting the same 40% fee with respect to New York hospitals and other providers participating in the 340B program).
[39] See, e.g., HHS, Congressional Justification for HRSA for FY 2012 (describing a cost recovery fee initially set at 0.1% of the total 340B drug purchase paid by participating covered entities); HHS, Congressional Justification for HRSA for FY 2021 (describing a similar fee mechanism).
[40] See, e.g., H.R. 1559, 340B Protection and Accountability Act of 2019, Mar. 6, 2019, https://www.congress.gov/bill/116th-congress/house-bill/1559?s=1&r=8.

In the absence of clear and meaningful program requirements, Congress should step in to clarify covered entities' statutory compliance obligations.

In response to a covered entity's lawsuit challenging HRSA's authority to enforce audit findings, HRSA concluded that it "would no longer issue [audit] findings based solely on noncompliance with guidance."[41] This has resulted in instances where HRSA auditors:

- "did not issue diversion findings for dispensing 340B drugs to ineligible individuals as defined by HRSA guidance"; and
- "did not issue duplicate discount findings for a failure to follow a state's Medicaid requirements, including billing the state Medicaid office for a 340B drug without using a claim identifier to indicate a drug purchased at the 340B discounted price."[42]

In reaching this conclusion, HRSA has abdicated its responsibility to ensure that covered entities comply with their obligations under the 340B statute. Its decision has left the 340B program without meaningful guardrails to prevent unlawful diversion and duplicate discounts, thereby threatening the program's long-term viability and its ability to serve vulnerable patients. PhRMA has repeatedly urged HRSA to clarify the patient definition and covered entities' obligations to avoid duplicate discounts in Medicaid fee-for-service and managed care.[43]

Policy Recommendation. Given HRSA's current position that it will not seek to enforce these key program requirements in current guidance, Congress should step in and clarify these (and other) program requirements through statutory changes described in our comments below. In doing so, Congress should also clearly state that 340B is a federal program governed exclusively by federal law and that states are not permitted to grant additional rights or impose additional obligations related to the program. Accordingly, the federal 340B statute should expressly preempt all state laws related to the program.

2. What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Congress should only enact contract pharmacy policies as part of comprehensive reforms that address patient affordability and program integrity concerns that have been long identified with the use of contract pharmacies.

Put plainly, contract pharmacies are found nowhere in the 340B statute. In fact, Congress was careful in defining which entities are entitled to 340B pricing by setting out a clear definition of a "covered entity." Congress did not include "pharmacies" as an example of a covered entity when the program was enacted. The concept of "contract pharmacies" was initially introduced through HRSA sub-regulatory guidance to address situations where a covered entity did not have an in-house pharmacy capable of dispensing 340B-discounted medicines. In those situations, HRSA's guidance permitted a covered entity to contract with one outside pharmacy, which represented a direct relationship between the covered entity and the pharmacy and required oversight by the covered entity to ensure compliance with program requirements.[44]

In 2010, HRSA expanded this sub-regulatory guidance to permit any covered entity to contract with an unlimited number of outside pharmacies, regardless of whether the covered entity has an in-house pharmacy. Importantly, HRSA's 2010 guidance simultaneously relaxed oversight of contract pharmacy arrangements by moving from comprehensive annual audits of all contract pharmacy arrangements to a mere *recommendation* that covered entities *self-audit* a small sample of contract pharmacy claims.[45] In January 2023, the U.S. Court of Appeals for the

[41] GAO, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, Dec. 2020, https://www.gao.gov/products/gao-21-107.
[42] Id.
[43] See, e.g., PhRMA, Petition for 340B ADR Rulemaking, Nov. 24, 2020, https://phrma.org/en/resource-center/Topics/Medicaid/PhRMA-Petition-to-HHS-for-Rulemaking-Regarding-an-Administrative-Dispute-Resolution-Process-for-the-340B-Drug-Pricing-Program; PhRMA Comments on HRSA Proposed 340B Omnibus Guidance, Oct. 27, 2015, https://www.regulations.gov/comment/HRSA-2015-0002-0553.
[44] 61 Fed. Reg. 43549 (Aug. 23, 1996).
[45] 75 Fed. Reg. 10272 (Mar. 5, 2010).

Third Circuit invalidated HRSA violation letters and an HHS advisory opinion predicated on HRSA's view that the 340B statute required manufacturers to deliver 340B-discounted medicines to an unlimited number of contract pharmacies, consistent with the agency's 2010 guidance. The Court found that "Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies. So by trying to enforce that supposed requirement, the government overstepped the statute's bounds."[46]

Since the 2010 guidance, contract pharmacy arrangements have grown by more than 5,000%.[47] However, there is little evidence to suggest that patients have benefited from contract pharmacy expansion. Growth of pharmacy contracts with 340B hospitals has not been found to be correlated with higher uninsured rates, poverty rates, or areas of medical underservice.[48] This is partly because HRSA's 2010 guidance does not even purport to require contract pharmacies to ensure low-income and uninsured patients directly benefit from 340B discounts at the pharmacy counter.

Independent government watchdogs have reported that when DSHs use contract pharmacies, it is common for pharmacies to not pass through 340B discounts to uninsured patients.[49,50,51] Unlike at a covered entity's on-site pharmacy, a prescription filled at a contract pharmacy often is not identified as being eligible for a 340B discount until after the prescription is filled.[52] For this reason, patients see no difference between filling scripts at a contract pharmacy or at a pharmacy that does not have an arrangement with a 340B covered entity. Without uniform and enforceable requirements to identify and designate 340B-eligible prescriptions, contract pharmacies generally have no way to know at the point of dispensing which prescriptions are for 340B patients.[53] As a result, contract pharmacies do not appear to increase or expand access to discounted medicines.

In fact, most 340B-eligible patients appear to receive no direct cost-sharing benefit from 340B prescriptions filled at contract pharmacies—a recent analysis found substantial evidence that 340B discounts were shared with patients in only 1.4% of eligible pharmacy claims.[54] Furthermore, several studies have confirmed that the expansion of contract pharmacies tends to be in less diverse, higher income neighborhoods and not in medically underserved areas.[55,56] For example, from 2011 to 2019, the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino communities declined, while the share of 340B pharmacies in the highest-income neighborhoods increased.[57]

Policy Recommendation. Without comprehensive reforms to strengthen foundational elements of the 340B program, such as a clearer patient definition, hospital eligibility child site standards, a requirement that 340B hospitals use program profits to help vulnerable patients afford their medicines, and establishment of a neutral claims data clearinghouse to improve identification of 340B prescriptions, simply codifying contract pharmacies will exacerbate current trends in runaway program growth and abuse with no offsetting benefit for patients most in need or program integrity improvements. To realign the 340B program to benefit low-income and uninsured patients, we believe, at a minimum, 340B hospitals (including their child sites) and their contract pharmacies should be required to pass through 340B discounts to reduce out-of-pocket costs on medicines for these patients based on their ability to pay.

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[46] Sanofi Aventis U.S. v. U.S. Dep't of Health and Human Servs. et al., Slip. Op. at 21, Nos. 21-3167, 21-3379 (3d. Cir. Jan. 30, 2023).
[47] BRG, Analysis of HRSA OPAIS Database, Jul. 2022.
[48] Nikpay, Sayeh, et al., Association of 340B Contract Pharmacy Growth with County-Level Characteristics, American Journal of Managed Care, May 10, 2022, https://www.ajmc.com/view/association-of-340b-contract-pharmacy-growth-with-county-level-characteristics.
[49] OIG, Contract Pharmacy Arrangements in the 340B Program, Feb. 2014, https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp.
[50] GAO, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, Jul. 2018, https://www.gao.gov/products/gao-18-480.
[51] GAO, Information About Hospitals That Received an Eligibility Exception as a Result of COVID-19, May 2023, https://www.gao.gov/products/gao-23-106095.
[52] Id.
[53] OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, Jun. 2016, https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.
[54] Rory Martin and Kepler Illich, Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?, IQVIA, Oct. 10, 2022, https://www.iqvia.com/locations/united-states/library/fact-sheets/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.
[55] AIR340B. 340B: A Missed Opportunity to Address those that are Medically Underserved. July 2023. https://340breform.org/wp-content/uploads/2023/07/340B_MUA_July23-4.pdf
[56] Avalere, 340B Hospital Child Sites and Contract Pharmacy Demographics, Apr. 2022, https://avalere.com/insights/340b-hospital-child-sites-and-contract-pharmacy-demographics.
[57] Lin, John K., et al., Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics, JAMA Health Forum, Jun. 17, 2022, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530.

3. What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

Congress should address the for-profit, vertically integrated middlemen that have flooded this safety-net program by limiting the fees they can charge covered entities.

Since HRSA released its 2010 unlimited contract pharmacy guidance, an entire cottage industry of 340B "middlemen" consisting of for-profit pharmacies, third-party administrators (TPAs), and consultants has flourished with one goal—helping covered entities maximize profits from the 340B program (while generating significant profits for themselves through fees).[58] With no role for them contemplated in the 340B statute, these middlemen have entered the program and siphoned off significant profits for their own benefit and taking from the program's intended recipients—low-income and vulnerable patients and the safety-net providers that care for them.

The profit opportunities stemming from the 340B program have played a significant role in restructuring the health care system such that "vertically integrated supply chains consisting of pharmacies, pharmaceutical benefit managers and health plans…can leverage their market power to drive growth in the 340B program and capture profits related to 340B sales."[59] A guide for employers on PBM arrangements describes the 340B program as intending to serve low-income and uninsured patients but "instead enriches intermediaries across the supply chain, adding costs for purchasers and patients."[60]

PBMs and their vertically integrated chain and specialty pharmacies can leverage their market power and their control over vast pharmacy networks to extract significant fees from 340B covered entities and maximize their own profits, while leaving rural and safety net providers with fewer resources to expand care and provide affordable medicines to vulnerable patients in their communities. To provide context for the vast dominance and vertical entanglements among the contract pharmacy supply chain, consider the following:

- More than half of the top 20 companies in the Fortune 500 generate profit from the 340B program.[61]
- Over half of the 340B profits retained by contract pharmacies are estimated to be concentrated in just four Fortune 50 companies, that are also likely associated with either a health plan, PBM, third-party administrator, and/or specialty pharmacy.[62]
- Currently, more than 20% of contract pharmacy arrangements are between 340B covered entities and PBM-affiliated specialty pharmacies, and that figure will only continue to grow.[63]
- Two of the most dominant national contract pharmacy chains have both reported they heavily rely on the 340B program for their profits and any negative change in their relationship with the program could materially impact their financial performance and impact their ability to exceed earnings projections.[64]
- The top five providers of contract pharmacy services alone generated $3 billion in 340B profits in 2022[65]

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[58] See, e.g., Senator Charles Grassley, Letter to Walgreens CEO Gregory Watson, Jul. 21, 2013, http://www.pembrokeconsulting.com/pdfs/Grassley_340B_Letter_to_Walgreens_31July2013.pdf.
[59] Berkeley Research Group, For-Profit Pharmacy Participation in the 340B Program, Oct. 2020, https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/.
[60] National Alliance of Healthcare Purchaser Coalitions, A Playbook for Employers – Addressing Pharmacy Benefit Management Misalignment, Jun. 2023, https://www.nationalalliancehealth.org/wp-content/uploads/NationalAlliance_PBM_PB_2023_A.pdf.
[61] Fortune, Fortune 500, https://fortune.com/fortune500/ (accessed Jun. 2022).
[62] Berkeley Research Group, For-Profit Pharmacy Participation in the 340B Program, Oct. 2020, https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.
[63] Fein AJ., Specialty Pharmacies and PBMs Hop on the 340B Money Train, Drug Channels, Aug. 1, 2019, https://www.drugchannels.net/2019/08/specialty-pharmacies-and-pbms-hop-on.html.
[64] See Nona Tepper, Drugmakers Restricting 340B Pharmacy Sales Threaten PBMs Profits, Modern Healthcare, Jun. 9, 2023, https://www.modernhealthcare.com/payment/drugmakers-340b-sales-pbms-pharmacy-benefit-managers-caremark-express-scripts-optumrx; Barrons, CVS Health Stock Gets Downgraded, Mar. 29, 2022, https://www.barrons.com/amp/articles/cvs-health-stock-downgrade-51648567375; CVS Health Corporation, Annual Report (Form 10-K) at 22-23, Feb. 9, 2022, https://bit.ly/3HVWvn5; Walgreens Boots Alliance, Inc., Annual Report (Form 10-K) at 23, Oct. 15, 2020, https://bit.ly/3ISDfIA.
[65] Drug Channels, Five Pharmacy Chains and PBMs Dominate 2022's Still-Booming 340B Contract Pharmacy Market, Jul. 12, 2022, https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html.

Policy Recommendation. To ensure program discounts are reaching patients, Congress should limit the nature and amount of fees pharmacies and other for-profit entities charge to perform 340B-related services on behalf of covered entities.

4. What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

Congress should support operationalization of statutory duplicate discount prohibitions by requiring the development of a neutral claims "clearinghouse."

The 340B statute creates an absolute prohibition on covered entities purchasing a covered outpatient drug at a 340B discount that also generates a Medicaid rebate (*i.e.*, Medicaid/340B "duplicate discounts").[66] Despite this straightforward statutory imperative, current prevention methods are insufficient to address the duplicate discounts that persist throughout the 340B program. This is due, in part, to the lack of uniform and effective requirements covered entities must use to properly identify 340B claims. Contract pharmacy arrangements, and the particular complexities these arrangements present in the managed Medicaid context, have been cited by independent government agencies as contributing to the problems with duplicate discounts.[67,68] To date, neither HRSA nor the Centers for Medicare & Medicaid Services (CMS) has taken effective steps to prevent these statutory violations and address longstanding program integrity concerns.[69,70,71]

In identifying the top unimplemented recommendations to reduce fraud and abuse in HHS programs, OIG has stated, "CMS and HRSA should ensure that States can pay correctly for 340B-purchased drugs billed to Medicaid, by requiring claim-level methods to identify 340B drugs and sharing the official 340B ceiling prices".[72] More recently, in May of this year, GAO notified HHS Secretary Becerra of the following "high priority" recommendations that warrant his "continued personal attention" because, upon implementation, they may "eliminat[e] mismanagement, fraud, and abuse":

- "The Administrator of [HRSA] should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs."
- "The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities."[73]

CMS recently proposed to require Medicaid managed care organizations (MCOs) to include unique Medicaid-specific bank identification number/processor control number (BIN/PCN) identifiers on all Medicaid MCO pharmacy benefit cards. If CMS' regulation is finalized, these identifiers could more easily identify Medicaid managed care enrollees and facilitate efforts to prevent 340B/Medicaid duplicate discounts.[74] As PhRMA noted in its comments to CMS on the proposed rule, the inclusion of identifiers on benefit cards, by itself, will not fully address the risk of 340B duplicate discounts in Medicaid managed care. Additional steps are needed to identify 340B claims and achieve the statutory imperative of zero instances of Medicaid/340B duplicate discounts.[75] To this end, PhRMA supports requiring states and MCOs to: (i) implement claim-level methods to identify claims for 340B-discounted medicines in Medicaid

[66] Public Health Service Act § 340B(a)(5)(i).
[67] OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, June 2016. https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.
[68] GAO, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, Jul. 2018, https://www.gao.gov/products/gao-18-480.
[69] GAO, Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvements, Sept. 2011, https://www.gao.gov/products/gao-11-836.
[70] OIG, Contract Pharmacy Arrangements in the 340B Program, Feb. 2014, https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp.
[71] GAO, Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, Jan. 2020, https://www.gao.gov/products/gao-20-212.
[72] OIG, Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste and Abuse in HHS Programs, Aug. 2020, https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2020.pdf.
[73] GAO, Priority Open Recommendations: Department of Health and Human Services (May 2023), https://www.gao.gov/products/gao-23-106467.
[74] 88 Fed. Reg. 34246 (May 26, 2023).
[75] PhRMA comments Re: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program [CMS-2434-P], July 25, 2023. https://phrma.org/resource-center/Topics/Medicaid/PhRMA-Comments-on-Medicaid-Drug-Rebate-Program-Proposed-Rule

across all dispensing methods (including contract pharmacies), and (ii) establish processes to ensure that Medicaid rebate invoices exclude claims for 340B-discounted medicines. Such processes should also clarify the obligations of state Medicaid agencies, MCOs, and covered entities in timely and fully resolving all instances of identified duplicate discounts—both in fee-for-service and managed Medicaid. If CMS does not act to implement these requirements, Congress should mandate that the agency do so.

Recent Medicare statutory changes enacted as part of the Inflation Reduction Act (IRA) will necessitate implementation of robust and coordinated processes to identify 340B-eligible claims and ensure compliance with newly enacted duplicate discount prohibitions. First, the IRA prohibits 340B units from being included in the calculations for Medicare Part B and Part D inflation rebates.[76] Second, the IRA's "nonduplication" provision generally states that a manufacturer of a selected drug is not required to provide access to the maximum fair price (MFP) for a selected drug that is subject to a 340B discount where the 340B ceiling price is lower than the MFP for the drug.[77] To ensure compliance with these statutory commands, manufacturers must have appropriate access to claims-level data sufficient to verify that duplicate claims have been excluded.

Policy Recommendation. A neutral third-party claims clearinghouse has been cited by numerous 340B stakeholders as a viable approach to facilitate improved identification and verification of 340B-eligible drug claims and achieve compliance with duplicate discount prohibitions in Medicaid and Medicare. The sharing of basic claims-level data can help ensure 340B discounts are being properly claimed, that all stakeholders are operating in a compliant manner, and that low-income and vulnerable patients are able to benefit.

5. What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?

To ensure the 340B program delivers fully on its promise for patients, Congress must clearly define an eligible "patient" to whom benefits must be delivered.

Despite this centrality of the statutory term "patient" in defining the 340B program's scope, it has been more than 30 years since the 340B program was created, and the definition of this term has been a source of confusion and abuse. Indeed, there is broad consensus that the lack of specificity in the current (1996) patient definition[78] invites abuse. For example:

- "[S]ome 340B covered entities may have interpreted the [patient] definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program…." (HRSA, 2007).[79]

- "As a result of the lack of specificity in the guidance, HRSA has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus … for whom the entity does not actually have the responsibility for care." (GAO, 2011).[80]

- "[C]overed entities … use different methods to identify 340B-eligible [patients and] prescriptions to prevent diversion in their contract pharmacy arrangements. In some cases, these different methods lead to differing determinations of 340B eligibility…. [T]wo covered entities may categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) …. [T]here is inconsistency within the 340B program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible." (HHS OIG, 2014)[81]

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[76] Social Security Act §§ 1847A(i)(3)(B)(ii)(I), 1860D-14A(b)(1)(B); see also CMS, Part B Inflation Rebate Guidance: Use of the 340B Modifiers, Dec. 20, 2022, https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.
[77] Social Security Act § 1193(d).
[78] 61 Fed. Reg. 55156 (Oct. 24, 1996).
[79] 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007) (setting forth HRSA's proposed but never finalized clarifications to its 1996 patient definition guidance).
[80] GAO, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, Sept. 2011, https://www.gao.gov/products/gao-11-836.
[81] OIG, Contract Pharmacy Arrangements in the 340B Program, Feb. 2014, https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp.

- "HRSA has outlined three criteria for who is an eligible patient, but some of these criteria are not clearly defined." (MedPAC, 2015).[82]

- "HRSA's current patient definition guidance does not account for the complexity of contract pharmacy arrangements.... Depending on the interpretation of HRSA's patient definition, some 340B provider eligibility determinations would be considered diversion and others would not." (HHS OIG, 2018).[83]

Covered entities have interpreted the term "patient" broadly, going well beyond HRSA's 1996 guidance to claim 340B discounts on medicines dispensed to individuals never intended under the program. Certain hospitals have developed complex arrangements, often supported by for-profit consultants, that appear aimed primarily at increasing 340B profits by capturing as many purported "patients" as possible, rather than more fully serving uninsured and low-income patients.[84]

Policy Recommendation. PhRMA has repeatedly urged HRSA to issue a clear and adequate patient definition.[85] Since HRSA has not and is currently not enforcing its existing 1996 patient definition, it is time for Congress to step in to clarify the definition in statute. A statutory patient definition should, at a minimum:

- Assess an individual's status as a "patient" on a prescription-by-prescription and order-by-order basis;
- Specify requirements for relationships between the covered entity claiming a 340B discount on a medicine, the practitioner prescribing the medicine, and the individual furnished the medicine, including a temporal component sufficient to demonstrate an ongoing provider-patient relationship between the covered entity and the individual; and
- Clarify the scope of outpatient health care services relative to which a covered entity can claim 340B discounts on medicines and the relationship between each such service and the medicine furnished to an individual as a result of such service.

Congress must modernize hospital eligibility criteria and extend those criteria to off-campus outpatient facilities. These standards should create a strong nexus between 340B discounts and benefits to vulnerable patients.

For a program established by Congress to benefit underserved patients and the true safety-net facilities that care for them, current eligibility standards for participating hospitals are woefully outdated, overly broad with few metrics for accountability, and inadequate in ways to allow hospitals to worsen health inequities. One of the 340B program's key failings over the past three decades has been to address exploitation of the program by certain hospitals (primarily driven by large health systems) largely focused on driving higher 340B program profits by increasing service volume in wealthier areas with higher rates of commercial insurance—with little regard for the needs of communities that rely on the safety net. Program eligibility policies intended to strengthen rural provider participation in the program have also been gamed by urban hospitals, further diverting savings away from safety-net providers who rely on the program most.

There were 45 hospitals in the 340B program when it first started. Today that number has grown to over 2,700,[86] and nearly two-thirds of all participating 340B hospitals are private, non-profit hospitals, far outpacing public

[82] MedPAC, Report to Congress: Overview of the 340B Drug Pricing Program, May 2015, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf.
[83] Oral Testimony of Ann Maxwell, Assistant Inspector General, OIG, Senate Health, Education, Labor & Pensions (HELP) Committee, May 15, 2018.
[84] See, e.g., Comprehensive Pharmacy Solutions, Referral Prescription Capture Drives Significant 340B Savings, https://perspectives.cps.com/referral-prescription-capture-drives-significant-340b-savings-a-cps-case-study; SpendMend Pharmacy, 340B Referral Capture Service, https://www.spendmend.com/solutions/pharmacy-solutions/340b-referral-capture/; Par8o, 340B Program Compliance In Regards to Referrals for Consultation, https://learn.par8o.com/hubfs/340B%20Program%20Compliance%20in%20Regards%20to%20Referrals%20for%20Consultation.pdf;
[85] See, e.g., PhRMA, Petition for 340B ADR Rulemaking, Nov. 24, 2020, https://phrma.org/en/resource-center/Topics/Medicaid/PhRMA-Petition-to-HHS-for-Rulemaking-Regarding-an-Administrative-Dispute-Resolution-Process-for-the-340B-Drug-Pricing-Program; PhRMA Comments on HRSA Proposed 340B Omnibus Guidance, Oct. 27, 2015, https://www.regulations.gov/comment/HRSA-2015-0002-0553.
[86] BRG Analysis of HRSA OPAIS Database. July 2023.

and government hospitals.[87] With 60% of acute care hospitals participating in a program intended to support true safety-net facilities,[88] it is clear that hospital eligibility criteria must be reexamined. The current DSH metric utilized for 340B eligibility does not target the 340B program's intended patient population or even represent outpatient care, raising questions about whether the program can meet the needs of those in medically underserved areas who disproportionately lack access to primary care.

DSHs qualify for the 340B program based, in part, on their disproportionate share adjustment percentage.[89] However, this metric has two main flaws which makes it an incongruent and poor indicator of a safety-net program. First, the metric relates to the *inpatient population* of Medicaid patients and Medicare patients receiving Supplemental Security Income (i.e., limited income Medicare patients) admitted to the hospital, yet 340B is an outpatient program. By basing the program off an inpatient metric, this means when a 340B hospital expands its off-campus outpatient departments in wealthier areas to increase their outpatient mix among Medicare and the privately insured, that has no impact on its disproportionate share adjustment percentage. In a report to Congress, MedPAC reported it found little correlation between hospitals' disproportionate share adjustment percentages and whether they served high percentages of uninsured patients.[90] So long as hospitals meet the minimum *inpatient* threshold, they (and all of their associated off-campus outpatient sites) remain eligible to receive 340B discounts.

The second shortcoming with the current disproportionate share adjustment metric is it does not account for free or discounted care provided to vulnerable and low-income patients. Increased participation in the 340B program has not been associated with corresponding increases in hospital reported uncompensated care.[91] Furthermore, increases in profit at nonprofit hospitals were not correlated with increases in charity care; the opposite was true at for-profit hospitals.[92] Rather than reinvesting their 340B profits into patient care services or lowering the cost of prescriptions for patients who need it most, these same non-profit hospitals are engaging in aggressive debt collection and often score among the worst performers in levels of charity care, penalizing the very at-risk communities they should be serving.[93]

The 340B statue defines the types of hospitals that can participate in the program with particular specificity[94] but never mentions the participation of off-campus outpatient facilities associated with these hospitals. Although there is no basis in the statute for including these sites, in 1994, HRSA unilaterally issued guidance dramatically expanding 340B by permitting child sites to participate – even if they are only loosely connected to the parent hospital and without regard for whether they serve a disadvantaged population.[95] In 1994, there were 34 child sites. Nearly three decades later, in 2023, this had increased to over 30,000, of which more than 75% are affiliated with a 340B DSH hospital.[96]

Child sites have become a significant source of 340B program growth. The *New York Times* article published last fall[97] depicted in stunning terms how child sites create incentives that shift care to more expensive and less convenient settings (as 340B hospitals buy up smaller facilities to generate more revenue), increase costs, and drive

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[87] GAO, Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, Dec. 2019, https://www.gao.gov/assets/710/705854.pdf.
[88] MedPAC, Report to Congress: Medicare and the Health Care Delivery System, Jun. 2022, https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_SEC.pdf.
[89] Public Health Service Act § 340B(a)(4)(L)(ii).
[90] MedPAC, Report to Congress: Medicare Payment Policy, Mar. 2007, https://www.medpac.gov/document/march-2007-report-to-the-congress-medicare-payment-policy/.
[91] Sunita Desai & J. Michael McWilliams, 340B Drug Pricing Program and Hospital Provision of Uncompensated Care, American Journal of Managed Care, Oct. 11, 2021, https://www.ajmc.com/view/340b-drug-pricing-program-and-hospital-provision-of-uncompensated-care.
[92] Jenkins, Derek, and Vivian Ho, Nonprofit Hospitals: Profits And Cash Reserves Grow, Charity Care Does Not, Health Affairs, Jun. 2023, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.01542.
[93] This Nonprofit Health System Cuts off Patients with Medical Debt, The New York Times, Jun. 2022, https://www.nytimes.com/2023/06/01/business/allina-health-hospital-debt.html.
[94] Public Health Service Act § 340B(a)(4)(L)-(O).
[95] 59 Fed. Reg. 47884, 47885 (September 19, 1994).
[96] HRSA OPAIS Database, Jun. 2023.
[97] Thomas K, Silver-Greenberg J., How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits, The New York Times, Sept. 27, 2022. https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html.

consolidation that can negatively impact patient access to care. Government reports reinforce this concern, indicating that hospitals frequently exploit HRSA's guidance on child site eligibility, which has not been revisited since 1994.[98]

Urban-to-rural reclassifications are another hospital eligibility policy that has emerged as an area of abuse in the 340B program.[99] In 2016, CMS policy changes had the effect of permitting certain large urban hospitals to qualify for 340B as rural referral centers (RRCs). However, this change came with no requirements that these hospitals be located in rural areas or treat a certain proportion of rural patients.[100] A recent *Wall Street Journal* article described this policy as a "quirk in federal law" that allowed hospitals located in the heart of metropolitan areas to qualify for 340B as RRCs when they otherwise would not qualify under the original disproportionate share adjustment threshold because they do not admit enough low-income Medicare and Medicaid inpatients.[101] RRC eligibility to participate in 340B, while ostensibly intended to help rural patients and their providers, has opened the door for more large urban hospitals to game entry into the 340B program using a lower disproportionate share threshold. We see this trend in 340B registration data. Indeed, RRCs represent the fastest growing segment of 340B hospital purchases, increasing their 340B medicine purchases by more than 700% over 5 years—a rate greater than any other 340B hospital type.[102]

Policy Recommendation. Hospital eligibility standards must be strengthened and aligned with the intent of Congress so that only true safety-net hospitals and providers qualify for the program. This would include a minimal charity care threshold and prohibition on aggressive medical debt collections. There should also be greater oversight and enforceable standards for private hospitals regarding the government contracts that allow them to qualify for the 340B program.[103] Child sites should also be subject to the new requirements applied to the parent hospital, such as meeting a calculation that ensures they are serving a certain proportion of low-income and vulnerable patients, providing a broad range of services (not just furnishing a medicine), and adhering to the parent hospital's policy of passing through 340B discounts to reduce out-of-pocket amounts on medicines for low-income and uninsured patients. In addition, any newly considered reporting and transparency requirements (see response to Question 6 below) should apply to both the parent hospital and individual child sites. This would help ensure that hospital child sites better serve safety net populations.

Congress should require HRSA to update manufacturer audit guidelines and establish stronger financial penalties that promote covered entity compliance.

The 340B statute specifically permits manufacturers to audit covered entities' compliance with the law's diversion and duplicate discount prohibitions, subject only to HRSA guidelines on the "number, scope, and duration" of these audits.[104] HRSA's manufacturer audit guidelines, which have been in place since 1996, are problematic because they impose onerous and unnecessary barriers on manufacturer audits that extend well beyond the "number, scope, and duration" limits permitted by the statute.[105] These barriers effectively foreclose manufacturer audits of covered entities. HRSA has explicitly recognized this problem, stating "over the history of the 340B program, manufacturers have rarely utilized the process in the [HRSA] guidelines to conduct an audit."[106] In November 2022, HRSA acknowledged that "[o]ver the last 3 years, two manufacturers have requested to audit covered entities."[107]

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[98] GAO, Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, Jun. 2015, https://www.gao.gov/products/gao-15-442; 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994).
[99] AIR340B. What's in a Name? Rural Referral Centers Capture 340B Discounts Without Serving Rural, Vulnerable Patients. July 2023, https://340breform.org/wp-content/uploads/2023/07/340B-RRC-Issue-Brief.pdf
[100] 81 Fed. Reg. 23428 (Apr. 21, 2016).
[101] Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients, The Wall Street Journal, Dec. 2022, https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899.
[102] Drug Channels Institute, The 340B Program Climbed to $44 Billion in 2021 – with Hospitals Grabbing Most of the Money, Aug. 2022, https://drugchannelsinstitute.com/files/HRSA-340B_Sales_by_entity_type_2015-2021-August2022.pdf.
[103] GAO, Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, Dec. 2019, https://www.gao.gov/assets/710/705854.pdf.
[104] Public Health Service Act § 340B(a)(5)(C).
[105] See, e.g., PhRMA Comments on HRSA 340B Administrative Dispute Resolution Proposed Rule (Jan. 30, 2023), https://www.regulations.gov/comment/HRSA-2022-0001-0094; Complaint, PhRMA v. Cochran, No. 8:21-cv-00198-DLB (D. Md. Jan. 22, 2021); PhRMA, Petition for 340B ADR Rulemaking, Nov. 24, 2020, https://phrma.org/en/resource-center/Topics/Medicaid/PhRMA-Petition-to-HHS-for-Rulemaking-Regarding-an-Administrative-Dispute-Resolution-Process-for-the-340B-Drug-Pricing-Program.
[106] 75 Fed Reg. 57233, 57235 (Sept. 20, 2010).
[107] 87 Fed. Reg. 73516, 73518 (Nov. 30, 2022).

Policy Recommendation. The infrequency of manufacturer audits of covered entities runs counter to the goals of promoting covered entity compliance with the statutory diversion and duplicate discount prohibitions. Congress should require HRSA to issue revised audit guidelines that enable manufacturers to conduct appropriate covered entity oversight (including by permitting manufacturers to use their internal staff to conduct such audits). Additionally, Congress should consider statutory changes to hold covered entities accountable for non-compliance discovered through audits or otherwise. Such changes should include meaningful financial penalties designed to promote compliance (*i.e.*, more than repayment of 340B discounts to affected manufacturers) and other program integrity measures commensurate with the nature and extent of the violation.

6. What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?

Congress should require covered entities to report basic information to ensure the 340B program is working as intended.

Enacting fundamental improvements in transparency is an essential step in ensuring that the 340B program provides measurable patient benefit and operates consistent with congressional intent. Currently, 340B transparency practices across the range of providers participating in the 340B program are highly variable—and in many instances wholly inadequate or non-existent. As an example, certain safety-net providers, such as federally qualified health centers, must report data to HRSA demonstrating, among other things, how they are providing care to underserved communities.[108] DSHs and their associated child sites, on the other hand, are not subject to any 340B reporting requirements. As a result, policymakers and stakeholders are unable to evaluate whether the program is benefitting patients, or objectively confirm that patients fully benefit from the program. Economists who have long studied the impacts of the 340B program have noted that greater transparency will help low-income communities.[109] Specific data are needed to quantify patient benefit in terms of the number of vulnerable patients who benefit from the 340B program and how covered entities use the 340B discounts they receive to help low-income patients.

Policy Recommendation. At a minimum, covered entities should have similar and meaningful reporting requirements to ensure that vulnerable patients benefit from the program and that the program is operating as intended. Much of this data is already collected by providers for other purposes and, therefore, would not represent a new burdensome obligation. Examples of common-sense reporting requirements include:

- The number and share of individuals treated by a covered entity (including at a child site) who are dispensed or administered 340B medicines, broken down by payer status (*e.g.*, Medicare, Medicaid, privately insured, uninsured);
- Aggregate annual payer reimbursement on claims for 340B medicines and aggregate annual acquisition cost for such medicines);
- The total amount a covered entity spends to subsidize out-of-pocket costs for patients receiving 340B medicines;
- Amount of charity care provided at each 340B hospital and its associated child sites, broken down by parent and each child site; and
- Public disclosure of contracts between private non-profit hospitals and state or local governments describing health care services provided to low-income individuals not eligible for Medicare or Medicaid.

We caution against including a requirement in transparency legislation that requires 340B providers to report how they use program profits. As policy experts have noted, "it is unclear what can be learned from asking providers to report

[108] See, e.g., 42 U.S.C. § 254b; HRSA, Uniform Data System, Health Center Data Reporting Requirements, 2023 Manual, https://bphc.hrsa.gov/sites/default/files/bphc/data-reporting/2023-uds-manual.pdf.
[109] R. Conti, 340B Drug Discount Program: Why More Transparency Will Help Low-Income Communities, Commonwealth Fund, Mar. 15, 2018, https://www.commonwealthfund.org/publications/newsletter-article/2018/apr/340b-drug-discount-program-why-more-transparency-will-help.

how they use 340B funds. Because money is fungible, providers [would] have broad flexibility in reporting what the 340B-derived funds notionally paid for." Given this flexibility, providers' responses "are likely to be of little use…."[110]

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PhRMA appreciates the opportunity to provide our perspectives on policy solutions we believe can strengthen the 340B program in delivering more sustained clinical and affordability benefits to vulnerable patients. We believe that the significant discounts biopharmaceutical manufacturers provide under the 340B program should serve a targeted purpose: helping low-income uninsured and other vulnerable patients obtain the outpatient medicines they need. All covered entities qualifying for the program should be accountable for compliance with applicable program requirements. Comprehensive legislative reforms are needed to realign the 340B program to put it on a sustainable, long-term footing and, most importantly, ensure it supports vulnerable patients and true safety-net providers.

PhRMA reiterates our support for the 340B program. We are committed to working with Congress, the Administration, and other program stakeholders to develop patient-focused policy solutions for the sustainability and success of this essential safety-net program. We appreciate the opportunity to comment. Should you wish to discuss any aspect of our comments, please contact Carolyn Ha and Corbin Santo.

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[110] L. Adler, M. Fiedler & B. Ippolito, Assessing Recent Health Care Proposals from the House Committee on Energy and Commerce, USC-Brookings Schaeffer Initiative for Health Policy, updated May 25, 2023, https://www.brookings.edu/articles/assessing-recent-health-care-proposals-from-the-house-committee-on-energy-and-commerce/.

Appendix: Key 340B Government Reports

Multiple independent government reports from the GAO and OIG over the past decade have issued concerning findings that touch on almost every aspect of the 340B program, from program eligibility standards to the lack of a benefit for vulnerable patients. These reports have produced a significant number of policy recommendations, many of which have not been implemented, and underscore the need for fundamental, comprehensive reforms to strengthen the program.

- **2023 GAO: 340B Drug Discount Program: Information about Hospitals that Received an Eligibility Exemption as a Result of COVID-19**. GAO-23-106095. May 11, 2023.
  - Of all the excepted hospitals[111], only one (a sole community hospital) had increases each year in the amounts of charity care, uncompensated care, and total unreimbursed and uncompensated care as a percentage of total facility revenue. Over the same four-year time period (2017-2020), two DSH hospitals had decreases each year in all three types of care (p. 13).
  - Nearly half of the excepted hospitals who have one or more active contract pharmacies reported that they do not provide discounts on the prices patients pay for drugs at their contract pharmacies (p. 16).
  - More than half of excepted hospitals that previously received a 340B Program audit from HRSA received at least one statutory noncompliance finding (e.g. duplicate discounts or diversion of 340B program drugs to ineligible patients); twenty percent received more than one finding of noncompliance (p. 19).

- **2020 GAO: Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements.** GAO-21-107. December 14, 2020.
  - As of September 2020, HRSA had issued more than 1,500 findings of noncompliance in covered entity audits since fiscal year 2012. More than one-third of those findings were due to diversion (340B drugs dispensed to patients not eligible for the 340B program) (p. 13).
  - GAO continues to be *"...concerned that **HRSA lacks reasonable assurance that audits are appropriately identifying nongovernmental hospitals that may be participating in the 340B program** based on contracts that are inconsistent with program requirements or HRSA guidance..."* GAO continues to *"...believe that **allowing hospitals to fail to demonstrate that they meet the statutory requirement** of having contracts in place **to participate in the 340B program without consequences** undermines the effectiveness of HRSA's audit process and **increases the risk that ineligible hospitals will receive discounts under the program**"* (p. 21).

- **2020 GAO: 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement.** GAO-20-212. January 21, 2020.
  - The potential for duplicate discounts has increased due to several factors: substantial growth of the program and expansion of the Medicaid Drug Rebate Program (MDRP) due to the Affordable Care Act by requiring drug manufacturers to provide rebates for drugs provided under Medicaid Managed Care. Contract pharmacy participation has also **greatly increased from 1,300 to 23,000 (nearly 17-fold)** (p. 2).
  - *"**HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts**,"* (Executive Summary) which GAO stated *"not only puts drug manufacturers at risk of providing duplicate discounts, but also **compromises 340B program integrity**"* (p. 27)

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[111] Enacted in March 2022, the Consolidated Appropriations Act, 2022, allowed hospitals that were covered entities participating in the 340B Program on January 26, 2020, to request from HRSA a temporary exception to the 340B Program's DSH percentage eligibility requirement and continue participating in the program if they were unable to meet the requirement because of factors related to the COVID-19 public health emergency.

- **2019 GAO: 340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements.** GAO-20-108. December 11, 2019.
  - The number of non-governmental hospitals participating in the program has grown, more than tripling in the past decade (since 2009). As of 1/1/2019, nongovernmental hospitals account for more than 2/3 of the hospitals participating in the 340B program (p. 6).
  - After analyzing contract documentation for more than 250 private, nonprofit hospitals participating in the 340B program, GAO concluded that *"Given the weaknesses in HRSA's oversight,* ***some hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible****"* (p. 23). For example, GAO observed that 13 of the hospitals reviewed that currently participate in the 340B program had contracts with no requirement to provide care to low-income, vulnerable patients (Executive Summary).
  - *"HRSA's current processes and procedures do not provide reasonable assurance that nongovernmental hospitals seeking to participate and benefit from the 340B Program meet the program's eligibility requirements…****continued growth in the number of participating hospitals and 340B purchased drugs highlights the need for HRSA to improve its oversight processes.*** *This is critical to safeguarding the integrity of the 340B Program."* (p. 23).

- **2018 GAO: Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement.** GAO-18-480. June 21, 2018.
  - ***"HRSA does not have complete data on the total number of contract pharmacy arrangements in the 340B program to inform its oversight efforts****."* (p. 35)
  - HRSA does not require CEs to separately register contract pharmacies for each child site for which a contractual relationship exists. GAO states that given the data reviewed, it is possible there are as many as 866,388 contract pharmacy arrangements, which is higher than what is reported in HRSA's database (p. 20).
  - According to HRSA officials, because of these requirements, manufacturers do not have complete information on which CE sites have contracts with a pharmacy to dispense 340B drugs. (p. 36)
  - Hospitals were more likely than grantees to have at least one contract pharmacy arrangement (69.3% vs. 22.8%) (p. 16). Grantees had fewer contract pharmacies on average than DSH hospitals. At least one hospital had 439 contract pharmacy arrangements (p. 18).

- **2018 GAO: Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program.** GAO-18-521R. June 18, 2018.
  - In 2016, a much higher percentage of 340B general acute care hospitals (340B DSH) were teaching hospitals compared with their non-340B counterparts, whereas the same percentage of 340B and non-340B SCHs were teaching hospitals (p. 7).
  - ***"The median amount of charity care provided by all 340B hospitals in our analysis was similar to the median amount provided by all non-340B hospitals****"* (p. 7).

- **2016 OIG**: **State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates.** OIG-05-14-00430. June 6, 2016.
  - If a State does not accurately identify 340B drug claims, both duplicate discounts and forgone rebates—that is, unclaimed rebates to which States are legally entitled—may occur. Duplicate discounts result in manufacturers paying too much in rebates, while forgone rebates result in States paying too much for drugs (Executive Summary).
  - OIG continues to "*recommend that CMS require the use of claim-level methods to identify 340B claims. We believe that* ***claim-level methods can improve accuracy in identifying 340B claims, and thereby reduce the risk of duplicate discounts and forgone rebates***." (p. 18).

- **2015 GAO: Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.** GAO-15-442. June 5, 2015.
  - *"Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs, and the 340B statute does not restrict covered entities from using drugs purchased at the 340B discounted price for Medicare Part B*

beneficiaries. Consequently, ***there is a financial incentive at these hospitals to prescribe more drugs and more expensive drugs to Medicare beneficiaries in order to maximize the revenue*** *generated by the difference between the cost of the drug and Medicare's reimbursement"* (p. 29).

- *"On average, per beneficiary* ***Medicare spending on Part B drugs in 2008 and 2012 was substantially higher at 340B DSH hospitals compared with non-340B hospitals****—yet we did not find that these differences could be readily explained by hospital characteristics or patients' health status"* (p. 30).
  - *"The spending differences between 340B DSH hospitals and non-340B hospitals remained even after we accounted for teaching status, ownership type, or location (i.e., urban or rural). For example, among both teaching and nonteaching hospitals, average per beneficiary Part B drug spending was much higher at 340B DSH hospitals than at non-340B hospitals"* (p. 22).
  - *"Further,* ***these differences were not explained by the factors we examined that might disproportionately affect hospitals that treat higher proportions of low-income patients.*** *For example, among hospitals with high levels of charity care or high levels of uncompensated care, and among hospitals with a high DSH adjustment percentage—all indicators that these hospitals treat a higher proportion of low-income patients—Part B drug spending was much higher among 340B DSH hospitals in both 2008 and 2012"* (p. 24).
- ***"Congress should consider eliminating the incentive to prescribe more drugs or more expensive drugs than necessary to treat Medicare Part B beneficiaries at 340B hospitals"*** (Executive Summary).

- **2014 OIG**: **Contract Pharmacy Arrangements in the 340B Program** (OEI-05-13-00431) February 4, 2014.
  - *"Contract pharmacy arrangements create complications in preventing diversion, and covered entities are addressing these complications in different ways"* (p. 1). *"****There is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible"*** (p. 3).
  - *"Contract pharmacy arrangements create complications in preventing duplicate discounts"* (p. 3).
  - *"Some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies.* ***Neither the 340B statute nor HRSA guidance addresses whether covered entities must do so; however, if covered entities do not, uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies****... Of the 32 covered entities for which finalized HRSA audits resulted in adverse findings, 10 were cited for diversion and/or duplicate discounts through contract pharmacies"* (p. 2).
  - *"Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance"* (p. 2). *"****Without adequate oversight, the complications created by contract pharmacy arrangements may introduce vulnerabilities to the 340B Program****"* (p. 16).

- **2011 GAO: Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement.** GAO-11-836. September 23, 2011.
  - *"Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program. Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies"* (p. 28).
  - *"We found that* ***HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent.*** *Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance"* (p. 33).