

PRESCRIBING OVERSIGHT: STRENGTHENING HRSA’S AUDIT AUTHORITY IN THE 340B DRUG PRICING PROGRAM

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INTRODUCTION

The rising cost of prescription drugs continues to impose a significant burden on patients, providers, and the healthcare system.¹ In response to concerns that federal pricing policies were unintentionally increasing drug costs for safety-net providers—including hospitals and clinics that furnish a disproportionate share of care to low-income, uninsured, and medically underserved populations—Congress enacted the 340B Drug Pricing Program in 1992 as part of the Veterans Health Care Act.² The program was designed to allow certain hospitals and clinics serving low-income and underserved populations to purchase outpatient prescription drugs at deeply discounted prices, thereby enabling them to stretch limited resources and expand access to care for vulnerable patients.³

1. See, e.g., Sasha Guttentag, *Survey: More Than a Third of Americans Still Struggle to Afford Their Prescription Medications*, GOODRX [July 13, 2023], <https://www.goodrx.com/healthcare-access/research/medication-debt-survey-2023> [https://perma.cc/3LYC-5WSG] (asserting that over one-third of Americans have difficulty affording their prescription medications, resulting in financial debt or nonadherence to medical recommendations); Rachel Reed, *How Could Reducing Prescription Drug Prices Save Patients Money?*, HARV. L. TODAY (Dec. 11, 2024), <https://hls.harvard.edu/today/how-could-reducing-prescription-drug-prices-save-patients-money/> [https://perma.cc/M962-ZYT7] (reporting that “median launch prices of new drugs increased from just over \$2,000 per year in 2008 to \$180,000 per year in 2021”); *The 340B Hospital Markup Program Is Costing Taxpayers & Employers Billions*, PHRMA (Oct. 17, 2025), <https://phrma.org/resources/the-340b-hospital-markup-program-is-costing-taxpayers-employers-billions> [https://perma.cc/P4V3-68YJ].

2. Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 493, 4967; ANDREW W. MULCAHY, COURTNEY ARMSTRONG, JEFFREY LEWIS & SOEREN MATTKE, *THE 340B PRESCRIPTION DRUG DISCOUNT PROGRAM: ORIGINS, IMPLEMENTATION, AND POST-REFORM FUTURE*, RAND CORP. 1, 236 (2014); Ryan P. Knox & Ameet Sarpatwari, *The 340B Drug Pricing Program: Administration, Litigation, and Reform*, 77 OKLA. L. REV. 229, 235–36 (2025). See generally Bruce Siegel, Marsha Regenstein & Peter Shin, *Symposium Articles: Part II: Devising Solutions: Health Reform and the Safety Net: Big Opportunities; Major Risks*, 32 J.L. MED. & ETHICS 426 (2004) (describing the structure and challenges facing the safety-net).

3. 42 U.S.C. § 256b (2012); H.R. REP. NO. 102-384, pt. 2, at 12 (1992).

Since its enactment, the 340B Program has grown dramatically in size, scope, and economic significance.⁴ What began as a narrow remedial measure has evolved into one of the largest federal drug discount programs in the United States, with 340B drug purchases climbing to \$81.4 billion in 2024 and program sales increasing 129.4% from 2018 to 2023—more than three times the growth rate of non-340B drug sales.⁵ Participation has expanded across hospitals, clinics, and pharmacies, making 340B a critical source of financial support for many safety-net providers.⁶

The rapid expansion of the 340B Program is not an abstract policy issue—it is increasingly harming patients, employers, and taxpayers through higher costs and reduced access to care.⁷ For example, patients receiving routine oncology or infusion care at hospital-owned outpatient departments often pay far higher coinsurance than they would at an independent physician's office, even though the hospital acquired the drug at a steep discount.⁸ Independent research shows that drug spending per patient is nearly 200% higher at 340B hospitals compared to non-340B hospitals, a cost burden that ultimately falls on patients and taxpayers.⁹ Data indicates that abusive hospital behavior, including program overutilization and expansion of 340B eligibility far beyond the program's original safety-net intent, drives this

4. See Kolton Gustafson, Glynis Reede & Lisa Joldersma, *340B Purchase Data Highlights Continued Program Growth*, AVALERE HEALTH (Dec. 22, 2025), <https://advisory.avalere-health.com/insights/340b-purchase-data-highlights-continued-program-growth-2> [<https://perma.cc/3R2V-Q3R4>]; Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to \$124B in 2023*, IQVIA 2 (2024), <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-update-on-size-of-340b-program-report-2024.pdf> [<https://perma.cc/9E9R-KUPV>]; see also ELEANOR BLALOCK, MEASURING THE RELATIVE SIZE OF THE 340B PROGRAM: 2022 UPDATE, BERKELEY RSCH. GRP. 5 (2024) (“Even at the discounted 340B price, the 340B program is larger than all other federal drug programs considered, except for Medicare Part D.”).

5. See Gustafson et al., *supra* note 4; Martin & Karne, *supra* note 4.

6. See Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 WM & MARY L. REV. 637, 639 (2015); Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty*, 22 J. HEALTH CARE L. & POL'Y 25, 47, 64 (2019); Samuel Thomas & Kevin Schulman, *The Unintended Consequences of the 340B Safety-Net Drug Discount Program*, 55 HEALTH SERVS. RSCH. 153, 153–54 (2020).

7. See John Tozzi, Tanaz Meghhjani & Mathieu Benhamou, *One Generic Cancer Drug Costs \$35. Or \$134. Or \$13,000.*, BLOOMBERG (Dec. 17, 2025, at 17:00 ET), <https://www.bloomberg.com/features/2025-cancer-drug-markups> [<https://perma.cc/2U9D-SULB>].

8. *Id.*

9. See Eliza Maciag, *Data Shows Tax-Exempt Hospital Profit-Seeking Behavior, Not Drug Prices, Is Driving Explosive 340B Expansion*, PHRMA (Jan. 8, 2026), <https://phrma.org/blog/data-shows-tax-exempt-hospital-profit-seeking-behavior-not-drug-prices-is-driving-explosive-340b-expansion> [<https://perma.cc/GSG5-2MM8>].

growth.¹⁰ Covered entities routinely purchase medicines at deeply discounted 340B prices and then mark them up by thousands of dollars or more, with no requirement that the savings be passed on to patients.¹¹ Large, tax-exempt hospital systems are exploiting these margins by shifting care away from physician offices into more expensive hospital settings to boost revenue.¹² Because 340B hospitals enjoy a significant competitive advantage, the program incentivizes health systems to acquire independent physician practices and convert them into hospital outpatient departments, fundamentally distorting local health care markets.¹³ As competition diminishes and care migrates to higher-cost settings, prices rise across the system, helping to explain the growing impact on Medicaid spending and overall health care costs.¹⁴

At the same time, the program's rapid expansion has placed increasing strain on its statutory and administrative framework.¹⁵ The Health Resources and Services Administration (HRSA), the agency charged with administering the program, operates under the 340B statute, which provides only limited guidance on key operational questions and confers narrow enforcement authority.¹⁶ As the health care delivery system has become more consolidated and complex, these statutory constraints have increasingly limited HRSA's ability to ensure consistent and effective oversight.¹⁷ For

10. *Id.*

11. See Molly Jenkins, *CBO: 340B Program Costs Taxpayers, No Evidence Patients Benefit*, PHRMA (Sep. 10, 2025), <https://phrma.org/blog/cbo-340b-program-costs-taxpayers-no-evidence-patients-benefit> [<https://perma.cc/AE2G-245P>].

12. See ELEANOR BLALOCK & CARLEE LAUNSBACH, *SITE-OF-CARE SHIFT FOR PHYSICIAN-ADMINISTERED DRUG THERAPIES: 2026 UPDATE*, BERKELEY RSCH GRP. 4–6 (2026).

13. *Id.* at 2, 6; see Drew Voytal, *340B Spending Is Exploding, Forcing Prices Up for Patients, Employers and Government Programs*, PHRMA (Nov. 13, 2024), <https://phrma.org/blog/340b-spending-is-exploding-forcing-prices-up-for-patients-employers-and-government-programs> [<https://perma.cc/E298-MDRB>].

14. See Jenkins, *supra* note 11.

15. See Knox & Sarpatwari, *supra* note 2, at 234.

16. See *id.* (explaining that narrower readings statutory delegation of authority risks jeopardizing the program).

17. See U.S. GOV'T ACCOUNTABILITY OFF., *GAO-11-836, DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT* 21–28 (2011) [hereinafter *GAO 2011 REPORT*] (criticizing the program's lack of oversight, contending that the agency "cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk" because of its reliance on self-policing and nonspecific guidance); see also U.S. GOV'T ACCOUNTABILITY OFF., *GAO-18-480, DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT* 35 (2018) [hereinafter *GAO 2018 REPORT*] (discussing weaknesses in HRSA's oversight, including incomplete data on contract pharmacy

example, in the absence of clear statutory guidance or binding regulations, covered entities have adopted broad, and often self-serving, interpretations of who qualifies as a “patient.”¹⁸ These entities are able to claim 340B discounts for individuals with only tenuous connections to their clinical services or are not offering the 340B drugs to their uninsured patients because HRSA is currently conducting inefficient and insufficient audits.¹⁹ Covered entities generate revenue by purchasing drugs at 340B prices and then billing insurers or patients at standard, non-discounted reimbursement rates.²⁰ In pursuit of this, 340B hospitals are reportedly shifting the “site-of-care” to outpatient settings by acquiring independent physician offices.²¹ With no restrictions on how hospitals utilize the monetary margin created, this strategy enables them to increase revenue.²² This ambiguity has allowed large hospital systems to accrue millions of dollars in 340B revenue, often without evidence that those savings are reinvested in indigent care.²³ At the same time,

arrangements in the 340B Program, deficiencies in its audit process, and insufficient guidance for covered entities overseeing contract pharmacies).

18. See Thomas & Schulman, *supra* note 6; Fisher, *supra* note 6, at 27; see also Sally Greenberg, *Unveiling the Flaws in the 340B Drug Pricing Program: Hospitals, Medical Debt, and Consumer Struggles*, NAT'L CONSUMERS LEAGUE (Sep. 18, 2023), <https://nclnet.org/340b-drug-pricing-program-flaws/> [<https://perma.cc/G4CF-VZ6Y>] (describing how hospitals keep discounts as profit while overcharging patients and aggressively pursuing medical debt collection, ultimately harming consumers instead of helping them).

19. See U.S. GOV'T ACCOUNTABILITY OFF., GAO-26-108784, 340B DRUG DISCOUNT PROGRAM: AGENCY OVERSIGHT HAS IMPROVED, BUT ACTIONS NEEDED TO ADDRESS WEAKNESSES 11–12 (2025) [hereinafter GAO 2025 REPORT]; e.g., Memorandum from Stuart Wright, Deputy Inspector Gen. for Evaluation & Inspections, on Contract Pharmacy Arrangements in the 340B Program to Mary K. Wakefield, Adm'r, Health Res. & Servs. Admin. 14–15 (Feb. 4, 2014) <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf> [<https://perma.cc/2323-B2FN>].

20. See Knox & Sarpatwari, *supra* note 2, at 239.

21. See BLALOCK & LAUNSBACH, *supra* note 12, at 2.

22. See *id.* at 6.

23. See, e.g., Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 NEW ENG. J. MED. 539, 546 (2018) (finding no evidence that hospitals invest 340B profits into safety-net care); Anthony M. DiGiorgio & Wayne Winegarden, *Reforming 340B to Serve the Interests of Patients, Not Institutions*, JAMA HEALTH F., July 2024, at 1 (finding that some evidence shows participating hospitals devote fewer resources to underserved populations than non-participating ones, documentation of expansion into wealthier neighborhoods, and contract pharmacy growth may steer the benefits to more commercially insured patients). But see Caryn Levite Marshall, Comment, *Exacerbating Ambiguity: Why the Final 340B Administrative Dispute Resolution Rule Is a Distraction from Needed Reform*, 53 SETON HALL L. REV. 1743, 1753 (2023) (“Program growth is not in itself a bad thing.”).

patients may continue to face high coinsurance or out-of-pocket costs, undermining the 340B statute's central purpose.²⁴

As a result, the 340B Program has become the subject of sustained scrutiny from Congress, courts, oversight agencies, and industry stakeholders.²⁵ The legislative intent behind the 340B Program is clear: to protect and strengthen safety-net providers and to ensure that indigent populations receive affordable care.²⁶ Yet, due to statutory ambiguities and HRSA's limited enforcement authority, the program has strayed from its original purpose.²⁷ Questions persist as to who should benefit from 340B discounts, how savings should be allocated, and whether the program continues to serve its intended populations.²⁸ Judicial decisions have repeatedly emphasized that HRSA's authority is confined to the powers expressly delegated by Congress, restricting the agency's ability to clarify statutory ambiguities or adapt the program through rulemaking.²⁹

24. See Thomas & Schulman, *supra* note 6, at 154. Nicholas C. Fisher articulated the current landscape:

As drug manufacturers and covered entities attempt to out-strategize one another, the patient is the one who ends up suffering. Although patients benefit from the program as covered entities provide additional services and uncompensated care, indigent patients are harmed by significant increases in the cost of medications or insurance premiums. However, given the inelastic demand of health care, one has to assume that patients would not prefer the increase but are willing to accept the tradeoff for services that may be lifesaving.

Fisher, *supra* note 6, at 64–65.

25. Congress has conducted hearings with more frequency as the program continues to expand dramatically. See, e.g., *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Com.*, 114th Cong. (2015); *Perspectives on the 340B Drug Pricing Program: Hearing Before the Comm. on Health, Educ., Lab., & Pensions*, 115th Cong. (2018); *The 340B Program: Examining Its Growth and Impact on Patients: Hearing Before the Comm. on Health, Educ., Lab., & Pensions*, 119th Cong. (2025). Federal courts have also weighed in as increasing issues with interpretations arise. See *infra* Part II.B. The U.S. Government Accountability Office (GAO) has also made numerous recommendations to HRSA. See, e.g., GAO 2025 REPORT, *supra* note 19, at 9–10, 14–15; GAO 2018 REPORT, *supra* note 17, at 46; GAO 2011 REPORT, *supra* note 17, at 34–35. Industry stakeholders have competing interests and participate in the debate at varying levels, with national, for-profit pharmacies dominating. See Marshall, *supra* note 23, at 1752.

26. H.R. REP. NO. 102-384, pt. 2, at 12 (1992).

27. See, e.g., Peter B. Bach & Rachel E. Sachs, *Expansion of the Medicare 340B Payment Program: Hospital Participation, Prescribing Patterns and Reimbursement, and Legal Challenges*, 320 JAMA 2311, 2311–12 (2018); Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities*, 33 HEALTH AFFS. 1786, 1789–91 (2014).

28. See Baer, *supra* note 6, at 648 (emphasizing the immediate problems of an ambiguous “definition of [] patient” and the profiteering of certain covered entities).

29. See HANNAH-ALISE ROGERS, CONG. RSCH. SERV., R48696, THE 340B DRUG DISCOUNT PROGRAM: LITIGATION TOPICS AND TRENDS 35–37 (2025).

Consequently, program oversight and enforcement rely heavily on nonbinding guidance documents and voluntary compliance, raising concerns about program legitimacy and transparency.³⁰

This Comment argues that statutory ambiguity and constrained administrative authority have eroded the 340B Program's fidelity to congressional intent and proposes reforms to restore the program's integrity. Part I reviews the statutory and legislative foundations of the 340B Program.³¹ Part II analyzes the limits of HRSA's current enforcement authority and the impact of judicial constraints on program administration.³² Part III proposes targeted reforms focused on audit-based enforcement and incentive-driven compliance that would strengthen oversight within existing legal limits while preserving the program's core mission.³³ Ultimately, this Comment argues that recalibrating oversight mechanisms is essential to ensuring that the 340B Program continues to function as a tool for expanding access to care for low-income and underserved populations.

I. OVERVIEW OF THE 340B PROGRAM

A. *Congressional Intent in Enacting the 340B Program*

Congress established the 340B Drug Pricing Program as part of the Veterans Health Care Act of 1992³⁴ to address a pricing issue caused by the Medicaid Drug Rebate Program.³⁵ Prior to that time, pharmaceutical manufacturers regularly offered voluntary discounts to safety-net providers such as public hospitals and community clinics.³⁶ The enactment of the Medicaid Drug Rebate Program in 1990 required manufacturers to offer Medicaid their "best price," which led manufacturers to withdraw the voluntary discounts previously extended to safety-net providers.³⁷ Without those discounts, safety-net providers and their

30. See GAO 2025 REPORT, *supra* note 19, at 9–15; see also Knox & Sarpatwari, *supra* note 2, at 277 (arguing that "reforms must be implemented in ways that support the future of the program and that do not raise additional concerns that could threaten the sustainability, legitimacy, and ongoing existence of the 340B Program").

31. See *infra* Part I.

32. See *infra* Part II.

33. See *infra* Part III.

34. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 340B, 106 Stat. 4943, 4967–71 (codified as amended at 42 U.S.C. § 256b (2015)).

35. H.R. REP. NO. 102-384, pt. 2, at 11–12 (1992).

36. See MULCAHY ET AL., *supra* note 2, at 5.

37. *Id.*; Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388-143.

patients were faced with increased prescription drug costs.³⁸ And so, two years later, Congress created the 340B Program to remedy this problem.³⁹

Congress designed the program to help hospitals and clinics serving low-income and underserved populations “stretch scarce [f]ederal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”⁴⁰ As the House Report accompanying the Veterans Health Care Act explained, the program sought to ensure that “[f]ederally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans” could access drug discounts without compromising financial stability.⁴¹ Congress clearly intended the program to benefit entities providing direct care to low-income and uninsured individuals, not to serve as a general revenue-generation mechanism for hospitals.⁴² The program permits certain hospitals and clinics that serve low-income and underserved populations to purchase prescription drugs at discounted prices and to use the revenue generated from those purchases to subsidize operational costs.⁴³ In doing so, the 340B Program enables qualifying hospitals and clinics to reach more indigent patients and to provide expanded and specialized services.⁴⁴

B. Program Administration and Eligibility Requirements

Congress tasked HRSA with administering the program by entering into pharmaceutical pricing agreements (PPAs) with manufacturers, developing the certification process for covered entities, establishing the Prime Vendor Program, notifying manufacturers and state agencies of participating entities, and establishing audit procedures to identify noncompliance and require repayment of overcharges or underpayments.⁴⁵ The Affordable Care Act later

38. See MULCAHY ET AL., *supra* note 2, at 5. See generally Siegel et al., *supra* note 2 (summarizing the history and scope of care provided by safety-net providers).

39. See H.R. REP. NO. 102-384, pt. 2, at 12.

40. *Id.*

41. *Id.*

42. See *id.*; see also Peter J. Pitts & Robert Popovian, *340B and the Warped Rhetoric of Healthcare Compassion*, FOOD & DRUG L. INST. UPDATE MAG., Fall 2022 (highlighting that hospitals generating substantial revenue are spending less on charity and community reinvestment).

43. Knox & Sarpatwari, *supra* note 2, at 229, 232–33.

44. See *340B at a Glance*, 340B HEALTH, https://www.340bhealth.org/files/340B_At_A_Glance.pdf [<https://perma.cc/3GL8-2ZEU>] (last visited Apr. 16, 2026) (advocating that 340B savings serve “uninsured, underinsured, or [patients] on Medicaid . . . enabl[ing] a wide range of services, including free or heavily discounted prescription drugs, trauma care, care for HIV/AIDS, and treatment for opioid and other substance use disorders”).

45. 42 U.S.C. § 256b(a)(1), (a)(7), (a)(8), (a)(5)(C)–(D).

strengthened the program by requiring HRSA to establish an administrative dispute resolution process, issue regulations on civil monetary penalties, and develop mechanisms for specified improvements to compliance related to overcharges and pricing violations.⁴⁶

The program applies to manufacturers participating in Medicaid and manufacturers who opt in.⁴⁷ Under the statutory framework, drug manufacturers that participate in Medicaid must sell outpatient drugs to eligible covered entities, qualifying hospitals, and clinics at substantial upfront discounts.⁴⁸ The 340B Program is restricted to outpatient prescription drugs and does not include bundled payments for inpatient care.⁴⁹ Additionally, drugs prescribed for rare diseases, known as orphan drugs, are excluded from the program following the Affordable Care Act expansion.⁵⁰

Participation eligibility is determined by the characteristics of the hospital or clinic, not by individual patients.⁵¹ These covered entity categories include six hospital categories and multiple federal grantee categories.⁵² Hospital covered entities include disproportionate share hospitals, critical access hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals.⁵³ Federal grantee covered entities include federally-qualified health centers (FQHCs) and other statutorily specified clinics and programs.⁵⁴

46. 42 U.S.C. § 256b(d)(3)(A), (d)(1)(B)(vi), (d)(1)(A); *see, e.g.*, Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 18001).

47. MULCAHY ET AL., *supra* note 2, at 2.

48. Knox & Sarpatwari, *supra* note 2, at 236. These discounts allow patients-in-need to receive brand name drugs at a fraction of the cost. *Id.* at 237.

49. *See* MULCAHY ET AL., *supra* note 2, at 9.

50. *Id.* at 10.

51. *Id.* at 2–3 (noting that not all patients receiving care at a covered entity can receive 340B drugs).

52. *See 340B Eligibility*, HEALTH RES. & SERVS. ADMIN., <http://www.hrsa.gov/opa/eligibilityandregistration/index.html> [<https://perma.cc/GK8J-PSG6>] (last updated June 2024).

53. 42 U.S.C. § 256b(a)(4). All hospital covered entities, except for critical access hospitals, have an additional disproportionate share hospital (DSH) adjustment percentage requirement for eligibility. MULCAHY ET AL., *supra* note 2, at 3. The percentage “varies based on the type of hospital and is used as a stand-in measure to identify low-income communities.” Marshall, *supra* note 23, at 1747.

54. These include federally-qualified health centers (FQHCs) and FQHC look-alikes, clinics receiving funds to treat sexually transmitted diseases, clinics receiving funds to treat tuberculosis, clinics receiving grants for outpatient early HIV/AIDS intervention services, comprehensive hemophilia diagnostic treatment centers, family planning clinics, black lung clinics, health centers for residents of public housing, Native Hawaiian health centers, Ryan White HIV/AIDS program grantees, state AIDS drug purchasing assistance programs, and tribal and urban Indian organizations. *See* 42 U.S.C. § 256b(a)(4).

Covered entities may dispense purchased drugs at an in-house pharmacy or a separate “contract pharmacy.”⁵⁵ Covered entities purchase the discounted drugs, next the drugs are delivered to covered entities’ contract pharmacies, and these contract pharmacies then dispense the discounted drugs to patients of the covered entity.⁵⁶ Although entities purchase drugs at discounted prices, they may bill insurers or patients at standard reimbursement rates and retain the difference as revenue.⁵⁷

Two statutory restrictions govern covered entity participation in the 340B program. First, entities may not engage in duplicate discounting by purchasing drugs at 340B prices while also triggering Medicaid rebates.⁵⁸ Second, covered entities may not divert 340B drugs to ineligible patients.⁵⁹ These restrictions are intended to maintain the integrity of the program and ensure that discounted drugs benefit the populations Congress sought to support.⁶⁰ HRSA can enforce these rules through its oversight and audit procedures.⁶¹

C. Audit and Oversight Procedures for Covered Entities and Manufacturers

HRSA conducts audits to ensure that covered entities and drug manufacturers comply with statutory program requirements.⁶² Audits of covered entities typically assess whether they meet eligibility requirements, maintain accurate policies and procedures, and comply with program rules such as preventing duplicate discounts and diversion.⁶³ These audits frequently include a review of a sample of prescriptions filled over a six-month period, as well as annual recertification and other program checks to ensure ongoing

55. Knox & Sarpatwari, *supra* note 2, at 238–39; *see also* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (allowing covered entities “to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts”).

56. *See* Knox & Sarpatwari, *supra* note 2, at 239 (citing Ryan P. Knox, Aaron S. Kesselheim & Ameet Sarpatwari, *Risks to the 340B Drug Pricing Program Related to Manufacturer Restrictions on Drug Availability*, 327 JAMA 1647, 1647–48 (2022)).

57. *See id.*

58. 42 U.S.C. § 256b(a)(5)(A).

59. *Id.* § 256b(a)(5)(B).

60. *See* Health Mgmt. Assocs., *340B Duplicate Discounts: Enforcement Inconsistent and Weak Due to Lack of Data Transparency and Despite Federal Prohibition 2* (2025), https://www.healthmanagement.com/wp-content/uploads/HMA_340BDuplicateDiscounts_Feb2025v2.pdf [<https://perma.cc/RNN8-KBLA>] (finding that duplicate discounting could cause financial instability by requiring drug manufacturers to provide two discounts on the same sale, potentially undermining their revenue).

61. 42 U.S.C. § 256b(a)(5)(C).

62. *Program Integrity*, HEALTH RES. & SERVS. ADMIN. (Apr. 2026), <https://www.hrsa.gov/opa/program-integrity> [<https://perma.cc/NXE9-34R4>].

63. *See* GAO 2025 REPORT, *supra* note 19, at 9–10.

adherence to federal requirements.⁶⁴ When an audit targets a covered entity at the request of a manufacturer, HRSA notifies the entity, requests relevant documents and records, and examines policies, internal controls, and sampled prescriptions for potential noncompliance.⁶⁵ If HRSA identifies areas of noncompliance, it communicates preliminary findings to the entity and requires the submission of a corrective action plan (CAP).⁶⁶ The entity must submit a CAP outlining the scope of the noncompliance, steps for remediation, and timelines for implementation.⁶⁷ HRSA closes the audit after the entity attests that it implemented its CAP, although HRSA does not verify that the entity has fully corrected every instance of noncompliance before closing the audit.⁶⁸

HRSA also audits drug manufacturers to ensure compliance with statutory 340B pricing requirements.⁶⁹ Manufacturers must offer covered outpatient drugs to registered covered entities at or below the 340B ceiling price.⁷⁰ Auditors review policies, internal controls, and a sample of sales transactions to determine adherence to the statute.⁷¹ If HRSA identifies noncompliance, manufacturers must submit a CAP within 60 days.⁷² HRSA closes the audit once the manufacturer confirms that the CAP has been fully implemented and any required repayment to covered entities has been completed.⁷³

HRSA audits provide a structured mechanism for monitoring compliance and documenting program operations; however, the current implementation highlights how HRSA's limited authority constrains enforcement and leaves significant gaps in oversight.⁷⁴

II. HRSA'S LIMITED AUTHORITY AND ONGOING CHALLENGES

A. Statutory Constraints: Patient Definition, Orphan Drugs, and Contract Pharmacies

Congress limited HRSA's enforcement authority to a few narrowly defined areas, which constrains the agency's ability to effectively regulate and

64. See *id.* at 10.

65. *Id.* at 10–11, 11 n.21 (highlighting the difference in audit requirements between targeted and randomly selected audits); see *Program Integrity*, *supra* note 62.

66. GAO 2025 REPORT, *supra* note 19, at 10.

67. *Id.* at 10–11.

68. *Id.* (noting that the process “does not require most audited covered entities to provide documentation that they implemented their corrective action plans prior to HRSA closing the audits”).

69. *Program Integrity*, *supra* note 62.

70. 42 U.S.C. § 256b(a)(1).

71. See *Program Integrity*, *supra* note 62.

72. *Id.*

73. *Id.*

74. See GAO 2025 REPORT, *supra* note 19, at 10.

administer the program.⁷⁵ While HRSA is obligated to administer pharmaceutical pricing agreements, certify covered entities, and conduct audits, it lacks general rulemaking authority to define patient eligibility, regulate contract pharmacy arrangements, or otherwise clarify program obligations.⁷⁶ HRSA's attempts to regulate beyond its express statutory authority have frequently been challenged in court and consistently struck down.⁷⁷ These limitations have created persistent ambiguity in program implementation, which has left certain areas—patient eligibility, drug distribution, and contract pharmacy arrangements—particularly vulnerable to exploitation.⁷⁸ These gaps directly weaken HRSA's ability to monitor the program for statutory compliance.⁷⁹

The statute's failure to define "patient" has proven particularly problematic. HRSA's 1996 guidance attempted to fill this gap by requiring an established clinical relationship between the individual and the covered entity.⁸⁰ The guidance stated that only individuals that receive a range of health care services beyond prescription drugs, and who have "established a relationship" with the covered entity (i.e., the covered entity maintains the patient's health record) are eligible to receive 340B-purchased drugs.⁸¹ The agency adopted this definition to prevent diversion of 340B-purchased drugs to patients who do not receive outpatient health care services from a covered entity.⁸² Notably, the guidance does not impose patient eligibility criteria based on financial need or insurance status, meaning individuals with private or public health insurance may also qualify and access 340B-purchased drugs alongside uninsured and indigent patients.⁸³ Federal courts have consistently rejected attempts to enforce this guidance as binding law.⁸⁴ As a result, covered entities have adopted expansive interpretations of patient eligibility, sometimes claiming discounts for individuals with minimal clinical connections to the entity.⁸⁵ This statutory silence has enabled broad and inconsistent interpretations, allowing large hospital systems and

75. See generally 42 U.S.C. § 256b (outlining statutory limitations and HRSA's role in overseeing the program).

76. Knox & Sarpatwari, *supra* note 2, at 244–45.

77. See *infra* Part II.B.

78. See Fisher, *supra* note 6, at 64.

79. See GAO 2025 REPORT, *supra* note 19.

80. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157 (Oct. 24, 1996).

81. *Id.*

82. See GAO 2011 REPORT, *supra* note 17, at 11–12.

83. *Id.* at 2 & n.6.

84. See *infra* Part II.B.

85. Knox & Sarpatwari, *supra* note 2, at 241.

contract pharmacies to profit from 340B discounts without ensuring that savings benefit low-income patients.⁸⁶

The 340B statute excludes orphan drugs, e.g., medications designed to treat rare diseases, from discounted pricing for most covered entities, a restriction later reinforced by the Affordable Care Act.⁸⁷ HRSA issued a rule providing that covered entities could only purchase orphan drugs at the 340B discount for such drugs that are “transferred, prescribed, sold, or otherwise used for the rare condition or disease for which that orphan drug was designated under.”⁸⁸ While the intent of this exclusion was to preserve incentives for the development of treatments for rare conditions, it has introduced additional compliance challenges.⁸⁹ Covered entities that purchase orphan drugs for non-orphan indications must carefully track usage to avoid program violations, but there is no requirement for pharmacies to know at the point of sale why a drug was administered.⁹⁰

Contract pharmacy arrangements allow covered entities to dispense 340B drugs through third-party pharmacies, expanding patient access but also complicating program oversight.⁹¹ Despite the program’s expansion to allow these arrangements, HRSA does not have explicit authority to regulate the contractual terms or operations of these pharmacies, limiting the agency’s ability to monitor compliance effectively as the program continues to grow.⁹² Between 2010 and 2021, the number of contract pharmacies surged, growing from 1,300 pharmacies in 2010 to nearly 28,000 pharmacies by 2021.⁹³ This rapid expansion has opened the door for exploitation and program noncompliance, as HRSA does not require covered entities to register each site of a contract pharmacy arrangement, nor does the agency impose restrictions that would mandate frequent or any form of oversight of each site to ensure compliance.⁹⁴ Covered entities and their contract pharmacies may interpret patient eligibility and drug distribution rules broadly, leading to inconsistent

86. See U.S. GOV’T ACCOUNTABILITY OFF., GAO-20-212, 340B DRUG DISCOUNT PROGRAM: OVERSIGHT NEEDS IMPROVEMENT 26 (2020); GAO 2011 REPORT, *supra* note 17, at 29.

87. 42 U.S.C. § 256b(e).

88. Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 78 Fed. Reg. 44,016, 44,027 (July 23, 2013).

89. See Knox & Sarpatwari, *supra* note 2, at 248.

90. *Id.* (flagging that contract pharmacies may find it difficult in practice to differentiate proper designation with an improper designation).

91. *Id.* at 254 (emphasizing that “community pharmacies,” who participate in these arrangements “make receiving prescription drugs more convenient for patients”).

92. See, e.g., Sanofi-Aventis U.S. LLC v. U.S. Dep’t of Health & Hum. Servs., 58 F.4th 696, 706 (3d Cir. 2023).

93. Knox & Sarpatwari, *supra* note 2, at 255 (citation omitted).

94. GAO 2025 REPORT, *supra* note 19, at 13.

application of 340B discounts.⁹⁵ Without stronger regulatory control and more robust monitoring, the 340B program risks being undermined in its mission to provide affordable medications to underserved populations.

B. Judicial Constraints on HRSA's Enforcement Authority

Federal courts have consistently emphasized that HRSA's authority in administering the 340B Program is strictly limited by statute. While Congress delegated specific responsibilities to HRSA, it did not grant broad rulemaking authority.⁹⁶ Courts have repeatedly rejected attempts to expand HRSA's regulatory reach beyond the statute, emphasizing that significant programmatic changes must come from Congress, not the agency.⁹⁷ A central theme in 340B judicial decisions is the limitation of HRSA's authority when the statute is silent on key operational aspects of the program, particularly patient eligibility, drug distribution, and contract pharmacy arrangements.⁹⁸

Patient eligibility is a key area where courts have imposed limits on HRSA's authority. In *Genesis Healthcare, Inc. v. Becerra*,⁹⁹ the District Court for the District of South Carolina ruled that HRSA cannot extend the 340B Program by broadly interpreting patient eligibility beyond the statute's explicit terms.¹⁰⁰ Specifically, the court held that HRSA's attempt to redefine "patient" extended the agency's statutory power.¹⁰¹ This ruling highlights the broader judicial trend of restricting HRSA's ability to expand the 340B Program beyond the scope defined by Congress.¹⁰²

Courts have also imposed clear limits on HRSA's authority over contract pharmacy arrangements. In *Sanofi-Aventis U.S. LLC v. United States Department of Health & Human Services*,¹⁰³ the Third Circuit invalidated HRSA's attempt to require manufacturers to accommodate specific distribution

95. See generally ROGERS, *supra* note 29, at 3–5 (discussing litigation challenges regarding contract pharmacy use).

96. See, e.g., *Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28, 40 (D.D.C. 2014). For an agency to promulgate legislative rules, i.e., legally binding regulations, Congress must provide the agency with that authority via statute. *United States v. Mead*, 533 U.S. 218, 226–27 (2001).

97. See, e.g., *Sanofi-Aventis*, 58 F.4th at 699, 704, 707; *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459–63 (D.C. Cir. 2024).

98. See ROGERS, *supra* note 29, at 3.

99. 701 F. Supp. 3d 312 (D.S.C. 2023).

100. *Id.* at 324 (finding that HRSA's "patient" definition was "contrary to the plain language of the 340B statute").

101. *Id.* at 330.

102. See ROGERS, *supra* note 29, at 3–5.

103. 58 F.4th 696 (3d Cir. 2023).

arrangements.¹⁰⁴ The court found that the statute did not grant HRSA the power to regulate such practices.¹⁰⁵ It found the enforcement letter to be “arbitrary and capricious” under the Administrative Procedure Act, clarified that the statute’s use of the word “offer” does not obligate manufacturers to deliver drugs to any covered entity at any time, and noted that manufacturers may impose reasonable conditions on their offers.¹⁰⁶ This ruling highlighted that Congress may have anticipated contract pharmacy arrangements only for entities lacking in-house pharmacies.¹⁰⁷

The D.C. Circuit’s decision in *Novartis Pharmaceuticals Corp. v. Johnson*¹⁰⁸ reinforced this limitation.¹⁰⁹ The court held that HRSA overstepped its enforcement authority because the statutory silence regarding contract pharmacy and deliveries “preserves” the ability of manufacturers to impose conditions on covered entities’ contract pharmacy use.¹¹⁰ The court clarified that the 340B statute does not address drug delivery or distribution to patients.¹¹¹ This decision concluded that HRSA lacked the authority to impose requirements on manufacturers in the area where the statute is silent.¹¹²

The Supreme Court’s ruling in *Astra USA, Inc. v. Santa Clara County*¹¹³ further clarified the limited scope of enforcement under the 340B Program.¹¹⁴ The Court held that the statute does not provide a private right of action, meaning that private entities, such as covered entities or whistleblowers, cannot use external legal mechanisms to enforce compliance with 340B pricing requirements.¹¹⁵ The Court reasoned that Congress chose not to include a private right of action in the statute and chose to strengthen HRSA’s enforcement authority through the Affordable Care Act.¹¹⁶ This decision reinforced the idea that only HRSA can enforce the statute’s provisions.¹¹⁷

104. *Id.* at 706.

105. *See id.* at 703 (stating that the agency’s interpretation should be followed only to the extent that it had the “power to persuade” (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944))).

106. *Id.* at 703, 706–07.

107. *Id.* at 706.

108. 102 F.4th 452 (D.C. Cir. 2024).

109. *See id.* at 464.

110. *Id.* at 460.

111. *Id.*

112. *See id.* at 464.

113. 563 U.S. 110 (2011).

114. *Id.* at 121.

115. *Id.* at 117–18.

116. *Id.* at 118, 121–22.

117. *See id.* at 121; *see also* *Mosaic Health, Inc. v. Sanofi-Aventis U.S. LLC*, 156 F.4th 68, 78–79 (2d Cir. 2025) (affirming that HRSA lacks authority to infer powers not grounded in the statutory text and that the statute does not provide a private right of action); *AIDS Healthcare Found. v. Apexus*,

In *Pharmaceutical Research & Manufacturers of America v. United States Department of Health & Human Services*,¹¹⁸ the District Court for the District of Columbia reinforced the narrow scope of HRSA's rulemaking authority.¹¹⁹ The court ruled that Congress did not delegate broad rulemaking power over the 340B Program to HRSA.¹²⁰ It emphasized that HRSA's authority is limited to areas explicitly enumerated in the statute, such as establishing an administrative dispute resolution process and defining ceiling-price methodologies.¹²¹ This decision further underscores the principle that HRSA's regulatory reach is constrained by the specific powers granted by Congress.

Judicial constraints further highlight the practical consequences of HRSA's limited authority. The Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*¹²² eliminated substantial judicial deference, specifically *Chevron* deference, to agency interpretations of ambiguous statutes.¹²³ Without *Chevron* deference, HRSA's informal guidance documents attempting to clarify statutory ambiguities, such as the definition of a "patient," carry limited legal weight.¹²⁴ As a result, HRSA is left dependent on audits and voluntary compliance to enforce program rules.

C. Auditing Challenges and Compliance Gaps in the 340B Program

The Government Accountability Office (GAO) has repeatedly warned that statutory ambiguity undermines 340B's program integrity.¹²⁵ Since 2015, HRSA has only audited approximately 200 covered entities per year, and as the number of covered entities has increased, the percentage of entities audited has steadily declined, reaching just 0.33% in 2024.¹²⁶ Although

LLC, No. 22-8450, 2023 WL 3149268, at *2 (C.D. Cal. Apr. 10, 2023) (holding that enforcement must remain with HRSA, and that private parties cannot sue manufacturers for alleged 340B violations).

118. 43 F. Supp. 3d 28 (D.D.C. 2014).

119. *Id.* at 40.

120. *Id.*

121. *Id.* at 41.

122. 603 U.S. 369 (2024).

123. *Id.* at 412.

124. *See id.* at 431–32 (recalling that “courts may extend respectful consideration to another branch’s interpretation of the law, but the weight due those interpretations must always ‘depend upon the[ir] thoroughness . . . , the validity of [their] reasoning, [their] consistency with earlier and later pronouncements, and all those factors which give [them] power to persuade’” (alterations in original) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944))).

125. U.S. GOV’T ACCOUNTABILITY OFF., GAO-20-212, 340B DRUG DISCOUNT PROGRAM: OVERSIGHT NEEDS IMPROVEMENT 26 (2020).

126. *ADVI Analysis: HRSA 340B Covered Entity Audits*, ADVI (Mar. 10, 2025), <https://www.advi.com/insight/advi-analysis-hrsa-340b-covered-entity-audits> [<https://perma.cc/Z9JN-HD4K>].

audit data reveals high rates of noncompliance, including statutory noncompliance with diversion and duplicate discounting, the volume of audits remains small relative to the number of participating entities.¹²⁷ This limited enforcement capacity is incompatible with the program's rapid growth and increasing complexity.¹²⁸

HRSA's early reliance on self-policing by covered entities and manufacturers further weakened oversight.¹²⁹ From the program's inception until 2012, HRSA did not conduct any audits.¹³⁰ Between 2012 and 2020, HRSA performed only 1,242 audits, a small fraction of the roughly 50,000 participating covered entities.¹³¹ GAO's findings from 2012 to 2016 revealed high noncompliance rates ranging from 63 to 82%.¹³² GAO concluded that more than one-third of audited entities uncovered violations relating to diversion, duplicate discounting, or eligibility violations.¹³³

These findings highlight that HRSA's current enforcement regime is insufficient to deter ongoing violations or meaningfully address the exploitation of the 340B Program. In response to GAO's 2018 report on HRSA's inadequate oversight, the agency began conducting selective compliance audits.¹³⁴ However, even with this change, audit results can take months to complete from start to finish.¹³⁵ Despite this authority, HRSA's current enforcement framework remains underdeveloped.¹³⁶ Audit selection relies heavily on random sampling, with relatively few audits triggered by tips, complaints, data analytics, or prior findings.¹³⁷ GAO has noted that HRSA requires only covered entities subjected to targeted audits to document their methodology for assessing noncompliance and to provide evidence that their corrective action plan has been implemented.¹³⁸ Additionally, HRSA audits covered entities far more frequently than manufacturers, creating a

127. *Id.*

128. See Marshall, *supra* note 23, at 1754 ("If the program were smaller, those 200 audits would constitute much more meaningful program oversight.").

129. Mulcahy et al., *supra* note 2, at 7.

130. Knox & Sarpatwari, *supra* note 2, at 267.

131. *Id.*; see Marshall, *supra* note 23, at 1761.

132. Knox & Sarpatwari, *supra* note 2, at 268.

133. *Id.* (citing U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-107, DRUG PRICING PROGRAM: HHS USES MULTIPLE MECHANISMS TO HELP ENSURE COMPLIANCE WITH 340B REQUIREMENTS 3, 13–14 (2020)).

134. GAO 2025 REPORT, *supra* note 19, at 11.

135. See *A HRSA Audit Guidebook*, 340B REPORT (Sep. 19, 2024), <https://340breport.com/a-hrsa-audit-guidebook-cps-sponcon/> [<https://perma.cc/XZ8E-CJU8>].

136. See Fisher, *supra* note 6, at 70.

137. See *id.* at 38; GAO 2025 REPORT, *supra* note 19, at 11.

138. GAO 2025 REPORT, *supra* note 19, at 11 n.21.

perceived enforcement imbalance that undermines confidence in program administration.¹³⁹ These inconsistent audit standards, variable documentation requirements, and prolonged resolution timelines weaken the corrective and deterrent effect of audits.¹⁴⁰

HRSA encourages entities to conduct internal audits, but the varied methods used by covered entities and contract pharmacies to track 340B-purchased drugs create significant inconsistencies in monitoring and reporting.¹⁴¹ These enforcement deficiencies perpetuate compliance gaps and enable large hospital systems to leverage 340B discounts to generate substantial revenue while offering unclear benefits to patients.¹⁴² Some studies suggest that patients treated at 340B hospitals may face higher out-of-pocket costs, while smaller or rural providers struggle to compete with integrated systems that use 340B savings to expand market share.¹⁴³ HRSA's limited

139. See *Trends in Audit Findings for 340B Hospitals and Drug Companies*, AM. HOSP. ASSOC. (June 2025), <https://www.aha.org/system/files/media/file/2025/06/More-Drug-Company-Oversight-Needed-to-Maintain-Compliance-with-340B-Program-Rules.pdf> [<https://perma.cc/342F-RND2>].

140. See ADVI, *supra* note 126 (lack of clarity in what standards HRSA uses to audit); Lowell M. Zeta, *Comprehensive Legislative Reform to Protect the Integrity of the 340B Drug Discount Program*, 70 FOOD DRUG L.J. 481, 488–89 (2015) (HRSA's guidelines opens opportunity for variable documentation expectations); GAO 2025 REPORT, *supra* note 19, at 11 (closed audits before confirmation noncompliance was addressed).

141. See *340B Eligibility*, *supra* note 52; Memorandum from Stuart Wright, *supra* note 19, at 9–15.

142. See Bach & Sachs, *supra* note 27, at 2312.

143. See, e.g., James C. Robinson, Christopher Whaley & Sanket S. Dhruva, *Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance*, 390 NEW ENG. J. MED. 338, 338 (2024) (showing that 340B hospitals “imposed large price markups and retained a substantial share of total insurer spending on physician-administered drugs for patients with private insurance”); Jianhui Hu & David R. Nerenz, *Outpatient Chemotherapy Drug Costs and Expensive Chemotherapy Drug Use in 340B and Non-340B Hospitals: An Observational Study*, 25 BMC HEALTH SERV. RSCH. 157, 5–7 (2025) (finding that Medicare chemotherapy patients at 340B hospitals had higher drug costs and greater use of expensive medications, though this may reflect their “more advanced-stage cancers,” which are associated with higher costs and drug use); Robert J. Nordyke, James Motyka & Julie A. Patterson, *The Association of 340B Program Drug Margins with Covered Entity Characteristics*, 62 J. HEALTH CARE ORG., PROVISION, & FIN. 1, 6 (2025) (finding that 340B providers that serve wealthier and better-insured populations have higher margins on 340B drug purchases, suggesting that entities may be incentivized to treat more commercially insured patients because they capture larger margins); see also Sarah Jane Tribble, *Rural Hospitals Continue to Struggle to Pay for Lifesaving Drugs*, HEALTHCARE FIN. NEWS (Sep. 18, 2017, at 11:43 ET), <https://www.healthcarefinancenews.com/news/rural-hospitals-continue-struggle-pay-lifesaving-drugs> [<https://perma.cc/Q3FB-R64K>] (describing challenges for rural hospitals in affording prescription drug stocks for patients); *Final Report: Trends in Hospital Inpatient Drug Costs: Issues and Challenges*, NORC UNIV. CHI. 11–14 (2016),

statutory authority perpetuates a cycle of ambiguity, litigation, and inefficiency, further hindering the agency's ability to ensure accountability in a multibillion-dollar federal discount program.¹⁴⁴ As a result, the 340B Program has drifted from its core mission of affordability and access toward a model that increasingly facilitates substantial revenue generation for large hospital systems, often without meaningful indication that those funds are reinvested in patient care.¹⁴⁵

III. RECOMMENDATIONS FOR STRENGTHENING OVERSIGHT WITHIN STATUTORY LIMITS

A. Modernize HRSA's Oversight Strategy Around Audit-Based Enforcement

Congress designed audits, not rulemaking, as HRSA's primary enforcement mechanism under the 340B statute.¹⁴⁶ Although the 340B Program provides meaningful value to the healthcare system, its rapid growth, financial scale, and operational complexity have outpaced HRSA's current enforcement infrastructure.¹⁴⁷ HRSA's limited rulemaking authority constrains its ability to resolve statutory ambiguities prospectively, but Congress granted the agency broad authority to enforce existing prohibitions on diversion and duplicate discounting through audits.¹⁴⁸ Targeted, risk-based audits, executed directly by HRSA or supervised independent third-party auditors, can address patient eligibility ambiguity, the risks posed by complex hospital systems, and contract pharmacy oversight challenges, all while remaining within the agency's statutory authority and restoring program legitimacy.¹⁴⁹ Systematic auditing strengthens the health care system by

<https://www.aha.org/system/files/2018-01/aha-fah-rx-report.pdf> [<https://perma.cc/K2YX-8HH4>] (describing the impact of high prescription drug prices on hospitals, including issues of resource allocation).

144. See BLALOCK, *supra* note 4.

145. Fisher, *supra* note 6, at 71.

146. See 42 U.S.C. § 256b(a)(5)(C). Congress historically limited HRSA's rulemaking authority under Section 340B, and the judiciary has repeatedly rejected HRSA's attempts to resolve statutory ambiguities via regulation (e.g., orphan drug, contract pharmacy, binding patient definitions). See *supra* Part II.A–B.

147. See Fisher, *supra* note 6, at 64–65; Marshall, *supra* note 23, at 1757 (“The dramatic increase in the number of covered entities and contract pharmacy arrangements has diluted HRSA's ability to effectively oversee the program and overwhelmed the mechanisms it has in place.”).

148. See 42 U.S.C. § 256b(a)(5)(A)–(B).

149. See Fisher, *supra* note 6, at 40; Stephen Barlas, *Federal Investigative Report Questions 340B Contract Pharmacy Programs: Office of Pharmacy Affairs Promises Regulatory Response*, 39 PHARMACY & THERAPEUTICS 232, 232 (2014).

detering “wasteful or fraudulent spending” and promoting more efficient allocation of resources.¹⁵⁰

To implement these reforms, HRSA should conduct audits directly or through supervised independent auditors, rather than relying on entities to self-audit and self-attest to corrective actions.¹⁵¹ Allowing regulated entities to police their own compliance reflects a structural failure that undermines audit rigor and public confidence.¹⁵² Reliance on financially interested entities further undermines audit credibility and consistency, particularly given that only a small number of covered entities currently hire independent auditors.¹⁵³ Moreover, industry participants themselves have acknowledged that independent auditing could substantially reduce noncompliance.¹⁵⁴

HRSA can expand audit capacity by issuing a general statement of policy that updates its existing audit strategy.¹⁵⁵ Federal agencies are generally not required to publish such statements that reflect priorities or risk-based targeting so long as they do not create new legal rights or obligations.¹⁵⁶ However, policy statements indicate the manner in which an agency intends to exercise a discretionary function.¹⁵⁷ And so, issuing a policy statement that the agency intends to increase auditing and implement risk-based targeting is not determinative of issues or rights and does not require publication in the Federal Register.¹⁵⁸

150. Caitlin Pardue, Comment, *How Will I Know? An Auditing Privilege and Health Care Compliance+*, 65 EMORY L.J. 1139, 1140 (2016).

151. See GAO 2018 REPORT, *supra* note 17, at 44–45 (noting a lack of “assurance” in covered entities sufficiently discovering and reporting internal noncompliance).

152. See Fisher, *supra* note 6, at 40.

153. *Id.* at 69.

154. Barlas, *supra* note 149 (stating that Robert Nahoopii, CEO and co-founder of a 340B management company, has suggested that unintended diversions could be “eliminated” using internal audits and independent auditors).

155. See *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 95 (2015) (citing Administrative Procedure Act, 5 U.S.C. § 553(b)(A)) (affirming that the APA’s notice-and-comment process does not apply to general statements of policy); *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993) (holding that the policy letters of the agency were interpretive rules because they had legal effect); e.g., HEALTH RES. & SERVS. ADMIN., OFF. OF PHARMACY AFFS., RELEASE NO. 2012-1.1, CLARIFICATION OF HRSA AUDITS OF 340B COVERED ENTITIES (2013) (giving notice of new auditing practices).

156. See *Am. Mining Cong.*, 995 F.2d at 1112; see also *Azar v. Allina Health Servs.*, 587 U.S. 566, 574 (2019) (citing 5 U.S.C. § 553(b)(A)) (asserting that under the APA, general statements of policy are not substantive and are treated as interpretive rules).

157. See *Pac. Gas & Elec. Co. v. Fed. Power Comm’n*, 506 F.2d 33, 38 (D.C. Cir. 1974) (clarifying that “[a] policy statement announces the agency’s tentative intentions for the future” and “does not establish a ‘binding norm’”).

158. See *Guardian Fed. Sav. & Loan Ass’n v. Fed. Sav. & Loan Ins.*, 589 F.2d 658, 664–67 (D.C. Cir. 1978).

1. *Expand Audit Volume to Match Program Scale and Financial Risk*

The scope of HRSA's audit activity is disproportionate to the size and financial significance of the 340B Program.¹⁵⁹ As program participation and revenues have increased, audit coverage has remained largely stagnant, reducing the probability of review and allowing noncompliance to persist undetected.¹⁶⁰ This low probability of review weakens deterrence, places excessive reliance on self-policing and voluntary compliance.¹⁶¹

Increasing audit capacity is essential to preserve program integrity, reinforce accountability, and signal credible oversight. Audit resources should prioritize audits based on material risk, targeting covered entities and manufacturers with large 340B revenues, extensive and complex contract pharmacy networks, or prior noncompliance findings.¹⁶² As of 2025, HRSA conducts 90% of audits through random selection based on certain risk-based criteria and only 10% through targeted review based on stakeholder tips or prior noncompliance findings.¹⁶³ Random audits can support general compliance monitoring, but they are insufficient unless accompanied by a higher audit volume and a focus on areas of material or reported risk.¹⁶⁴ Audit coverage has declined from approximately 0.63% of covered entities in 2015 to

159. See GAO 2025 REPORT, *supra* note 19, at 17.

160. See Fisher, *supra* note 6, at 64; see also Knox & Sarpatwari, *supra* note 2, at 282 (noting that, in fiscal year 2023, the agency had only 23 full-time federal employees).

161. See GAO 2025 REPORT, *supra* note 19, at 11–15 (noting that HRSA's process for closing audits does not require fully addressing all identified forms of noncompliance and primarily relies on covered entities to self-attest the entity is now in compliance). See generally Heiko Gerlach, *Self-Reporting, Investigation, and Evidentiary Standards*, 56 J.L. & ECON. 1061 (2013) (arguing that self-reporting is more likely to occur if full amnesty is offered but is less efficient when the level of harm is high, and that a hard-evidence standard provides greater deterrence).

162. See Fisher, *supra* note 6, at 39 (discussing that the current risk-based audits implemented by HRSA “focus[] on covered entities deemed to be at a higher risk of noncompliance,” rather than drug manufacturers). But see *Trends in Audit Findings for 340B Hospitals and Drug Companies*, AM. HOSP. ASSOC. (June 2025), <https://www.aha.org/system/files/media/file/2025/06/More-Drug-Company-Oversight-Needed-to-Maintain-Compliance-with-340B-Program-Rules.pdf> [<https://perma.cc/3G9B-QH8L>] (asserting that federal audits “shows high rates of compliance for audited 340B hospitals and consistently high rates of non-compliance among audited drug companies”).

163. See GAO 2018 REPORT, *supra* note 17, at 15 (asserting that the agency random selection process evaluates the volume of 340B drug purchases, the number of contract pharmacies, time in the program, program complexity, and any history of violations or allegations of statutory noncompliance).

164. See ADVI, *supra* note 126; Fisher, *supra* note 6, at 70–71; see also GAO 2018 REPORT, *supra* note 17, at 36–37 (indicating that HRSA lacks data on contract pharmacy arrangements which would inform effective monitoring of the program).

0.33% in 2024 while program spending has grown.¹⁶⁵ Concentrating audits on large systems with complex operations is justified because these entities pose greater fiscal and programmatic risk than small or rural providers with under-resourced healthcare infrastructure and coverage.¹⁶⁶

2. *Adopt a Primarily Risk-Based Audit Targeting Strategy*

HRSA should adopt a risk-based audit strategy that concentrates enforcement primarily on entities most likely to engage in diversion or duplicate discounting. Research indicates that a subset of covered entities, disproportionate share hospitals (DSHs), is exploiting the program by shifting prescribing behavior and aggressively acquiring outpatient physician practices, which are strategies that maximize 340B profits rather than directly supporting care for vulnerable populations.¹⁶⁷ This concentration of financial benefits persists despite declining levels of indigent care and partly due to the absence of requirements for DSHs to demonstrate how 340B revenues are used to advance the program's safety-net mission.¹⁶⁸ Large, integrated hospital systems typically manage more complex prescribing and dispensing arrangements, increasing the likelihood of inadvertent or systematic noncompliance.¹⁶⁹

This form of risk-based targeting would protect smaller providers by avoiding unnecessary administrative burden while directing oversight where noncompliance could have the greatest downstream impact.¹⁷⁰ HRSA

165. See ADVI, *supra* note 126.

166. See generally Sameer Vohra, Carolyn Pointer, Amanda Fogleman, Thomas Albers, Anish Patel & Elizabeth Weeks, *Designing Policy Solutions to Build a Healthier Rural America*, 48 J.L. MED. & ETHICS 491, 491–92 (2020) (arguing that rural communities face greater disparities regarding access to healthcare than urban communities); AM. HOSP. ASSOC., *supra* note 162 (reporting that HRSA “scrutinizes 340B hospitals at [ten] times the rate of drug companies,” even though they show “greater rates of compliance as compared to drug companies”).

167. See Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments*, SCHAEFFER CTR. WHITE PAPER SERIES, Oct. 2021, at 10.

168. See *id.*; Bach & Sachs, *supra* note 27, at 2311.

169. See Mulligan, *supra* note 167, at 9 (asserting that contract pharmacies arrangements increase the risk of drug diversion because they “simultaneously serve patients of covered entities and non-340B providers”); Bach & Sachs, *supra* note 27, at 2311 (reporting that some 340B hospitals are acquiring outpatient practices—particularly high-cost prescribing specialties like oncology—while not passing drug discounts on to low-income patients).

170. See Fisher, *supra* note 6, at 39–40 (arguing that the risk of noncompliance increased when HRSA's audits were limited and overly dependent on self-policing); AM. HOSP. ASSOC., *supra* note 162 (arguing that HRSA audits should be more narrowly tailored to the entities at highest risk of noncompliance, and should not allow self-policing and policing of others by entities at high risk of noncompliance); GAO 2018 REPORT, *supra* note 17, at 15–16 (reporting that HRSA's audits “randomly selected based on risk-based criteria” yielded significant instances of noncompliance).

already employs a criteria-based selection system and should refine those criteria to prioritize indicators of material risk identified and reported by GAO and industry stakeholders.¹⁷¹ These indicators could include not only the number of contract pharmacies, but also data concerning the use of 340B drugs dispensed at those pharmacies and information related to patient eligibility, particularly for smaller, independent practices acquired by large 340B hospital systems.¹⁷² HRSA could further enhance transparency and deterrence by adopting a practice similar to the U.S. Department of Health and Human Services Office of Inspector General's (OIG's) annual publication of its Work Plan, which reevaluates the agency's enforcement priorities each fiscal year and puts the industry on notice to proactively comply.¹⁷³ OIG routinely identifies relative programmatic risks and redirects enforcement priorities in most need of attention, and HRSA should mirror its internal procedures to likewise redirect auditing priorities.¹⁷⁴

3. *Ensure Independent and Credible Oversight of Contract Pharmacies*

Contract pharmacy arrangements present distinct structural risks because they routinely dispense drugs to both 340B and non-340B patients within the same infrastructure.¹⁷⁵ This commingling increases the likelihood of diversion and duplicate discounting, particularly when oversight relies on self-policing by financially interested entities.¹⁷⁶ Current reliance on self-audits and self-attestation undermines audit credibility and public confidence.¹⁷⁷

To address these risks, HRSA should conduct audits directly or supervise independent third-party auditors to ensure consistent and impartial oversight, and Congress should appropriate additional funding to support this

171. See GAO 2018 REPORT, *supra* note 17, at 15–16, 30–36; BLALOCK & LAUNSBACH, *supra* note 12.

172. See GAO 2018 REPORT, *supra* note 17, at 30–36; BLALOCK & LAUNSBACH, *supra* note 12; Bach & Sachs, *supra* note 27.

173. See *About the Work Plan*, U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/reports/work-plan/about-the-work-plan/> [<https://perma.cc/G7M2-E44A>] (last visited Apr. 10, 2026).

174. See *id.*

175. See Mulligan, *supra* note 167, at 9; Knox & Sarpatwari, *supra* note 2, at 257.

176. See Mulligan, *supra* note 167, at 9.

177. See GAO 2025 REPORT, *supra* note 19, at 11; Brian Matney, *340B Program Success Depends on the Quality of Self-Auditing*, HEALTHCARE FIN. MGMT. ASS'N, <https://www.hfma.org/legal-and-regulatory-compliance/340b-program-success-depends-on-the-quality-of-self-auditing/> [<https://perma.cc/UP8H-ZAV6>] (last updated Nov. 7, 2022, at 08:42 ET).

goal.¹⁷⁸ Covered entities should be required to demonstrate implementation of corrective action plans through verifiable evidence and formal reporting mechanisms. These measures would enhance transparency, promote voluntary compliance, and strengthen deterrence across the program by signaling that HRSA is taking its enforcement authority seriously.

4. *Use Audits to Operationalize Patient Eligibility*

HRSA's ability to enforce the 340B Program is constrained by the absence of a binding statutory definition of "patient," which limits the agency's capacity to apply uniform, prospective standards.¹⁷⁹ Congressional action would provide the clearest and most durable solution to this ambiguity.¹⁸⁰ In the interim, however, HRSA should continue to use audits to scrutinize the nature of the relationship between covered entities and individuals receiving 340B drugs, pressing entities to demonstrate provider responsibility for patient care on a case-by-case basis. By systematically documenting these findings and building an internal database of patient-provider relationship models, HRSA can both strengthen current enforcement and generate an empirical record.¹⁸¹ That record would equip Congress with concrete evidence of how the lack of statutory clarity impedes oversight and would substantiate the need for additional authority to enforce the program consistent with congressional intent.¹⁸²

178. See Barlas, *supra* note 149, at 232, 290; Press Release, U.S. Senate Committee on Health, Education, Labor & Pensions, Chairman Cassidy Unveils Landmark Discussion Draft to Fix 340B, Lower Health Costs for American Patients & Families (June 29, 2026), <https://www.help.senate.gov/rep/newsroom/press/chairman-cassidy-unveils-landmark-discussion-draft-to-fix-340b-lower-health-costs-for-american-patients-and-families> [<https://perma.cc/L4YW-9SZG>] (proposing solutions to "[p]rovide crucial regulatory clarity" and "[f]ix Program operations and put it on a sustainable path to lower health care costs for all Americans"). But see Giuliana Grossi, *White House Proposes Deep Cuts to HHS in FY2026 Budget, Reducing NIH to 8 Centers*, AM. J. MANAGED CARE (June 4, 2025), <https://www.ajmc.com/view/white-house-proposes-deep-cuts-to-hhs-in-fy2026-budget-reducing-nih-to-8-centers> [<https://perma.cc/57LW-D9XT>] (reporting that the White House proposed that CMS receive HRSA's current annual budget of \$12 million to manage the program instead).

179. See Fisher, *supra* note 6, at 66–68.

180. See Alicia Gilbert, *340B: The Shoulder of Frankenstein's Monster*, 2023 HARV. J. ON LEGIS. ONLINE 27, 37 (2023).

181. See GAO 2025 REPORT, *supra* note 19, at 13 (discussing that a lack of data collection contributes to HRSA's ability to effectively enforce the program).

182. See Pamela Herd, Donald Moynihan & Amy Widman, *Tackling Administrative Burdens: The Legal Framework and Innovative Practices*, 76 ADMIN. L. REV. 243, 261 (2024) (illustrating that ACUS has studied "how agencies can take specific steps, either internally or in conjunction with other agencies or institutions, to improve access to benefits or programs designed for public use").

B. Supplement Audit Enforcement with Incentive-Based Compliance Mechanisms

Because HRSA lacks broad rulemaking authority, incentive-based compliance mechanisms may provide a legally viable complement to audit enforcement.¹⁸³ Properly structured incentives can encourage proactive compliance, improve documentation, and reduce diversion risk while remaining within statutory limits.¹⁸⁴ By pairing penalties for noncompliance with rewards for demonstrated adherence, HRSA can concentrate enforcement resources on high-risk entities while promoting voluntary alignment with congressional intent.¹⁸⁵

Unlike a general statement of policy announcing audit priorities, an incentive-based pilot program may require publication in the Federal Register if it constitutes a substantive rule with the force and effect of law.¹⁸⁶ Under the Administrative Procedure Act (APA), agencies must generally provide notice and an opportunity for public comment when promulgating legislative rules, and courts have repeatedly enforced those procedural requirements when agencies adopt binding policy rather than interpretive guidance.¹⁸⁷

Properly designed incentives, however, fall within HRSA's enforcement discretion.¹⁸⁸ Voluntary incentive programs are legally upheld when participation is optional, benefits relate to enforcement prioritization, and no penalties attach to nonparticipation, because decisions about enforcement allocation and the exercise of prosecutorial discretion are core executive functions. Courts have consistently recognized this principle, and analogous models include Centers for Medicare and Medicaid Services (CMS) self-disclosure protocols, Department of Justice cooperation credit frameworks, and HHS Office of Inspector General compliance guidance safe harbors.¹⁸⁹

183. See Connor Raso, *Agency Avoidance of Rulemaking Procedures*, 67 ADMIN. L. REV. 65, 68 (2015) (arguing that agencies may prefer alternative methods to make policy to avoid the burden of the rulemaking process).

184. See generally Joseph E. Murphy, *Using Incentives in Your Compliance and Ethics Program*, SOC'Y OF CORP. COMPLIANCE & ETHICS (Nov. 2011), <https://assets.corporatecompliance.org/Portals/1/PDF/Resources/IncentivesCEProgram-Murphy.pdf> [<https://perma.cc/ME9B-2W9B>] (discussing how aligning incentives can drive behavior in the context of business and increasing levels of misconduct).

185. See discussion Part III.A.

186. See Administrative Procedure Act, 5 U.S.C. § 553(b)(A), (d)(2); 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed. Reg. 36,163 (Aug. 1, 2025).

187. See 5 U.S.C. § 553(b), (c); see e.g., *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251–52 (D.C. Cir. 2014); *Pac. Gas & Elec. Co. v. Fed. Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974).

188. See *Hocter v. U.S. Dep't of Agric.*, 82 F.3d 165, 167 (7th Cir. 1996) (“Every governmental agency that enforces a less than crystalline statute must interpret the statute, and it does the public a favor if it announces the interpretation in advance of enforcement.”).

189. The Centers for Medicare and Medicaid Services (CMS) has a Provider Pilot Program under their Compliance Review Program where selected volunteer participants test

Nevertheless, HRSA should publish new incentives online to provide covered entities and manufacturers with notice and to encourage active and robust participation in program enforcement.

1. *Create Voluntary Enhanced-Compliance Designations and Audit Safe Harbors*

HRSA could create voluntary enhanced-compliance designations for covered entities that demonstrate robust documentation, strong internal controls, and transparency.¹⁹⁰ By cooperating with HRSA's investigations, timely and appropriately remediating misconduct, and voluntarily disclosing misconduct, the agency can offer a designation or safe harbor against auditing.¹⁹¹ Entities meeting recommended compliance benchmarks, such as standardized documentation, internal audits, and compliance attestations, could receive operational benefits, including narrower audit scopes, longer intervals between audits, or reduced random selection. By linking designations to audit benefits, HRSA can encourage robust compliance without creating new binding rules, preserving agency discretion and minimizing litigation risk.

Federal health agencies routinely use voluntary incentives to promote compliance and quality improvement, especially in the healthcare context. Under the CMS Quality Payment Program (QPP), clinicians choose to participate in

compliance review processes. *Compliance Review Program*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/enforcement/compliance-review-program> [https://perma.cc/C4RR-6299] (last updated Mar. 16, 2026, at 18:53 ET). Participation is voluntary, and the agency's approach emphasizes remediation rather than penalties for volunteers in the pilot. *Id.* The Department of Justice publicly stated that absent aggravating factors, corporations that voluntarily self-disclose, cooperate fully, and timely remediate an offense may avoid prosecution or monitor requirements. *Voluntary Self Disclosure and Monitor Selection Policies*, U.S. DEPT OF JUST., <https://www.justice.gov/corporate-crime/voluntary-self-disclosure-and-monitor-selection-policies> [https://perma.cc/XJR8-QSAB] (last updated Mar. 8, 2024).

190. See Press Release, U.S. Department of Justice, Department of Justice Releases First-Ever Corporate Enforcement Policy for All Criminal Cases (Mar. 10, 2026), <https://www.justice.gov/opa/pr/departments-justice-releases-first-ever-corporate-enforcement-policy-all-criminal-cases> [https://perma.cc/A4H4-PC56] (announcing that under the Department of Justice's new Corporate Enforcement and Voluntary Self-Disclosure Policy, the agency may decline to prosecute companies that voluntarily disclose misconduct, cooperate with investigations, timely and appropriately remediate the conduct, and agree to pay restitution to victims).

191. See *id.*; see also Asher Zlotnik, *U.S. DOJ Implements Uniform Corporate Enforcement and Voluntary Self-Disclosure Framework Across All Components Except Antitrust*, SIDLEY AUSTIN LLP (Mar. 16, 2026), <https://www.sidley.com/en/insights/newsupdates/2026/03/us-doj-implements-uniform-corporate-enforcement-and-voluntary-self-disclosure-framework> [https://perma.cc/UPM6-REUQ] (explaining the framework's design and shedding light on the tiered system which has varying levels of benefits and outcomes depending on aggravating factors).

merit-based incentive payment systems or advanced alternative payment models that determine Medicare payment adjustments based on quality and cost.¹⁹² Participation can result in exemption from reporting and penalties, but physicians must use electronic health record technology, base payment on quality measures, and bear more than a nominal financial risk.¹⁹³ CMS has imposed a system, incentivizing clinicians to participate with large benefits balancing financial risk, and if HRSA imposes a similar system by providing benefits, then covered entities and manufacturers are more likely to come into compliance voluntarily and demonstrate compliance with documentation. This approach could mirror the historic CMS Electronic Health Record (EHR) Incentive Program. Under that program, CMS offered financial incentives for eligible professionals and hospitals that voluntarily adopted certified electronic health records and met “meaningful use” criteria.¹⁹⁴ Early-stage nonparticipation did not trigger penalties, so it does not impact the substantive rights of individuals who chose not to participate.¹⁹⁵ While the QPP and EHR programs are different from how HRSA audits the 340B Program, similar methods of incentivizing hospitals to engage with the government program could be beneficial.

HRSA's enhanced-compliance designation could provide benefits such as reduced audit frequency, expedited dispute resolution, or public recognition. Because participation would remain voluntary and tied to audit administration rather than binding rules, this model preserves agency discretion and minimizes litigation risk. Large health systems that value predictability and reputational benefits are particularly likely to participate.¹⁹⁶

2. *Leverage Transparency and Reporting as Reputational Incentives*

HRSA could tie voluntary disclosures regarding the use of 340B savings—such as funding for uncompensated care, reduced-cost medications, or community health programs—to reputational incentives. Entities that publish transparent reports could receive public recognition, financial awards, or reduced audit

192. See *About QPP*, QUALITY PAYMENT PROGRAM, <https://qpp.cms.gov/get-started/what-is-qpp/about-qpp> [<https://perma.cc/XF2B-EU7Q>] (last visited June 15, 2026).

193. See *id.*

194. *An Introduction to EHR Incentive Programs*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/medicaid-ehr-guide.pdf> [<https://perma.cc/5W4E-9M3N>] (last visited Apr. 25, 2026).

195. See *id.*

196. See Corinne Lewis, Celli Horstman, David Blumenthal & Melinda K. Abrams, *Value-Based Care Models*, COMMONWEALTH FUND (Feb. 7, 2023), <https://www.commonwealthfund.org/publications/explainer/2023/feb/value-based-care-what-it-is-why-its-needed> [<https://perma.cc/5EFD-8G6H>].

scrutiny.¹⁹⁷ Similar transparency-based incentives exist across federal enforcement programs to encourage self-policing, remediation, and voluntary compliance.¹⁹⁸ For example, under the Medicare Advantage Quality Star Ratings, plans with higher voluntary reporting scores receive public recognition and can market their performance, incentivizing compliance and quality improvement.¹⁹⁹ CMS also implements a Hospital Value-Based Purchasing Program, where hospitals receive public scores for quality metrics, creating reputational incentives to improve care.²⁰⁰ These transparency-based incentives encourage remediation and voluntary compliance. Because HRSA's current audit program already accommodates self-disclosures, implementing these incentives would require minimal additional administrative effort.²⁰¹

Together, these reforms leverage HRSA's existing audit authority to clarify compliance expectations, enhance accountability, and realign the 340B Program with congressional intent without exceeding statutory limits. Audit-based enforcement, supplemented by voluntary incentives and transparency, offers a legally sound and administratively flexible path forward until Congress provides explicit regulatory authority.

197. Currently, some covered entities are required to use 340B revenue per their grant requirements, but 340B hospitals do not have the same restriction. Mulligan, *supra* note 167, at 2.

198. The Department of Justice has adopted policies that reward entities that proactively self-report misconduct and remediate it with more favorable outcomes. See Thomas A. Hanusik & Daniel L. Zelenko, *Good Actors Win with the DOJ's New Policies on Corporate Crime*, CROWELL & MORING, LLP (Sep. 21, 2022), <https://www.crowell.com/en/insights/client-alerts/good-actors-win-with-the-doj-s-new-policies-on-corporate-crime> [<https://perma.cc/NMU2-ET62>]. Additionally, the Environmental Protection Agency historically provides penalty mitigation or reduced enforcement for entities that conduct voluntary self-audits and disclose in good faith. See Michael Boucher & Nina M. MacLeay, *Self-Audits in Transactional Due Diligence and Enforcement Contexts—Prepare Your Company*, STEPTOE LLP (Oct. 30, 2025), <https://www.steptoel.com/en/news-publications/self-audits-in-transactional-due-diligence-and-enforcement-contexts-prepare-your-company.html> [<https://perma.cc/WVT4-UZ7D>].

199. See *2025 Medicare Advantage and Part D Star Ratings*, CMS NEWSROOM (Oct. 10, 2024), <https://www.cms.gov/newsroom/fact-sheets/2025-medicare-advantage-and-part-d-star-ratings> [<https://perma.cc/EB5W-3HBV>].

200. See *Hospital Value-Based Purchasing Program*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-value-based-purchasing> [<https://perma.cc/T7E2-ERC4>] (last updated Mar. 10, 2026, at 23:46 ET).

201. See *Program Integrity*, *supra* note 62; Eoin P. Beirne, Nick A. LaPalme & Andrew Tucker Bobbit, *Voluntary Self-Disclosure and Whistleblower Awards Initiatives Are Alive and Well in 2025*, MINTZ (May 22, 2025), <https://www.mintz.com/insights-center/viewpoints/54931/2025-05-20-voluntary-self-disclosure-and-whistleblower-awards> [<https://perma.cc/2BRV-JSLU>]; see also Knox & Sarpatwari, *supra* note 2, at 282 (noting that HRSA has roughly twenty-three full-time federal employees and arguing more resources need to be allocated to HRSA to support program oversight).

CONCLUSION

The 340B Drug Pricing Program plays a vital role in supporting safety-net hospitals and clinics that serve low-income and uninsured populations, enabling these providers to stretch limited resources and expand access to care. Yet over time, statutory ambiguities, combined with HRSA's limited enforcement and rulemaking authority, have allowed some covered entities to prioritize revenue generation over patient benefit. Judicial constraints further limit HRSA's ability to clarify program requirements through binding regulations, leaving oversight reliant on selective audits and voluntary compliance. As a result, diversion, duplicate discounting, and inconsistent reinvestment of savings have weakened the program's alignment with congressional intent.

HRSA can improve oversight within its existing authority through enhanced, risk-based audits, timely resolution, standardized compliance tools, and greater transparency in reporting audit outcomes. Incentive-based mechanisms, such as voluntary enhanced-compliance designations, audit safe harbors, and reputational rewards, offer additional tools to encourage covered entities to adhere to program objectives without exceeding statutory limits. These approaches, focused on proportional enforcement, transparency, and corrective compliance, can restore integrity and consistency, ensuring that program benefits reach the populations they were designed to serve.

Ultimately, lasting reform requires congressional action. Congress should codify HRSA's rulemaking authority, clarify patient eligibility, and mandate annual reporting on how 340B savings are used to support low-income and uninsured patients. Together, these reforms would restore statutory fidelity, realign the program with its original purpose, and safeguard billions of federal dollars for the nation's most vulnerable populations, rather than allowing the program to drift toward revenue generation for large health systems.