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Nicholas C. Fisher

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THE 340B PROGRAM: A FEDERAL PROGRAM IN DESPERATE NEED OF REVISION AFTER TWO-AND-A-HALF DECADES OF UNCERTAINTY

NICHOLAS C. FISHER*

I. INTRODUCTION

For individuals with limited means, the exponential growth in pharmaceutical drug prices continues to be a common barrier in accessing life-saving prescription drugs. Although few people outside the health care and drug industry are familiar with the 340B Drug Pricing Program (340B Program), the program plays an integral role in how millions of Americans obtain prescription drugs.¹ The intent of the 340B Program is to help uninsured, indigent patients by giving qualifying health care facilities access to discounts for outpatient drugs.² However, after nearly two-and-a-half decades since its inception, it is debatable whether the program operates in accordance with its statutory foundation.³ Specifically, competing incentives between drug manufacturers and qualifying health care facilities, the lack of Congressional oversight, and vague language in the statute and regulations have turned this well-intended program into a revenue generating arrangement.⁴

The 340B Program is a federally facilitated program that imposes ceilings on prices drug manufacturers may charge for certain medications sold to qualifying health care facilities known as covered entities.⁵ All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B

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*The author is an Associate Attorney at Hunt Suedhoff Kalamaros. Prior to law school, the author spent nearly a decade working in retail and hospital pharmacies. The author is grateful to the Journal of Health Care Law & Policy for selecting this article and to Kristy, Samuel, and Benjamin for their unconditional love and support.

1. See discussion *infra* Section III.A.
2. See discussion *infra* Sections II.A, II.B.
3. See H.R. REP. NO. 102-384, pt. 2, at 12 (1992) (explaining that the program “provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans.”); see also discussion *infra* Part III.
4. See discussion *infra* Part IV.
5. See discussion *infra* Sections II.B, II.C.

Program.⁶ Moreover, drug manufacturers that desire to be reimbursed by Medicaid must participate in the program.⁷

The 340B Program has grown substantially since its inception in 1992—most notably since its expansion under the Patient Protection and Affordable Care Act in 2010.⁸ To illustrate the expansion, consider the following: the number of hospitals participating in the program grew from 591 to 1,673 between 2005 to 2011;⁹ the number of hospital and affiliated sites grew from 1,233 to 4,426;¹⁰ and in “July 2011, there were more than 16,500 covered entity sites enrolled in the 340B Program—about double the number in 2001.”¹¹

The 340B Program continues to grow at exponential rates. In 2013 alone, “covered entities and their affiliated sites spent over \$7 billion to purchase 340B drugs, three times the amount spent in 2005.”¹² In 2015, discounted purchases made under 340B hit \$12 billion.¹³ A December 2016 report estimates the program will reach \$20 billion in sales by 2019 and top \$23 billion in sales by 2021.¹⁴

Still, not everyone is convinced the 340B Program is being used for its original intentions. In theory, covered entities are supposed to buy the heavily discounted drugs and pass along the savings to their low-income patients. However, the 340B statute does not expressly tie patient eligibility to insurance status nor does it restrict how covered entities use revenue from the 340B Program. Critics of the program point out that hospitals with low numbers of indigent patients use the program to obtain drugs for outpatients who have Medicare or private insurance. In cases where insured patients are treated with

6. See discussion *infra* Section II.B.

7. See discussion *infra* Section II.B.

8. 42 U.S.C. § 256b (2012).

9. U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-836, DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT 27–28 (2011), <http://www.gao.gov/assets/330/323702.pdf> [hereinafter GAO, DRUG PRICING]. The GAO, Government Accountability Office, “is an independent, nonpartisan agency that works for Congress. Often called the ‘congressional watchdog,’ the GAO investigates how the federal government spends taxpayer dollars.” U.S. Gov't Accountability Off., *About GAO*, GAO.GOV (last visited Oct. 28, 2018), <https://www.gao.gov/about/index.html>.

10. *Id.* at 27–28.

11. *Id.* at 2–3.

12. MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: OVERVIEW OF THE 340B DRUG PRICING PROGRAM 11 (MedPAC ed. 2015) [hereinafter MEDPAC: DRUG PRICING]. The Medicare Payment Advisory Commission (MedPAC) “is a nonpartisan legislative branch agency that provides the U.S. Congress with analysis and policy advice on the Medicare program.” MEDICARE PAYMENT ADVISORY COMMISSION, <http://www.medpac.gov/> (last visited Oct. 28, 2018).

13. Adam J. Fein, *340B Purchases Hit \$12 Billion in 2015—and Almost Half of the Hospital Market, DRUG CHANNELS* (Feb. 23, 2016), <http://www.drugchannels.net/2016/02/340b-purchases-hit-12-billion-in.html>.

14. AARON VANDERVELDE & ELEANOR BLALOCK, BRG HEALTHCARE, 340B PROGRAM SALES FORECAST: 2016-2021, 2 (Berkeley Research Group ed. 2016), https://www.thinkbrg.com/media/publication/855_Vandervelde_Blalock_340B_Dec2016_WEB.pdf.

discounted drugs, the hospital is routinely reimbursed for the full price of the drug by the federal government or private insurance and the entity retains the difference. Critics argue that this is the antithesis of the 340B Program—a program designed to help impoverished patients with limited means. Meanwhile, advocates argue that qualifying providers are able to expand the type and volume of care they provide to the most vulnerable patient populations as a result of access to these lower cost medications.

Issues with the 340B Program stem from the lack of guidance. The law is inundated with vagueness and ambiguities. For example, the law requires that covered entities only use 340B drugs for individuals who are patients of the covered entity. However, the statute does not define the term “patient” due to the large number of covered entities and the wide diversity of eligible groups. In 2011, the U.S. Government Accountability Office (GAO) deemed the term was “not specific enough” and could be interpreted “either too broadly or too narrowly.”¹⁵ Despite the need for clarity and the call for an updated definition, there has yet to be a final update of the definition in over 20 years.

Fueling the fire, the Health Resources and Services Administration (HRSA)—the agency responsible for administering the program—has relied heavily on self-policing.¹⁶ Despite having the authority to conduct audits, a 2011 report found that HRSA had not conducted a single audit since the program’s inception in 1992.¹⁷ Meanwhile, drug manufacturers and covered entities continue to rely on their own interpretations of the law due to the lack of clear guidelines. As a result, both covered entities and drug manufacturers are incentivized to interpret the law in accordance with their respective interests.

Furthermore, in 2014, the D.C. Circuit held that HRSA—the federal agency vested with the responsibility to oversee and enforce the 340B Program—lacks broad rulemaking authority for the program.¹⁸ Prior to the ruling, HRSA used “interpretive guidance and statements of policy to provide guidance” to program participants.¹⁹ However, the court found that Congress had delegated only very limited rulemaking authority to HRSA. This ruling left HRSA’s rulemaking authority on shaky grounds and opened the door for additional legal challenges with a template to succeed.

The original intent of the program was to help lower outpatient drug prices for the uninsured. Due to inadequate oversight and lack of necessary direction,

15. GAO, DRUG PRICING, *supra* note 9, at 22.

16. GAO, DRUG PRICING, *supra* note 9, at 21.

17. GAO, DRUG PRICING, *supra* note 9, at 25.

18. Pharm. Research & Mfrs. of Am. v. U.S. Dep’t of Health & Human Serv. (*PhRMA I*), 43 F. Supp. 3d 28, 39 (D.D.C. 2014); Pharm. Research & Mfrs. of Am. v. U.S. Dept. of Health & Human Serv. (*PhRMA II*), 138 F. Supp. 3d 31, 48 (D.D.C. 2015).

19. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

both drug manufacturers and qualifying health care providers have run amok. The 340B Program faces several internal challenges due to its nuanced and cumbersome nature. Furthermore, there is rarely a simple solution for a complex problem. However, this paper proposes by updating a few key areas, not only would program participants have better guidance, but the program's original intent would be preserved.

A. Roadmap

This paper is divided into three parts. First, this paper tracks the history of the 340B Program. This section provides a comprehensive history and overview of the program by focusing on the program's configuration, the compliance requirements for covered entities and drug manufacturers, and the underpinnings of regulatory guidance. Second, this paper examines the 340B Program's explosive growth and rapid expansion under the Affordable Care Act and evaluates how increased growth has brought increased scrutiny. This section tracks the legal clashes between HHS and PhRMA over the orphan drug rule, and evaluates the standards used by the courts to determine that HHS has limited authority to issue binding guidance over the program. Additionally, this section provides a look at how these rulings undermine the administrative function of HRSA and how the success of PhRMA threatens the stability of the 340B Program by providing a roadmap for future challenges. The final section of this paper addresses five key areas of the program that, if updated, would help the program find its intended purpose—helping the indigent. This last section analyzes the program's lack of transparency, how ambiguities have crippled the program, and how the intrinsic nature of the program has locked drug manufacturers and covered entities into a zero-sum game. Moreover, this section also discusses how the failure of the federal government to amend the law undermines HRSA's ability to properly administer the program. This paper concludes that without congressional action and key updates, the 340B Program will remain in disarray.

II. HISTORY OF THE 340B DRUG PRICING PROGRAM

A. Medicaid Drug Rebate Program

The 340B Program is intrinsically tied to the Medicaid Drug Rebate Program. In 1990, Congress created the Medicaid Drug Rebate Program (MDRP) to help offset the costs of prescription drugs for Medicaid patients.²⁰ The program was enacted out of concern for the costs the Medicaid program was paying for outpatient drugs. The intent of the program was to restrain drug price

20. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, §4401, 104 Stat. 1388, 1388-143 (codified as amended at 42 U.S.C. § 1395ww (2012)).

increases for state Medicaid programs.²¹ Under the MDRP, drug manufacturers are required to enter into a rebate agreement with the Secretary of the U.S. Department of Health and Human Services in exchange for Medicaid coverage of the manufacturer's drugs.²²

The MDRP works by acting as an opt-in mechanism that affords state Medicaid programs the opportunity to reimburse pharmacies for drugs at discounted prices similar to those offered by drug manufacturers to other purchasers.²³ State Medicaid agencies submit requests for reimbursement to drug manufacturers for outpatient prescription drugs dispensed to Medicaid beneficiaries.²⁴ The drug manufacturer issues a rebate to the state Medicaid agency reflecting the discount from the full price of outpatient drugs to Medicaid beneficiaries.²⁵ In sum, the program requires drug manufacturers to offer state Medicaid programs discounts on outpatient drugs that would at least match the lowest price the drug is offered to other purchasers.²⁶

The drug manufacturers pay rebates that are determined by a formula that is based on a manufacturer's Average Manufacturer Price (AMP) and "best" price.²⁷ Both the AMP and best price are defined by legislation and regulation.²⁸ The MDRP was designed to help lower Medicaid spending on outpatient prescription drugs by ensuring states receive discounts similar to those provided to private purchasers.

i. Prior to 1990 Medicaid Drug Rebate Program (MDRP)

Prior to the MDRP, drug manufactures regularly offered discounts to the Department of Veteran Affairs hospitals and other safety-net providers serving the uninsured and indigent population.²⁹ The MDRP required the manufacturers

21. S. REP. NO. 102-259, at 6 (1992).

22. *Id.* at 6; 42 U.S.C. § 1396r-8 (2012); *Medicaid Drug Rebate Program*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (last updated Sept. 11, 2011).

23. § 4401, 104 Stat. 1388-143.

24. *Id.*

25. *Id.*

26. S. REP. NO. 102-259, at 6.

27. 42 U.S.C. § 1396r-8(c)(1)(A)(ii) (2012).

28. The term "average manufacturer price" means the average price paid to the manufacturer for the drug by (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer. *Id.* § 1396r-8(k)(1)(A). The best price is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity, excluding prices charged to certain federal programs, 340B covered entities, Medicare Part D plans, and certain other purchasers. *Id.* § 1396r-8(c)(1)(C); *Medicaid Program; Covered Outpatient Drugs*, 81 Fed. Reg. 5170, 5351 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447).

29. Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 WM. & MARY L. REV. 637, 641 (2015), <http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=3623&context=wmlr>. A safety-net provider is

to provide rebates to Medicaid for the lowest price they offered in the rest of the drug marketplace.³⁰ However, the MDRP failed to exempt these discounts from the Medicaid best price provision.³¹ After MDRP, drug manufacturers were disincentivized to continue giving discounts on drugs because the discounts would establish lower AMPs and best prices which would require drug manufacturers to pay larger rebates to Medicaid.³² As a result, there was an increase in drug costs.³³ In reaction to this unintended consequence from the MDRP, Congress created the 340B Drug Pricing Program to help the federal government and safety-net hospitals avoid financial hardships and to ensure that the uninsured and underinsured had access to prescription medicines.³⁴

B. 340B Drug Pricing Program

In 1992, Congress created the 340B Drug Pricing Program.³⁵ Enacted under the Veterans Health Care Act of 1992,³⁶ the program's name is derived from the provision in the Public Health Service Act that authorizes it.³⁷ The 340B Program is administered by the Office of Pharmacy Affairs (OPA), located within the Health Resources and Services Administration (HRSA), under the U.S. Department of Health and Human Services (HHS).³⁸ The intent of the 340B Program is to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."³⁹

a hospital or health system that provides a significant level of health care and related services to low-income, uninsured, and vulnerable populations. Dave A. Chokshi, MD, MSc, FACP, et al., *Health Reform and the Changing Safety Net in the United States*, NEJM CATALYST (Oct. 18 2017), <https://catalyst.nejm.org/health-reform-changing-safety-net/>.

30. ACAD. OF MANAGED CARE PHARMACY, THE BEST PRICE REQUIREMENT OF THE MEDICAID REBATE PROGRAM (2009), <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18692>.

31. *Id.*

32. *Overview of the 340B Drug Pricing Program*, 340B HEALTH, <https://www.340bhealth.org/340b-resources/340b-program/overview/> (last visited Oct. 28, 2018) (detailing the Medicaid drug rebate program 340B).

33. U.S. GOV'T ACCOUNTABILITY OFF., GAO/HRD-91-139, MEDICAID: CHANGES IN DRUG PRICES PAID BY VA AND DOD SINCE ENACTMENT OF REBATE PROVISIONS 1-2 (1991), <https://www.gao.gov/assets/220/214927.pdf>.

34. *See supra* note 32.

35. *See supra* note 32.

36. Veterans Health Care Act of 1992, Pub. L. No. 102-585, §§ 601–603, 106 Stat. 4943, 4962–75 (1992) (codified as amended at 42 U.S.C. § 256b (2015)).

37. *See* 42 U.S.C. § 256b (2012) (establishing that the Veterans Health Care Act of 1992 enacted section 340B of the Public Health Service Act "Limitation on Prices of Drugs Purchased by Covered Entities").

38. *See supra* note 32.

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

Eligibility for the 340B Program is defined by statute.⁴⁰ The program mandates discounts to qualifying health care providers serving indigent patients.⁴¹ Under the 340B Program, qualifying hospitals and other health care providers, known as covered entities, can obtain discounted prices on covered outpatient drugs from drug manufacturers.⁴² The 340B Program, like the MDRP, requires drug manufacturers to enter into a contract with the Secretary of HHS, called pharmaceutical pricing agreements (PPAs).⁴³ Under these agreements, the manufacturer of must agree to comply with 340B requirements—provide discounts to covered entities on covered outpatient drugs.⁴⁴

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers. However, both have strong incentives to participate. Qualifying covered entities “can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent off the cost of drugs, according to HRSA.”⁴⁵ Drug manufacturers must participate in the 340B Program in order to receive Medicaid reimbursement. Manufacturers participating in the 340B Program are required to provide these discounts on all covered outpatient drugs sold to participating 340B covered entities.⁴⁶

The 340B qualifying entities are allowed to buy drugs from drug manufacturers who agree to a ceiling price for covered drugs. The ceiling price is derived from manufacturer’s average and best price and rebates calculated under the MDRP.⁴⁷ HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug. The 340B Program is intended to set a standard price, the ceiling price, to prevent drug manufacturers from charging arbitrarily high prices.

40. See 42 U.S.C. § 256(b)(4) (establishing that covered entities includes a variety of health programs receiving federal funding or grants).

41. *Id.* § 256b(a)(4)(L). Although the qualifications for covered entities has expanded since the program’s inception, under the original 340B statute, covered entities were generally disproportionate share hospitals—hospitals that serve indigent populations. *Id.*; see also *Criteria for Hospital Participation in the 340B Drug Discount Program*, 340B HEALTH, <https://www.340bhealth.org/340b-resources/340b-program/criteria-for-hospital-participation/> (last visited Sept. 30, 2018) (explaining qualifications for hospitals to be deemed covered entities under 340B).

42. 42 U.S.C. § 256b(a)(1); see also 42 U.S.C. § 1396r-8(a)(1) (requiring that qualifying hospitals and health care providers enter into Agreements with the Secretary to obtain discounts).

43. 42 U.S.C. § 256b(a)(1).

44. 42 U.S.C. § 1396r-8(a)(5). In 2003, Congress required manufacturers of drugs covered under Medicare Part B to enter into agreements through § 303(i)(4) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2237 (codified as amended at 42 U.S.C. 1395w-4).

45. GAO, DRUG PRICING, *supra* note 9, at 2.

46. 42 U.S.C. § 256b(a)(1).

47. *Id.*; 42 U.S.C. 1396r-8(c), (k); *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 114–15 (2011).

*C. How the 340B Program Works**i. Covered Entities*

To be eligible for the 340B discounted prices, a covered outpatient drug must be provided to a patient of a covered entity.⁴⁸ Eligibility for the 340B Program is defined by statute.⁴⁹ Approved entities must register with HRSA, be approved by the agency, and follow program requirements. Once enrolled, covered entities are assigned an identification number that vendors must verify before an organization is allowed to purchase discounted drugs. Covered entities must recertify with HRSA through the OPA 340B database website annually.⁵⁰ Failure will result in removal from the 340B Program.⁵¹

The definition of covered entities includes six types of hospitals: disproportionate share hospitals (DSH); children's hospitals and cancer hospitals exempt from the Medicare prospective payment system; sole community hospitals; rural referral centers; and critical access hospitals.⁵² The 340B law has different eligibility requirements for each of the six types of hospitals. In addition, a qualified provider may have multiple sites that participate in the program as long as each site is registered with HRSA, and is an "integral" part of the covered entity—i.e. the facility is identified as reimbursable on the hospital's Medicaid cost report.⁵³

Under the original 340B statute, eligible hospitals included only DSHs.⁵⁴ Children's hospitals were added into the program in 2005,⁵⁵ but did not become eligible to enroll until 2009 when HRSA issued a guidance.⁵⁶ In 2010, the Patient Protection and Affordable Care Act (ACA) expanded the types of covered entities to include children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.⁵⁷

48. 42 U.S.C. §§ 256b(a)(4)(A)–(O).

49. *Id.* § 256b(a)(1).

50. *Annual Recertification*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/recertification/recertification.html> (last updated Sept. 2017).

51. *Id.*

52. 42 U.S.C. § 256b(a)(4).

53. Notice Regarding Section 602 of the Veteran Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 47,884, 47,886 (Sept. 19, 1994).

54. Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4968 (1992) (codified as amended at 42 U.S.C. 256b).

55. Deficit Reduction Act of 2005, Pub. L. No. 109-171 § 6004 120 Stat. 4, 61 (2015) (codified as amended 42 U.S.C. 1396r-8 (2012)).

56. See Notice Regarding the 340B Drug Pricing Program—Children's Hospitals, 74 Fed. Reg. 45,206, 45,206 (Sept. 1, 2009) (describing the process for registration in 2009 and the obligation of manufacturers to provide discounts to eligible children's hospitals).

57. Patient Protection and Affordable Care Act, Pub. L. 111-148, § 7101(a), 124 Stat. 119, 821–22 (2010) (codified as amended at 42 U.S.C. §§ 256b(a)(4)(M)–(O) (2012)); *PhRMA II*, 138 F. Supp. 3d 31,

Regardless of type of hospital, *all* 340B hospitals must meet three requirements with the exception of rural hospitals.⁵⁸ The first requirement mandates that the qualifying hospital is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act.⁵⁹ The second requirement is that the hospital have a sufficient Medicare disproportionate share hospital adjustment percentage for the most recent cost reporting period that ended before the calendar quarter involved.⁶⁰ The third requirement is that a DSH, children's hospital, or freestanding cancer hospital enters into a written certification stating that the entity will not obtain covered outpatient drugs through a group purchasing organization (GPO)⁶¹ or other group purchasing arrangement.⁶²

In addition to the six types of hospitals discussed, there are also eleven categories of non-hospital covered entities that are eligible for the 340B Program based on receiving federal funding, such as a grant, or meeting certain government requirements in providing care to the medically underserved.⁶³ A full list of eligible organizations/covered entities includes: Federally Qualified Health Centers (FQHCs); Federally Qualified Health Center "Look-Alikes"; Native Hawaiian Health Centers; Tribal / Urban Indian Health Centers; Ryan White HIV/AIDS Program Grantees; Black Lung Clinics; Comprehensive Hemophilia Diagnostic Treatment Centers; Title X Family Planning Clinics; Sexually Transmitted Disease Clinics; and Tuberculosis Clinics.⁶⁴

35 (2012). Children's hospitals were previously included under the DRA, *supra* note 55, however the ACA clarified eligibility.

58. *See* 42 U.S.C. § 256b(a)(4)(L) (describing three requirements pertaining to hospital ownership, disproportionate share adjustment percentages, and group purchasing organizations). Rural hospitals must only meet two requirements. *See id.* § 256(a)(4)(O) ("An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(C)(i)] . . . and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.").

59. *Id.* § 256(a)(4)(L)(i).

60. *See id.* § 256b(a)(4)(L)(ii) (explaining that the hospital must have had a disproportionate share adjustment percentage that was "greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of . . ." the Social Security Act).

61. *See id.* § 256b(a)(4)(L)(iii) (describing how a subsection (d) hospital meets the definition of a covered entity, if among other requirements, it "does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement"). A group purchasing organization (GPO) is an organization "created to leverage the collective [purchasing] power of . . . entities[] to obtain discounts from vendors" based on the collective buying power of the GPO members." GEORGE B. MOSELEY III, *MANAGING LEGAL COMPLIANCE IN THE HEALTH CARE INDUSTRY* 100 (2013).

62. 42 U.S.C. § 256b(a)(4)(L)(iii).

63. *See id.* § 256b(a)(4) (listing the different types of hospitals and non-hospital entities which are considered covered entities).

64. 42 U.S.C. § 1396d(l)(1)(B).

a. DSH Adjustment Percentage

All hospitals participating in 340B must have a minimum disproportionate share adjustment percentage with the exception of critical access hospitals.⁶⁵ Disproportionate share hospitals serve a significantly disproportionate number of low-income patients and receive payments from the Centers for Medicaid and Medicare Services (CMS)⁶⁶ to cover the costs of providing care to uninsured patients.⁶⁷ To qualify for the 340B Program, DSHs must have a DSH adjustment percentage greater than 11.75 and meet other criteria; sole community hospitals and rural referral centers must have an adjustment percentage of greater than 8 percent.⁶⁸

Critical access hospitals are not required to have a minimum DSH adjustment percentage. Both free-standing children's hospitals and cancer hospitals do not receive DSH adjustment payments, however, these hospitals must have a payer-mix that is greater than a DSH percentage of 11.75 percent. Outpatient sites affiliated with a hospital do not affect the hospital's DSH adjustment percentage because the percentage is based on a hospital's mix of inpatients. If a 340B hospital's DSH adjustment percentage falls below the minimum, then the hospital is required to inform HRSA—through the OPA—and the program will be terminated.⁶⁹

The DSH adjustment percentage was implemented in 1986 as part of the Medicare program so that hospitals with substantial low-income patient loads could receive higher payments to cover the higher costs of treating low-income patients.⁷⁰ “The DSH adjustment percentage is based on the DSH patient percentage which equals the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to

65. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,300–02 (Aug. 28, 2015); *see also* 42 U.S.C. § 256b(a)(4)(L)(i) (describing another type of hospital that is a covered entity under the Public Health Service Act).

66. *Disproportionate Share Hospitals*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/eligibility-andregistration/hospitals/disproportionate-share-hospitals/index.html> (last updated Sept. 2017).

67. *Id.* (“Disproportionate share hospitals are defined in Section 1886(d)(1)(B) of the Social Security Act.”).

68. 42 U.S.C. § 256b(a)(4)(L), (O).

69. MEDPAC, *supra* note 12, at 5.

70. *See* MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 70 (MedPAC ed. 2007) [hereinafter MEDPAC: MEDICARE PAYMENT POLICY] (discussing the implementation date of the DSH adjustment program and the purpose of the program); Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272 § 9105, 100 Stat. 82, 158–59 (1986) (codified as amended at 42 U.S.C. 1395ww(d)(5)).

patients eligible for Medicaid but not Medicare Part A.”⁷¹ The DSH Percentage is calculated using the following formula:⁷²

$$\begin{aligned} & (\text{Medicaid, Non-Medicare Days} / \text{Total Patient Days (All Payers)}) \\ & + (\text{Medicare SSI Days} / \text{Total Medicare Days}) \\ & = \text{DSH Percentage} \end{aligned}$$

Although the DSH adjustment percentage is the primary method of demonstrating that a hospital serves a disproportionate share of low-income patients, there is an exception to the 11.75 percent requirement that applies to large urban hospitals having 100 beds or more.⁷³ These hospitals must demonstrate that more than 30 percent of their total net inpatient care revenue comes from state and local government programs for indigent care other than Medicare or Medicaid.⁷⁴

The DSH adjustment percentage is based on the number of Medicaid and low-income Medicare patients treated on an inpatient basis.⁷⁵ However, the DSH formula does not account for uninsured patients.⁷⁶ In other words, a hospital could have a number of uninsured patients transitioning to Medicaid which would make the hospital more likely to qualify for 340B while simultaneously reducing the burden of uninsured care.⁷⁷ Critics of 340B take issue with the DSH metric as a proxy for eligibility because it fails to ensure the program is benefiting true safety-net hospitals that serve high numbers of indigent patients.⁷⁸

71. *Disproportionate Share Hospital (DSH), The Medicare DSH Adjustment (42 C.F.R. 412.106)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html> (last modified Mar. 19, 2018).

72. *Id.*; see also 42 C.F.R. § 412.106(b) (2017).

73. U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-442, *MEDICARE PART B DRUGS: ACTION NEEDED TO REDUCE FINANCIAL INCENTIVES TO PRESCRIBE 340B DRUGS AT PARTICIPATING HOSPITALS* 4, n.10 (2015), <https://www.gao.gov/assets/680/670676.pdf>.

74. 42 U.S.C. § 1395ww(d)(v)(F)(i)(II) (2012). These hospitals are known as “Pickle” hospitals—named for JJ Pickle, a former member of Congress. See *340B Drug Pricing Program, FAQs*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/faqs/> (last updated Sept. 2018) (stating that “The 11.75% requirement is waived for a few hospitals known as ‘Pickle’ hospitals . . .”).

75. *Medicare Learning Network Fact Sheet, Medicare Disproportionate Share Hospital*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 2017), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network.MLN/MLNProducts/downloads/Disproportionate_Share_Hospital.pdf.

76. Karyn Schwartz, *340B Paradox: As the Uninsured Rate Drops, 340B Program Continues to Grow*, PHARM. RESEARCH & MFRS. OF AM. (Apr. 2, 2015) <https://catalyst.pharma.org/340b-paradox-as-the-uninsured-rate-drops-340b-program-continues-to-grow>.

77. *Id.*

78. See *id.* (explaining that as the amount of uncompensated health care provided by hospitals continues to decrease, a greater number of facilities will qualify for the 340B program which critics argue will lead to the program’s “uncontrolled and unsustainable growth”).

b. Contract Pharmacies

Although the 340B statute does not explicitly mention contract pharmacies, “covered entities are free to choose how they provide 340B pharmacy services to their patients, subject to state and federal laws.”⁷⁹ Many covered entities provide 340B drugs through an in-house pharmacy.⁸⁰ However, 340B covered entities may contract with a pharmacy or pharmacies that are not part of the entity to provide services to the covered entity’s patients.⁸¹ These pharmacies are known as contract pharmacies.⁸²

Until 2010, only covered entities without an in-house pharmacy were allowed to contract with a single outside pharmacy to dispense drugs on their behalf.⁸³ In 2010, HRSA issued guidance allowing all covered entities to contract with multiple outside pharmacies.⁸⁴ Covered entities may elect to work with a contract pharmacy because the entity may not have access to an in-house pharmacy or the entity may want to supplement its services by using multiple contract pharmacies to increase patient access to 340B drugs.⁸⁵

The 340B entity must have a written, signed contract pharmacy agreement in place with the pharmacy or pharmacies prior to registering the pharmacy or pharmacies with the 340B Program.⁸⁶ HRSA notes that the covered entity has, and continues to bear, full responsibility and accountability for compliance with

79. *340B Drug Pricing Program, FAQs*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/faqs/> (last updated Sept. 2018).

80. See Bobby L. Clark et al., *The 340B Discount Program: Outpatient Prescription Dispensing Patterns Through Contract Pharmacies in 2012*, 33 HEALTH AFF. 2012, 2013 (2014) (explaining that covered entities may choose to dispense 340B prescriptions through an in-house pharmacy, single contract pharmacy, or multiple contract pharmacies).

81. Memorandum from Mary K. Wakefield, Adm’r, Health Res. and Servs. Admin., on Contract Pharmacy Arrangements in the 340B Program to Stuart Wright, Deputy Inspector General for Evaluation and Inspections (Feb. 4, 2014) (on file with the Department of Health and Human Services, Office of Inspector General) [hereinafter Wakefield].

82. *Id.*

83. See 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (permitting covered entities participating in the 340B Drug Pricing Program to use a single point for pharmacy services, either an in-house pharmacy or individual contract pharmacy).

84. See *id.* (permitting covered entities to “use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts . . .”).

85. See *Contract Pharmacy Services*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/implementation/contract/> (last updated Jan. 2018) (discussing how dispensing 340B drugs to patients through contract pharmacy services helps facilitate program participation for covered entities without appropriate “in-house” pharmacy services, and further can serve as supplemental services for covered entities with access to “in-house” pharmacy services).

86. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,277–79 (Mar. 5, 2010). Each contract pharmacy is required to register with the OPA to ensure that drug manufacturers and drug wholesalers are informed of the contract pharmacy agreement. *Id.* at 10,279. Until the contract pharmacy is approved by the OPA and listed on the 340B database, it is not eligible to be used by the covered entity. *June 2015—Office of Pharmacy Affairs Update*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/updates/2015/june.html> (last updated April 2017).

all requirements of the 340B Program which includes prevention of the diversion of covered drugs to individuals other than patients of the covered entity and duplicate discounts—both statutorily prohibited.⁸⁷ HRSA states that covered entities should “engage an independent organization to perform annual audits of the contract pharmacies and develop comprehensive written contract pharmacy policies and procedures that include the performance of independent audits of its contract pharmacies.”⁸⁸ “In situations where the covered entity is not providing oversight of its contract pharmacies, HRSA may remove those contract pharmacies from the 340B Program.”⁸⁹

Since 2010, there has been a rapid growth in the number of contract pharmacies which includes retail, specialty, and mail order pharmacies. As of July 2011, there were more than 7,000 contract pharmacy arrangements in the 340B Program.⁹⁰ Between 2010 and 2014, the number of pharmacies serving as contract pharmacies increased by 154 percent.⁹¹ According to HRSA, as of January 2015, the number of contract pharmacy arrangements in the program had increased to 36,000.⁹²

The increased use of contract pharmacies has contributed immensely to the growth of the 340B Program. Contract pharmacy arrangements are beneficial to covered entities for multiple reasons including allowing patients to fill prescriptions somewhere other than the covered entity and allowing the covered entity to supplement its services. However, contract pharmacies bring an increased risk of drug diversion and duplicate discounts due to the complexity of the arrangements, the expenses of sophisticated inventory tracking systems or third-party administrators, and the lack of a universal method that can accurately identify 340B claims.

c. Auditing Covered Entities

All 340B covered entities are required to ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements. Statutorily, HRSA has the authority to audit covered entities to

87. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. at 10,278. Drug diversion is when a 340B drug is provided to an individual who is not an eligible patient. A duplicate discount takes place when a manufacturer is billed for Medicaid rebates on drugs purchased at a 340B discount. Both are statutorily prohibited and are discussed further in section iv. *See* discussion *infra* Section III.C.iv.

88. *August 2016—Contract Pharmacy: Important Tips*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/updates/2016/august.html> (last updated April 2017).

89. *Id.*

90. U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-455T, DRUG DISCOUNT PROGRAM: STATUS OF GAO RECOMMENDATIONS TO IMPROVE 340B DRUG PRICING PROGRAM OVERSIGHT, 9 (2015), www.gao.gov/assets/670/669188.pdf [hereinafter GAO, DRUG DISCOUNT PROGRAM].

91. MEDPAC, *supra* note 12, at 9.

92. GAO, DRUG DISCOUNT PROGRAM, *supra* note 90, at 9 n.21.

ensure compliance with the 340B Program requirements.⁹³ Covered entities may be audited by manufacturers as well.⁹⁴ In addition to audits, 340B entities are annually required to recertify its eligibility to remain in the program, and its eligibility to continue purchasing covered outpatient drugs at discounted 340B prices.⁹⁵ This is to help ensure compliance with respect to eligibility status, as well as, compliance with the prohibition against GPOs, duplicate discounts, and drug diversion. Failure to maintain compliance may result in the covered entity being liable to manufacturers for refunds of discounts and being removed from the 340B Program.⁹⁶

An audit will include, at a minimum: a review of relevant policies and procedures and how they are operationalized; verification of eligibility, including GPO and outpatient clinic eligibility; verification of internal controls to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered inpatient or outpatient, HRSA Medicaid Exclusion File designations, and accuracy of covered entity's 340B database record; review of 340B Program compliance at covered entity, outpatient or associated facilities, and contract pharmacies; and testing of 340B drug transaction records on a sample basis.⁹⁷

The information collected in the audit must be submitted to HRSA through the OPA where it is reviewed. After HRSA reviews the audit, it will issue a report with a request for a corrective action plan (CAP), if necessary. If the covered entity agrees with the report, then the entity must submit a CAP to HRSA for approval. If the covered entity disagrees with the report, then the entity must submit supporting documentation of the entity's disagreement. OPA will review the covered entity's response and, may reissue a report, if necessary. A covered entity may be removed from the 340B Program if it fails to comply. Once the findings of the audit and any associated corrective action are finalized, OPA publishes the report on the OPA website.⁹⁸ Audit and compliance is a must with contract pharmacies. The covered entity is required to have fully auditable records to demonstrate compliance with all 340B Program requirements.⁹⁹ The contract pharmacy must provide the covered entity with reports consistent with customary business practices such as quarterly billing statements, status reports

93. 42 U.S.C. § 256b(a)(5)(C) (2012).

94. *Id.*

95. *Id.* § 256b(a)(7)(E).

96. *Id.* § 256b(a)(5)(D); *see also id.* § 256b(d)(2)(B)(v)(II) (discussing that where the Secretary determines there to be a violation, the covered entity will be removed from the drug discount program).

97. *Program Integrity*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/program-integrity/index.html> (last updated Mar. 2018).

98. *Id.*

99. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

of collections, and receiving and dispensing records.¹⁰⁰ “The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity.”¹⁰¹ Customary business records may be used for this purpose.¹⁰² The covered entity must establish a process for periodic comparison of its prescribing records with the contract pharmacy’s dispensing records to detect potential irregularities.¹⁰³ Any 340B Program violations found during internal or independent audits must be disclosed to HRSA along with the covered entity’s plan to address the violation.¹⁰⁴ A contract pharmacy will be removed from the 340B Program if the covered entity is not providing oversight of its contract pharmacy arrangement.¹⁰⁵

In a 2011 report, the GAO found that HRSA had not conducted a single audit in the nearly 20 years of the program’s existence.¹⁰⁶ In response, the GAO recommended HRSA conduct selective audits of 340B covered entities.¹⁰⁷ In 2012, HRSA implemented a risk-based and targeted approach to conducting audits on covered entities. The risk-based audits focused on covered entities deemed to be at a higher risk of noncompliance “due to the volume of purchases, increased complexity of the program administration, and use of contract pharmacies.”¹⁰⁸ The targeted audits were triggered by allegations of violations of 340B requirements, whether through whistleblowers, manufacturers, or self-reported. In 2012, HRSA audited 45 randomly selected covered entities for risk-based audits and six targeted covered entities based on information from stakeholders.¹⁰⁹ The audits encompassed more than 410 outpatient facilities and 860 contract pharmacy locations.¹¹⁰ HRSA has continued to audit covered entities and posts the results of the audit on its website.¹¹¹

100. *Id.* at 10,278.

101. *Id.*

102. *Id.*

103. *See id.* at 10,279 (“Such records can include: Prescription files, velocity report, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.”).

104. *Id.* at 10,274.

105. *See id.* at 10,278 (stating that a covered entity may be removed from the list of covered entities and no longer be eligible for 340B pricing because of its participation in drug diversion).

106. *See* GAO, DRUG PRICING, *supra* note 9, at 32–33 (explaining that, instead, “the agency largely relies on participants’ self-policing to ensure compliance with program requirements.”).

107. *Id.* at 34.

108. U.S. DEPT. OF HEALTH & HUM. SERVS., HEALTH RES. & SERVS. ADMIN., CLARIFICATION OF HRSA AUDITS OF 340B COVERED ENTITIES (2013), <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/auditclarification020813.pdf>.

109. GAO, DRUG DISCOUNT PROGRAM, *supra* note 90, at 10.

110. *Id.*

111. *Contract Pharmacy Services*, HEALTH RES. & SERV.’S. ADMIN., <https://www.hrsa.gov/opa/implementation/contract/> (last updated Jan. 2018).

HRSA's lack of auditing for the first 20 years and the heavy reliance on self-policing contributed to the failed oversight of HRSA and increased the risk of noncompliance. The self-policing was problematic because participants in the 340B Program had "little incentive to comply with program requirements, because few have faced sanctions for noncompliance."¹¹² Although HRSA has increased auditing in the last few years, much more is required to ensure program compliance.

ii. Pharmaceutical Pricing Agreements

To be eligible for the 340B Program, drug manufacturers are required to enter into a pharmaceutical pricing agreement (PPA) with the Secretary of HHS.¹¹³ PPAs are not transactional, bargained-for contracts.¹¹⁴ Rather, PPAs are uniform agreements that incorporate statutory obligations and list the responsibilities of both drug manufacturers and HHS under the 340B Program.¹¹⁵ Participation in the program is conditioned on a manufacturer's entry into a PPA for covered drugs purchased by 340B entities.¹¹⁶ The PPAs are similar to the MDRP agreements whereas they serve as the means by which drug manufacturers opt into the statutory scheme.¹¹⁷

Once a manufacturer enters into a PPA, that manufacturer is barred from charging covered entities drug prices exceeding a cap set by HHS.¹¹⁸ This is known as the ceiling price.¹¹⁹ A manufacturer agrees to charge covered entities no more than the predetermined price derived from the average and best prices and rebates calculated under the MDRP.¹²⁰ If a covered drug is "made available to any other purchaser at any price," then manufacturers must offer these drugs "for purchase at or below the applicable ceiling price" to any covered entity of the 340B Program.¹²¹

a. Ceiling Price

Under the PPA, manufacturers stipulate that they will charge 340B entities at or below a specified maximum price—the 340B ceiling price. The 340B ceiling price, based on a statutory cap, represents the maximum price a

112. GAO, DRUG PRICING, *supra* note 9, at 32–33.

113. 42 U.S.C. § 256b(a) (2012); *PhRMA II*, 138 F. Supp. 31, 34 (D.D.C. 2015).

114. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 113 (2011).

115. *Id.*

116. *Id.*

117. *Astra*, 536 U.S. at 113.

118. 42 U.S.C. § 256b(a)(1).

119. *See* 42 U.S.C. § 1396r-8(c) (stating how to calculate the ceiling price); *id.* § 1396r-8(c)(2)(D) (capping the total possible rebate percentage at 100 percent of the price of the drug).

120. *Astra*, 563 U.S. at 115; 42 U.S.C. § 256(a)(1).

121. 42 U.S.C. § 256b(a)(1).

manufacturer can charge for a 340B drug.¹²² Ceiling prices are guaranteed whether the 340B entity purchases drugs directly from manufacturers or through a wholesaler. The ceiling prices and key data used to calculate them are proprietary and are not shared with the general public. The MDRP's statute prohibits "HHS from disclosing pricing information in a form that could reveal the prices a manufacturer charges for drugs it produces."¹²³ However, the ACA requires HHS to give covered entities access to some of the information submitted by manufacturers.¹²⁴

The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage—commonly referred to as the Unit Rebate Amount (URA).¹²⁵ HRSA obtains the AMP and URA data from CMS as part of quarterly reporting for the MDRP.¹²⁶ Both HRSA and drug manufacturers separately calculate 340B ceiling prices each quarter by using the same statutorily-defined formula and the drug pricing data that manufacturers report to the CMS. The 340B ceiling price is specific to each 11-digit National Drug Code (NDC).

Defined under the MDRP, the AMP means the average price paid to the manufacturer for the drug by (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer.¹²⁷ The AMP is calculated from the preceding calendar quarter for the smallest unit of measure.¹²⁸ Manufacturers report these prices as proprietary information to CMS and may be subject to audit by HHS.

The URA is the amount of Medicaid rebate due for each unit of a drug.¹²⁹ HRSA calculates URAs using a statutory formula that is based on the formula used to calculate Medicaid drug rebates.¹³⁰ The statutory formula for the URA

122. 42 U.S.C. § 256b(a)(1). Manufacturers may sell a drug at a price that is lower than the ceiling price. *Id.* Additionally, covered entities may negotiate with manufacturers in order to pay prices below the ceiling price. *Overview of the 340B Drug Pricing Program*, 340B Health, <https://www.340bhealth.org/members/340b-program/overview/> (last visited Oct. 28, 2018).

123. *Astra*, 563 U.S. at 121; 42 U.S.C. § 1396r-8(b)(3)(D).

124. Patient Protection and Affordable Care Act Pub. L. No. 111-148, § 7102, 124 Stat. 119, 824 (2010) (codified as amended at 42 U.S.C. 256b(d)); 42 U.S.C. § 256b(d)(1)(B)(i)(I); *Astra*, 563 U.S. at 121 n.8.

125. *340B Ceiling Price Calculation*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/updates/2015/may.html> (last updated Apr. 2017); 42 U.S.C. § 256b(a)(1).

126. 42 U.S.C. § 1396r-8(a)(1). Manufacturers are required to submit their average manufacturer price (AMP) and their best price for each respective dosage form and strength of all prescription drugs to CMS as part of quarterly reporting for the MDRP. *Id.*

127. *Id.* § 1396r-8(k)(1)(A).

128. *Id.* § 256b(a)(1).

129. *See Unit Rebate Amount Calculation*, MEDICAID, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/index.html> (last visited Oct. 26, 2018).

130. *Id.* § 1396r-8.

varies based on whether the drug is categorized as a single-source, innovator multiple-source drug, a non-innovator multiple-source drug, a clotting factor, or exclusively pediatric drug.¹³¹ For single-source and multiple-source innovator drugs, the URA is the greater of (i) 23.1 percent of the AMP per unit or (ii) the difference between the AMP and the best price per unit; adjusted by the Consumer Price Index-Urban (CPI-U) based on launch date and current quarter AMP.¹³² For multiple-source non-innovator drugs, the URA equals 13 percent of the AMP per unit.¹³³ For clotting factors or exclusively pediatric drugs, the URA is the greater of (i) 17.1 percent of the AMP per unit or (ii) the difference between the AMP and the best price per unit; adjusted by the CPI-U based on launch date and current quarter AMP.¹³⁴

This figure is then multiplied by the package size and case package size to produce a price for the drugs.¹³⁵

$$340B \text{ Ceiling Price} = [(AMP) - (URA)] \times \text{Drug Package Size}$$

The ceiling price is calculated at the smallest unit of measure, to six decimal places.¹³⁶ HRSA is required to publish all 340B ceiling prices, rounded to two decimal places.¹³⁷ The URA can equal but not exceed 100 percent of the AMP for a period.¹³⁸ If the formula yields a price of zero or a negative number for a 340B drug, then HRSA has instructed manufacturers to set the price for that drug at a penny for the smallest unit of measure for that quarter—this has become known as HRSA’s “Penny Pricing Policy.”¹³⁹ In 2017, HRSA published

131. *Id.* CMS’ Medicaid Drug Rebate (MDR) system performs the URA calculation using the drug manufacturer’s pricing. The specific methodology used is determined by law and depends upon whether a drug is classified as single source, i.e., drugs for which there are no generic alternatives available on the market, innovator multiple-source, i.e., drugs that have FDA New Drug Application approval and for which there exists generic alternatives on the market, non-innovator multiple source, i.e., drugs that do not have FDA New Drug Application approval and are, in effect, generic drugs, a clotting factor drug, or an exclusively pediatric drug. *Medicaid Drug Rebate Program*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (last updated Sept. 11, 2018).

132. 42 U.S.C. § 1396r-8(c)(1) (2012). The URA for single-source and innovator multiple-source drugs is the greater of (AMP x 23.1%) or (AMP – the best price). *Id.*

133. 42 C.F.R. § 447.509(a)(6)(ii) (2016).

134. *Id.* §1396r-8(c)(1)(B)(iii).

135. *Id.* For example, the AMP minus the URA indicates the cost of one pill. HRSA calculates the price of the total number of pills in the bottle (package size), and then the price of the multiple packages (case package size), which results in the 340B ceiling price and the corresponding quantity at which covered entities actually purchase the covered outpatient drug. *Id.*

136. 42 C.F.R. § 10.10 (2017).

137. 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties Regulation, 82 Fed. Reg. 45,511 (Jan. 5, 2017) (codified at 42 C.F.R. pt. 10).

138. *Id.*

139. *See id.* (When the URA equals the AMP, the price for 1 unit of the drug would be \$.01).

regulations specifying how the 340B ceiling price is calculated for a drug—including commentary on HRSA’s Penny Pricing Policy—and creating standards for imposing civil monetary penalties (CMPs) on manufacturers that knowingly and intentionally overcharge covered entities.¹⁴⁰

b. Prime Vendor Programs (PVP)

The 340B Program requires HRSA to establish a Prime Vendor Program (PVP).¹⁴¹ “The purpose of the PVP is to develop, maintain, and coordinate a program capable of distribution, facilitation, and other activities in support of the 340B Program.”¹⁴² The PVP assists HRSA with the administration of the 340B Program and is managed by contractors. HRSA currently contracts with a company called Apexus to manage the PVP.¹⁴³

The PVP establishes a distribution network for pharmaceuticals to covered entities and negotiates prices for a portfolio of drugs below the 340B price.¹⁴⁴ Apexus can negotiate sub-ceiling prices on 340B drugs with manufacturers by pooling the purchasing power of covered entities. “The PVP is a voluntary program for 340B covered entities and serves its participants in three primary roles: (1) negotiating sub-340B pricing on pharmaceuticals; (2) establishing distribution solutions and networks that improve access to affordable medications; and (3) providing other value-added products and service.”¹⁴⁵ “As of April 2014, about 82 percent of covered entities participated in the PVP and accounted for \$5 billion in 340B drug purchases.”¹⁴⁶

iii. Patients of the Entity

Under the 340B Program, covered entities may only provide 340B drugs to individuals who are eligible patients of the entity.¹⁴⁷ However, the statute does not define the term “patient.” Due to the large number of covered entities and the wide diversity of eligible groups, the definition of a “patient” required flexibility

140. See generally 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (Jan. 5, 2017) (codified at 42 C.F.R. pt. 10).

141. 42 U.S.C. §256b(a)(8) (2012).

142. *340B Drug Pricing Program, FAQs*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/faqs/> (last updated Sept. 2018).

143. *About the PVP*, APEXUS, <https://www.340bpvp.com/about/> (last visited Oct. 28, 2018).

144. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. at 1229–30.

145. *340B Drug Pricing Program, FAQs*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/faqs/> (last updated Sept. 2018).

146. MEDPAC, *supra* note 12, at 7.

147. See 42 U.S.C. § 256b(a)(5)(B) (“[A] covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.”).

to ensure it covered each covered entity's patients.¹⁴⁸ In 1996, HRSA issued guidance on the 340B Program definition of patient.¹⁴⁹ In summary, an individual is a "patient" of a covered entity—with the exception of state-operated or funded AIDS drug purchasing assistance programs—only if: (1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements—e.g. referral for consultation—such that responsibility for the care provided remains with the covered entity; and (3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity—DHSs are exempt from this requirement.¹⁵⁰ Under this definition, covered entities are subject to all three requirements; hospitals are only subject to the first two.

An individual will not be considered a patient of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.¹⁵¹ In cases where an individual has received health care services from a non-covered entity resulting in a prescription, the administrative act of recording such information, incorporating it into the health record, and filling the prescription does not constitute health care services for the patient's health care for purposes of the 340B Program. If the outpatient is referred to a specialist, the patient is covered under 340B as long as the covered entity has responsibility for the patient.

In 2007, HSRA determined that "some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program."¹⁵² HRSA published proposed guidance intended to clarify the definition of a patient and update the 1996 guidance.¹⁵³ HRSA determined the clarification was necessary to "protect the

148. Notice Regarding Section 602 of the Veterans Healthcare Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157–58 (Oct. 24, 1996).

149. *Id.*

150. *Id.*

151. *See id.* at 55,158 (stating that, "[a]n individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHS Act will be considered a 'patient' of the covered entity for purposes of this definition if so registered as eligible by the state program.").

152. *See* Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient," 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007) (stating that under 340B it is illegal for covered entities to sell medications purchased under the program to persons who are not considered "patients" of the covered entity).

153. *Id.*

integrity of the 340B Program and to assist covered entities and other participants in their compliance efforts.”¹⁵⁴ However, HRSA withdrew this proposal following a May 2014 federal district court ruling.¹⁵⁵ Again in 2015, HRSA attempted to update the definition, but ultimately withdrew the proposal in January 2017.

The definition of patient is one of the key issues with the 340B Program. The current definition is outdated and problematic due to ambiguity. Moreover, the current definition allows anyone, regardless of wealth or insurance, to qualify for 340B discounted drugs. An updated definition is necessary in order to ensure covered entities remain in compliance and cut down on drug diversion.

iv. Covered Drugs

The 340B Program limits the price that manufacturers may charge certain covered entities for covered outpatient drugs; inpatient services are not covered.¹⁵⁶ A covered outpatient drug, defined in § 1927(k) of the Social Security Act, is summarized as FDA-approved prescription drug; over-the-counter (OTC) drugs written on a prescription; biological products that can be dispensed only by a prescription other than a vaccine; or FDA-approved insulin.¹⁵⁷ The term excludes inpatient drugs and drugs that are bundled with other services for payment purposes.

Covered entities have the responsibility to ensure that drugs purchased under the 340B Program are limited to outpatient use. Whether a drug qualifies as outpatient depends upon the factual circumstances surrounding the care of that particular individual. A hospital is required to develop appropriate tracking systems to ensure that covered outpatient drugs purchased through the 340B Program are not used for hospital inpatients. Proper tracking is critical in “mixed-use” settings, such as surgery departments, cardiac catheter labs, infusion centers, and emergency departments, where both inpatients and outpatients are treated. The entity is responsible for the use of the drugs and auditable records that demonstrate compliance with 340B Program requirements.¹⁵⁸

a. Drug Diversion and Duplicate Discount

The 340B Program forbids covered entities from reselling or otherwise transferring 340B discounted drugs to an individual who is not a patient of the

154. *Id.* at 1543.

155. *See PhRMA I*, 43 F. Supp. 3d 28, 31 (D.D.C. 2014) (holding that the Secretary of Health and Human Services lack the statutory authority to implement the orphan drug rule at issue in this case).

156. 42 U.S.C. § 256b(b)(2) (2012).

157. 42 U.S.C. § 1396r-8(k)(2); 42 U.S.C. § 256b(b)(2)(A).

158. *340B Drug Pricing Program, FAQs*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/faqs/> (last updated Sept. 2018).

entity.¹⁵⁹ Drug diversion occurs when a 340B drug is provided to an individual who is not an eligible patient. Thus, if a covered entity receives a 340B discount on a drug, then the entity may not “resell or otherwise transfer” the drug to anyone who is not a patient of the entity.¹⁶⁰ Covered entities are subject to audits and sanctions for violations of the diversion prohibition.¹⁶¹

Known as duplicate discounts, manufacturers may not provide a discounted 340B price and a Medicaid drug rebate for the same drug.¹⁶² In other words, manufacturers may not be billed for Medicaid rebates on drugs purchased at a 340B discount. Covered entities are required to have a mechanism in place to prevent duplicate discounts.¹⁶³

To help ensure that covered entities avoid duplicate discounts, when an entity is enrolled in the 340B Program, the entity must choose to “carve-in” or “carve-out” Medicaid patients. An entity that carves in their Medicaid patients should provide 340B drugs for their Medicaid patients and the state Medicaid program is not allowed to claim the rebates.¹⁶⁴ An entity that carves out their Medicaid patients will purchase drugs for their Medicaid patients through other means and the state Medicaid program is permitted to claim rebates on the drugs.¹⁶⁵

“HRSA maintains a file of covered entities that carve in Medicaid patients to help state Medicaid agencies identify claims for 340B drugs and prevent duplicate discounts.”¹⁶⁶ If a covered entity decides to bill Medicaid for drugs purchased under 340B, then *all* drugs billed under their Medicaid provider number or National Provider Identifier (NPI), must be listed in the HRSA Medicaid Exclusion File (MEF).¹⁶⁷ Covered entities that choose to carve-out—i.e. opt to purchase Medicaid drugs outside of the 340B Program—must ensure that *all* drugs billed under their Medicaid provider number or NPI are not listed in the MEF.

The MEF allows for states and manufacturers to see which drugs are not subject to Medicaid rebates and helps prevent duplicate discounts. Covered

159. 42 U.S.C. § 256b(a)(5)(B).

160. *Id.*

161. *Id.* § 256b(a)(5)(C)–(D).

162. *Id.* § 256b(a)(5)(A)(i).

163. *Id.* § 256b(a)(5)(A)(ii).

164. See MEDPAC, *supra* note 12, at 7 (“In 2013, 65 percent of hospital sites and 37 percent of nonhospital sites provided 340B drugs to Medicaid patients, i.e. carved in Medicaid patients.”).

165. *Duplicate Discount Prohibition*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html> (last updated Sept. 2017).

166. MEDPAC, *supra* note 12, at 9.

167. *Duplicate Discount Prohibition*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html> (last updated Sept. 2017). Adopted under HIPAA, the NPI is a unique identification number for covered health care providers issued by the Centers for Medicare and Medicaid Services. 45 C.F.R. § 162.406 (2005).

entities may request to change either their carve-in decision or the specific identifiers listed in the MEF at any time.¹⁶⁸ These requests take effect the following quarter pending the approval by OPA.¹⁶⁹ The covered entities are responsible for ensuring the information in the MEF is accurate each quarter and at the time of annual recertification.¹⁷⁰

Covered entities are required to permit HRSA and manufacturers to audit records that directly pertain to compliance with the prohibition of resale/transfer or double discounts.¹⁷¹ HRSA may terminate the manufacturer's PPA if found to be overcharging a covered entity, which would also terminate the manufacturer's eligibility for Medicaid coverage.¹⁷²

v. No Restriction on Revenue

The 340B statute does not restrict how covered entities may use revenue. The 340B Program does not prohibit covered entities from providing 340B drugs to individuals with Medicare or private insurance so long as the individual is a qualifying patient of the covered entity and the drug is not subject to a duplicate discount under Medicaid. Furthermore, a patient's income does not affect whether the patient is covered by the 340B Program.

Under the 340B Program, a covered entity may generate revenue when reimbursement for the covered outpatient drugs exceeds the discounted prices the entity paid for the drugs.¹⁷³ Covered entities may use these funds to expand the number of patients served, increase the scope of services offered to low-income and other patients, invest in capital, cover administrative costs, or for any other purpose.¹⁷⁴ Moreover, HRSA does not have the statutory authority to track how entities use this revenue.¹⁷⁵

Financial incentives drive both drug manufacturers and covered entities. The original intent of the 340B Program is to help uninsured, indigent patients by giving qualifying health care facilities access to discounts for outpatient drugs.¹⁷⁶ However, as the program grows, there are incredible financial incentives for both sides.

168. *Duplicate Discount Prohibition*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html> (last updated Sept. 2017).

169. *Id.*

170. *Id.*

171. 42 U.S.C. § 256b(a)(5)(C) (2012).

172. 42 U.S.C. § 1396r-8(b)(4)(B).

173. MEDPAC, *supra* note 12, at 8.

174. *Id.*

175. *Id.*

176. *Our View: 340B Benefits Vulnerable Patients, Essential Hospitals, Taxpayers*, AMERICA'S ESSENTIAL HOSPITALS (March 2016), <http://essentialhospitals.org/wp-content/uploads/2016/03/Our-View-340B-March-2016.pdf>.

III. CURRENT STATE OF AFFAIRS OF THE 340B DRUG PRICING PROGRAM

A. Recent Growth

Since the 340B Program was established in 1992, it has grown rapidly through both Congressional action and administrative action.¹⁷⁷ Most recently, the 340B Program expanded in 2010 under the ACA.¹⁷⁸ This expansion included expanding the eligibility of Medicaid, the beginning of multiple contract pharmacies, and broadening the eligibility of covered entities.¹⁷⁹ “According to HRSA officials, as of 2015 more than 11,000 covered entities were participating in the 340B Program—an increase of approximately 30 percent since 2008.”¹⁸⁰ Every state and the District of Columbia has 340B hospitals.¹⁸¹ Furthermore, in a November 2014 white paper analyzing the growth of the 340B Program, the Berkeley Research Group (BRG) predicted growth to be greater than \$11 billion by 2019.¹⁸² Yet, in 2015, discounted purchases made under 340B hit \$12 billion.¹⁸³

B. The Patient Protection and Affordable Care Act

In 2010, the 111th United States Congress enacted the Patient Protection and Affordable Care Act (ACA).¹⁸⁴ The ACA—as amended by section 2302 of the Health Care and Education Reconciliation Act (HCERA)—made several notable changes to the 340B Program including expanded participation in the program and expanded regulations in order to ensure 340B integrity.¹⁸⁵ The ACA not only expands Medicaid, but also state-level expansions in state-level Medicaid.¹⁸⁶ As a result, the ACA expands the scope of the Medicaid program

177. ANDREW W. MULCAHY ET AL., *THE 340B PRESCRIPTION DRUG DISCOUNT PROGRAM: ORIGINS, IMPLEMENTATION, AND POST-REFORM FUTURE*, 5 fig.3, 6 (2014).

178. *Id.* at 6.

179. *Id.* at 5–6 (discussing the extension of eligibility to critical access hospitals, sole community hospitals, rural referral centers, and cancer centers).

180. GAO, *DRUG DISCOUNT PROGRAM*, *supra* note 90, at 1.

181. *List of 340B Hospitals by State*, 340B HEALTH, <http://advocacy.340bhealth.org/340Bhospitalists> (last updated Apr. 2018).

182. AARON VANDERVELDE, *GROWTH OF THE 340B PROGRAM: PAST TRENDS, FUTURE PROJECTIONS 2* (2014).

183. Adam J. Fein, *340B Purchases Hit \$12 Billion in 2015—and Almost Half of the Hospital Market*, DRUG CHANNELS (Feb. 23, 2016), <https://www.drugchannels.net/2016/02/340b-purchases-hit-12-billion-in.html>.

184. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

185. §§ 7101(a), 7102(a), 124 Stat. at 821–25.

186. *A 50-State Look at Medicaid Expansion*, FAMILIES USA (May 2018), <https://familiesusa.org/product/50-state-look-medicaid-expansion>.

and increases the number of individuals states must cover.¹⁸⁷ The number of Medicaid patients served by a hospital affects its DSH adjustment percentage, which helps determine hospital eligibility for the 340B program.¹⁸⁸

i. Expanded Entities

The ACA expanded the 340B Program by expanding entity eligibility for the program to include additional types of hospitals such as certain children's hospitals and free-standing cancer hospitals, critical access hospitals (CAHs), rural referral centers (RRCs), and sole community hospitals (SCHs).¹⁸⁹

In 2010, HCERA¹⁹⁰ excluded orphan drugs from 340B pricing applicable to the newly added hospitals.¹⁹¹ Due to an ambiguity, covered entities contended orphan-designated drugs should be included in the 340B Program for the newly added covered entities, while drug manufacturers contended that all orphan-designated drugs should be excluded from the 340B Program for the newly added covered entities.¹⁹² This disagreement was the catalyst of two court battles.¹⁹³

ii. Expanded Regulations—Improvements to 340B Program Integrity

a. Overview

In addition to expanding eligibility for covered entities, the ACA contained provisions to improve 340B Program integrity.¹⁹⁴ The ACA explicitly authorized HRSA to issue regulations and provided for more rigorous enforcement.¹⁹⁵ Prior to the ACA, 340B did not explicitly provide authority for HRSA to issue regulations. HRSA simply “used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration.”¹⁹⁶ Under the ACA, Congress “chose to strengthen and formalize HRSA’s enforcement authority.”¹⁹⁷

187. *Medicaid Enrollment Changes Following the ACA*, MEDICAID & CHIP PAYMENT & ACCESS COMM., <https://www.macpac.gov/subtopic/medicaid-enrollment-changes-following-the-aca/>.

188. GAO, DRUG PRICING, *supra* note 9, at 27 n.62.

189. § 7101(a), 124 Stat. at 821–22; 42 U.S.C. § 256b(a)(4)(M)–(O) (2012).

190. Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010). The Act was signed into law by President Barack Obama on March 30, 2010.

191. § 2302, 124 Stat. at 1083.

192. *PhRMA I*, 43 F. Supp. 3d 28, 33–34 (D.D.C. 2014).

193. *PhRMA I*, 43 F. Supp. 3d at 39; *PhRMA II*, 138 F. Supp. 3d 31, 48–49 (D.D.C. 2015).

194. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102, 124 Stat. 119 823–26 (2010) (codified as amended 42 U.S.C. § 256b (2012)).

195. *Id.*

196. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

197. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 121–22 (2011).

b. Ceiling Price Calculation

Section 7102 of the ACA required HHS to develop a system to enable HHS to verify the accuracy of ceiling prices charged to covered entities which are calculated and reported by manufacturers.¹⁹⁸ HHS was required to develop and publish “precisely defined standards and methodology for the calculation of ceiling prices.”¹⁹⁹ This rule favored covered entities by assisting in obtaining refunds when overcharged by drug manufacturers.²⁰⁰ HRSA published a notice of proposed rulemaking in June 2015.²⁰¹ After closing the public comment period in August 2015, HRSA reopened the comment period for additional comments in April 2016.²⁰² In January 2017, HRSA published the final rule addressing the ceiling price calculations.²⁰³

First, the guidance adopts the statutory formula for calculating the 340B ceiling price—AMP for the smallest unit of measure minus URA.²⁰⁴ The final rule also indicates that the terms “package size” and “case package size” were removed.²⁰⁵ HHS plans to address these operational elements concerning the 340B ceiling price calculation in a future guidance associated with the 340B Program ceiling price reporting system.²⁰⁶

Next, the guidance finalized HRSA’s Penny Pricing policy.²⁰⁷ When ceiling price calculations result in a ceiling price that equals zero, the 340B ceiling price will be set at \$0.01—one penny.²⁰⁸ HRSA indicated that the “long-standing policy reflects a balance between the equities of different stakeholders and establishes a standard pricing method in the market.”²⁰⁹ HRSA indicated “any alternatives to penny pricing would violate the 340B ceiling price formula and would reward manufacturers for raising prices faster than inflation.”²¹⁰

198. § 7102, 124 Stat. at 826.

199. 42 U.S.C § 256b(d)(1)(B)(i)(I) (2012).

200. *Id.* § 256b(d)(1)(B)(ii).

201. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583, 34,583 (proposed June 17, 2015) (to be codified 42 C.F.R. pt. 10).

202. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Reopening of Comment Period, 81 Fed. Reg. 22,960, 22,960 (Apr. 19, 2016) (to be codified at 42 C.F.R. pt. 10).

203. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (Jan. 5, 2017) (to be codified as 42 C.F.R. pt. 10).

204. *Id.* at 1213.

205. *Id.* at 1214.

206. *Id.*

207. *See id.* at 1215–17 (noting commenters’ opposition to penny pricing, but finding that it best effectuates the statutory scheme); Press Release, Dept. of Health & Human Res., Clarification of Penny Pricing Policy (Nov. 21, 2011) (on file with Department of Health & Human Resources).

208. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. at 1215.

209. *Id.*

210. *Id.*

Finally, the guidance addressed pricing when a new drug is introduced.²¹¹ In general, the calculation of the ceiling price is based on the pricing data from the immediately preceding calendar quarter; however, for new drugs that data is not available. Thus, HRSA determined a new drug's AMP will be calculated within 30 days into the second quarter following its release.²¹² Once the AMP is calculated, drug manufacturers must contact the covered entities that overpaid for a drug and offer repayment for the difference within 120 days.²¹³ If a manufacturer fails to refund a covered entity within 120 day, then the manufacturer may be deemed to have knowingly and intentionally overcharged the covered entity resulting in civil monetary penalties.²¹⁴

HRSA published the final rule in January 2017, however, because 340B ceiling prices are calculated on a quarterly basis, HRSA intended to begin enforcing the rule beginning with prices offered April 1, 2017. On January 20, 2017, the Trump administration issued a Memorandum—entitled “Regulatory Freeze Pending Review”—directing agencies to temporarily postpone the effective date of regulations that had been published in the Federal Register but had not yet taken effect.²¹⁵ HHS initially delayed the effective date of the final rule to May 22, 2017, but subsequently changed the effective date of the final rule to July 1, 2018.²¹⁶

c. Civil Monetary Penalties—CMPs

The ACA also required HHS to develop and issue regulations for the 340B Program that established standards for the imposition of sanctions in the form of civil monetary penalties (CMPs) for manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug.²¹⁷ The CMPs shall not exceed \$5,000 for each instance of overcharge to a covered entity.²¹⁸ In September 2010, HRSA issued an advanced notice of proposed rulemaking on

211. *Id.* at 1217.

212. *Id.* at 1213. Prior to this guidance, drug manufacturers would estimate the ceiling price on a new drug. If the estimated price was higher than the eventually calculated AMP, then covered entities would have to pursue refunds. 340B Drug Pricing Program Ceiling price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583, 34,585 (proposed June 17, 2015) (to be codified at 40 C.F.R. pt. 10).

213. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. at 1218.

214. *Id.* at 1224.

215. Memorandum for the Heads of Executive Departments and Agencies; Regulatory Freeze Pending Review, 82 Fed. Reg. 8346, 8346 (Jan. 24, 2017).

216. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332, 14,333 (Mar. 20, 2017) (to be codified at 42 C.F.R. pt. 10); 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 45,511, 45,512 (Sept. 29, 2017) (to be codified at 42 C.F.R. pt. 10).

217. 42 U.S.C. § 256b(d)(1)(B)(vi)(III) (2012).

218. 42 U.S.C. § 256b(d)(1)(B)(vi)(II).

establishing the standards.²¹⁹ HRSA acknowledged that the regulations presented “a number of issues” since HRSA never had civil monetary penalty authority that addressed manufacturing overcharging of the 340B Program.²²⁰ Prior to the ACA, HRSA handled overcharge complaints through informal procedures.²²¹ However, the ACA directed HHS to develop formal procedures for resolving overcharge claims.²²² In June 2015, HHS issued notice of proposed rule set for the application of civil monetary penalties.²²³ In January 2017, HRSA issued a final rule on the 340B Manufacturer Civil Monetary Penalties Regulation.²²⁴

HRSA did not define the terms “knowingly” or “intentionally” in order to allow the Office of the Inspector General (OIG) the “necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.”²²⁵ HRSA listed several examples where it would not assume a manufacturer “knowingly and intentionally” overcharged a covered entity including: an isolated inadvertent, unintentional, or unrecognized error in calculating the 340B ceiling price; drug sales of a new drug during the estimation period that are higher than the later calculated price, so long as manufacturers issued a refund; sales made to a covered entity that did not identify as 340B-eligible at the time of purchase; and sales when a covered entity chooses to order non-340B priced drugs and the order is not due to a manufacturer’s refusal to sell or make drugs available at the 340B price.²²⁶ HRSA stated that specific intent to violate the 340B statute was not necessarily required to warrant the CMP.²²⁷ Manufacturers are responsible for 340B overcharges even if drugs are sold through a third party such as a wholesaler.²²⁸

The guidance was released on January 5, 2017 and enforcement of the rule was to begin on April 1, 2017. However, on January 20, 2017, the Trump administration issued a Memorandum—entitled “Regulatory Freeze Pending Review”—directing agencies to temporarily postpone the effective date of

219. 340B Drug Pricing Program Manufacturer Civil Monetary Penalties, 75 Fed. Reg. 57,230, 57,230–31 (Sept. 20, 2010) (to be codified at 42 C.F.R. ch. 1).

220. *Id.* at 57,231.

221. Manufacturer Audit Guidelines and Dispute Resolution Process 0905–ZA–19, 61 Fed. Reg. 65,406, 65,412 (Dec. 12, 1996); *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 115–16 (2011).

222. See 42 U.S.C. § 256b(d)(3)(A) (“Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased . . . and claims by manufacturers, after the conduct of audits[.]”).

223. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (June 17, 2015) (to be codified at 42 C.F.R. pt. 10).

224. 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (Jan. 5, 2017) (to be codified at 42 C.F.R. pt. 10).

225. *Id.* at 1222.

226. *Id.* at 1221.

227. *Id.* at 1222.

228. *Id.* at 1224.

regulations that had been published in the Federal Register but had not yet taken effect.²²⁹ HHS initially delayed the effective date of the final rule to May 22, 2017, but subsequently changed the effective date of the final rule to July 1, 2018.²³⁰

d. Administrative Dispute Resolution—ADR

Under the ACA, Congress directed HHS to create an administrative dispute resolution process for the 340B Program.²³¹ Prior to the ACA, the program followed an informal dispute resolution process from 1996.²³² HHS was tasked with establishing a binding administrative dispute resolution process to resolve claims raised by covered entities and drug manufacturers.²³³ HHS was directed to “promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drug” and “claims by manufacturers” following an audit.²³⁴ The process was to include “appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions.”²³⁵ These sanctions included civil monetary penalties of up to “\$5,000 for each instance of overcharging a covered entity that may have occurred.”²³⁶

HHS was tasked to promulgate the regulations within 180 days of the ACA—March 23, 2010.²³⁷ On September 20, 2010, HRSA issued a notice of proposed rulemaking to establish the process.²³⁸ In 2015, HRSA stated that “[f]uture rulemaking will address the administrative dispute resolution process.”²³⁹ In August 2016, HRSA released a notice of a proposed rule to formally regulate the ADR process for reviewing claims and resolving disputes

229. Memorandum for the Heads of Executive Departments and Agencies; Regulatory Freeze Pending Review, 82 Fed. Reg. 8346, 8346 (Jan. 24, 2017).

230. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332, 14,332–33 (Mar. 20, 2017) (to be codified at 42 C.F.R. pt. 10); 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 45,511, 45,511–13 (Sept. 29, 2017) (to be codified at 42 C.F.R. pt. 10).

231. 42 U.S.C. § 256b(d)(3) (2012).

232. See *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406, 65,406 (Dec. 12, 1996) (informing interested parties about the final guidelines regarding the informal dispute resolution process).

233. 42 U.S.C. § 256b(d)(3).

234. *Id.*

235. *Id.*

236. 42 U.S.C. § 256b(d)(1)(B)(vi)(II).

237. 42 U.S.C. § 256b(d)(3)(A).

238. 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sept. 20, 2010) (to be codified at 42 C.F.R. ch. 1).

239. 340B Drug Pricing Omnibus Guidance, 80 Fed. Reg. 52,300, 52,301 (Aug. 28, 2015).

under the 340B Program.²⁴⁰ The proposed rule addressed the establishment and implementation of a binding ADR process for certain disputes arising under the 340B Program.²⁴¹

“The purpose of the ADR process is to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers; and (2) claims by manufacturers, after a manufacturer has conducted an audit, that a covered entity has violated the prohibition on drug diversion patients or duplicate discounts.”²⁴² The proposed rule also established an Administrative Dispute Resolution Panel or 340B ADR Panel.²⁴³

The proposed rule was intended to replace the informal dispute resolution from 1996—over 20 years ago. Comments were invited until October 2016. However, no final notice has been issued.

e. Astra

The importance of having a formalized ADR is illustrated by *Astra USA, Inc. v. Santa Clara Cnty., Cal.*²⁴⁴ Under *Astra*, 340B entities may not bring lawsuits against drug manufacturers alleging they have been overcharged for the drugs purchased from the manufacturers pursuant to the PPA. The Supreme Court found no private right of action under the 340B Program. *Astra* made clear that covered entities were required to rely on the informal dispute resolution process prior to the guidance which left covered entities with few options when manufacturers overcharge them.

In 2006, Santa Clara County, California filed suit against Astra USA, Inc. and eight other pharmaceutical companies in *Cty. of Santa Clara v. Astra USA, Inc.*²⁴⁵ County and county operated medical facilities brought action against pharmaceutical manufacturers alleging that they had been overcharged for certain covered drugs in violation of the PPAs between the federal government and manufacturers. The United States District Court for the Northern District of California dismissed the complaint.²⁴⁶ On appeal, the United States Court of

240. 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381, 53,381 (Aug. 12, 2016) (to be codified at 42 C.F.R. pt. 10).

241. *Id.* at 53,381–82.

242. *Id.* at 53,382.

243. *Id.* The proposed 340B ADR Panel would include three members and would “ensure an unbiased and fair review of the claims, and reduce the individual burden associated with having a single decision-making official who is solely responsible for reviewing and resolving claims.” *Id.*

244. *See* 563 U.S. 110, 120 (2011) (emphasizing that 340B entities’ right to proceed in court, rather than through the formalized ADR process, could result in a “multitude of dispersed and uncoordinated lawsuits.”).

245. The District Court for the Northern District of California dismissed the complaint. The United States Court of Appeals for the Ninth Circuit reversed and remanded. The Supreme Court of the United States heard the case on January 19, 2011. *Astra USA, Inc v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011).

246. *Cty. of Santa Clara v. Astra USA, Inc.*, No. C 05-03740 WHA, 2006 WL 1344572, (N.D. Cal. May 17, 2006).

Appeals for the Ninth Circuit reversed and remanded.²⁴⁷ The Supreme Court granted certiorari.²⁴⁸ In an opinion authored by Justice Ginsburg, the Court held that 340B entities may not enforce ceiling-price contracts between drug manufacturers and HHS.²⁴⁹

Santa Clara County, operator of several 340B entities, alleged that drug manufacturers were overcharging 340B health care facilities in violation of the PPAs.²⁵⁰ Despite conceding that Congress authorized no private right of action under § 340B for entities claiming to be overcharged, Santa Clara argued that the 340B entities and the counties that fund them are the intended beneficiaries of the PPAs.²⁵¹ Thus, Santa Clara sought compensatory damages for the drug manufacturers' breach of contract.²⁵²

The Court determined that PPAs "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them."²⁵³ The agreements contain no negotiable terms and like the MDRP, the agreements simply serve as the means to opt into the statutory scheme.²⁵⁴ The Ninth Circuit had determined that by allowing covered entities to sue as intended beneficiaries of the PPA would spread the burden of enforcement instead of placing it entirely on the government.²⁵⁵ The Supreme Court disagreed. The Court deemed that Congress intended for "centralized enforcement" from the government.²⁵⁶ Otherwise, the absence of a private right of action would be rendered meaningless.²⁵⁷ The Court held suits by 340B entities would undermine the agency's efforts to administer both MDRP and 340B.²⁵⁸

C. Orphan Drugs

i. Background

As an amendment to the Federal Food, Drug, and Cosmetic Act, the Orphan Drug Act (ODA) was passed in 1983 "to facilitate the development of drugs for

247. *Cty. of Santa Clara v. Astra USA, Inc.*, 588 F.3d 1237, 1252 (9th Cir. 2009).

248. *Astra USA, Inc. v. Santa Clara Cty.*, Cal. 563 U.S. 110 (2011).

249. *Id.* at 113.

250. *Id.* at 116.

251. *See id.* at 116–17 ("Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities.").

252. *Id.* at 116.

253. *Id.* at 118.

254. *Id.*

255. *Cty. of Santa Clara v. Astra USA, Inc.*, 588 F.3d 1251 (9th Cir. 2009).

256. *Astra*, 566 U.S. at 119.

257. *Id.* at 118.

258. *Id.* at 120. The Court further notes that "the Ninth Circuit focused on the 340B Program in isolation[.] [I]t failed to recognize that the interests of States under the Medicaid Drug Rebate Program and covered entities under the 340B Program may conflict." *Id.* at 120 n.6.

rare diseases and conditions.”²⁵⁹ A rare disease or condition, or “orphan” disease, is defined as any disease or condition which affects less than 200,000 persons in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available a drug for such disease or condition will be recovered from sales.²⁶⁰ Drugs used to treat orphan diseases are, to no surprise, referred to as “orphan” drugs.

Congress passed the ODA after concluding that “because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss.”²⁶¹ To encourage the development of orphan drugs, the ODA provides incentives to drug manufacturers. These incentives include a seven-year market exclusivity period for the orphan drug—as opposed to a two-year period for regular drugs; a clinical tax credit for any expenses incurred in developing an orphan drug; research grants for clinical testing; and an exemption from new drug application fees.²⁶²

To become an orphan drug, a drug must qualify for an orphan designation.²⁶³ To qualify, both the drug and the disease or condition must meet specified criteria in the ODA and FDA’s implementing regulations.²⁶⁴ The Food and Drug Administration (FDA) oversees the designation and approval of orphan drugs. Specifically, the Office of Orphan Products Development (OOPD) “evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases.”²⁶⁵ Both the FDA and HRSA reside under HHS.

Although a drug may be designated as an orphan drug to treat a rare disease or condition, the drug may also be approved and used to treat multiple conditions, including non-orphan. For example, the drug Prozac (Fluoxetine) has an orphan designation to treat “autism and body dysmorphic disorder in children and adolescents, but is commonly prescribed for depression, a non-orphan

259. Orphan Drug Act, Pub. L. No. 97-414, § 1(b)(4), 96 Stat. 2049, 2049 (1983) (codified as amended at 21 U.S.C. § 360aa (2012)); *PhRMA I*, 43 F. Supp. 3d 28, 31 (D.D.C. 2014).

260. 21 U.S.C. § 360bb(a)(2).

261. § 1(b)(4), 96 Stat. at 2049.

262. 21 U.S.C. § 360cc(a); 26 U.S.C. § 45C (2012); 21 U.S.C. § 360ee; 21 U.S.C. § 379h(a)(1)(F); *PhRMA I*, 43 F. Supp. 3d at 31.

263. 21 C.F.R. §§ 316.20–316.21 (2018). The ODA provides for the granting of an orphan designation upon the request of a sponsor. *Id.* § 316.20. A sponsor seeking orphan designation for a drug must submit a request for designation to the Office of Orphan Products Development (OOPD) with the information required in 21 C.F.R. §§ 316.20–316.21.

264. 21 C.F.R. § 316.20.

265. *Developing Products for Rare Diseases and Conditions*, FDA, <https://www.fda.gov/forindustry/developingproductsforrareconditions/ucm2005525.html> (last updated Oct. 5, 2018).

condition.”²⁶⁶ In addition, a drug may have an orphan designation and be approved to treat a different disease or condition—although drugs may be developed exclusively for orphan designation.²⁶⁷

In 2010, HCERA, excluded orphan drugs from 340B pricing applicable to the newly added hospitals which include critical access hospitals, rural referral centers, sole community hospitals, and free-standing cancer hospitals. Subsection 340B(e), entitled “Exclusion of Orphan Drugs for Certain Covered Entities,” provided that “[f]or covered entities described in subparagraph (M), (N), or (O) of subsection (a)(4), the term ‘covered outpatient drug’ shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.”²⁶⁸ However, covered entities and drug manufacturers debated the meaning of the phrase “a drug designated . . . for a rare disease or condition.”²⁶⁹ Covered entities contended the meaning of the phrase was unclear, while drug manufacturers contended that all orphan-designated drugs, *whatever their use*, “were intended to be excluded from the 340B Program for the newly added covered entities.”²⁷⁰

In May 2011, HRSA issued a notice of proposed rulemaking concerning the orphan drug exclusion provision.²⁷¹ “The purpose of issuing this proposed rule is to clarify HHS’s stated effort in: (1) providing clarity in the marketplace; (2) maintaining the 340B savings and interests to the newly-eligible covered entities; and (3) protecting the financial incentives for manufacturing orphan drugs designated for a rare disease or condition as indicated in the Affordable Care Act as intended by Congress.”²⁷² In July 2013, HRSA issued a Final Rule interpreting section 340B(e).²⁷³

Under the Final Rule, HRSA indicated that “a covered outpatient drug does not include orphan drugs that are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which that orphan drug was designated under section 526 of the [Federal Food, Drug, and Cosmetics Act].”²⁷⁴ However, a covered outpatient drug includes “drugs that are designated under section 526 of the FFDCA when they are transferred, prescribed, sold, or otherwise used for any medically-accepted indication other than treating the rare disease or condition for which the drug was designated under section 526 of the

266. *PhRMA I*, 43 F. Supp. 3d at 30.

267. 21 C.F.R. § 316.23(b) (2018); *PhRMA II*, 138 F. Supp. 3d 31, 34 (D.D.C. 2015).

268. 42 U.S.C. § 256b(e) (2012)).

269. *PhRMA II*, 138 F. Supp. 3d at 36.

270. *Id.*

271. Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 76 Fed. Reg. 29,183 (May 20, 2011) (to be codified at 42 C.F.R. pt. 10).

272. *Id.* at 29,184.

273. *PhRMA I*, 43 F. Supp. 3d 28, 32 (D.D.C. 2014); 42 C.F.R. § 10.21 (2013).

274. *PhRMA I*, 43 F. Supp. 3d at 32 (quoting 42 C.F.R. § 10.21).

FFDCA.”²⁷⁵ In essence, when the newly-added covered entities purchased orphan drugs for their intended orphan use, the 340B price did not apply; yet when the newly-added covered entities purchased orphan drugs for a non-orphan use, the 340B price did apply.²⁷⁶ Drug manufacturers took issue with this interpretation and the Pharmaceutical Research and Manufacturers of America (PhRMA) challenged HRSA’s Final Rule in court.²⁷⁷

a. PhRMA I

In *Pharm. Research & Manufacturers of Am. v. United States Dep’t of Health & Human Servs. (PhRMA I)*, the issue was whether the newly-added covered entities must pay full price for orphan drugs when used for a non-orphan indication.²⁷⁸ Under HRSA’s Final Rule, section 340B(e) excludes orphan drugs only when they are used for the rare disease or condition for which they received an orphan designation. PhRMA argued (1) that the Final Rule “contravened the plain language of the statute,” and was “therefore invalid,” and (2) that HRSA lacked the authority to promulgate rules interpreting the orphan drug exclusion.²⁷⁹ HRSA argued (1) the statute is silent as to whether the orphan drugs exclusion applies to orphan drugs used for nonrare indications, and (2) HRSA was authorized by statute to “promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased” under 42 U.S.C. section 256b(d)(3)(A).²⁸⁰

The court noted that under the Administrative Procedure Act (APA), a reviewing court “shall hold unlawful and set aside agency action, findings, and conclusions found to be in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.”²⁸¹ Furthermore, the court explained that “[i]t is axiomatic that an administrative agency’s power to promulgate legislative regulations is limited to the authority delegated by Congress.”²⁸²

The court used *Chevron* deference to determine whether HHS had the authority to promulgate the Final Rule—the orphan drug rule.²⁸³ Under the *Chevron* two-step process, a court will first “question whether Congress has

275. 42 C.F.R. § 10.21.

276. *PhRMA I*, 43 F. Supp. 3d at 32.

277. *Id.* at 33.

278. *Id.* at 32.

279. *Id.* at 33, 37.

280. *Id.* at 40–41.

281. *Id.* at 35 (citing 5 U.S.C. § 706(2)(c) (2012)).

282. *Id.* at 35 (Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988)).

283. See *Chevron U.S.A., Inc. v. Nat. Def. Council, Inc.* 467 U.S. 837 (1984) (establishing the *Chevron* deference principle, which requires courts to defer to agency interpretations of statutes when presiding over administrative law disputes).

directly spoken to the precise question at issue.”²⁸⁴ The court noted that “[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”²⁸⁵ If Congress has not directly addressed the question at issue, then “the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation.”²⁸⁶ Second, “[i]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute.”²⁸⁷ The court again noted that “a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.”²⁸⁸

The court found that the statutory provisions HHS relied upon “are specific grants of authority that do not authorize the orphan drug rule.”²⁸⁹ Therefore, the court gave “effect to the unambiguously expressed intent of Congress,” and vacated the final rule under *Chevron* step one.²⁹⁰ The court found that HHS has acted beyond “the bounds of its statutory authority.”²⁹¹

In the alternative, HHS asked the court to “uphold the rule as an interpretive rule, as opposed to a legislative rule,” under an interpretive rule theory.²⁹² The court was skeptical that the Final Rule—promulgated through notice comment rulemaking and purported to have a binding legal effect—could be classified as an interpretive rule.²⁹³ After noting HHS’s argument was “half-hearted,” the court concluded the rule was legislative because “the rule (1) underwent notice and comment rulemaking—the hallmark of a legislative rule—and (2) it has a ‘legal effect’ on the parties so regulated because the interpretation of ‘covered outpatient drug,’ as well as the compliance procedures impose obligations on covered entities and manufacturers alike.”²⁹⁴

The court held that Congress “specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2)

284. *PhRMA I*, 43 F. Supp. 3d. at 35 (citing *Chevron*, 467 U.S. at 842–43).

285. *Id.* (quoting *Chevron*, 467 U.S. at 842–43).

286. *Id.* (quoting *Chevron*, 467 U.S. at 843).

287. *Id.* at 36 (quoting *Chevron*, 467 U.S. at 844).

288. *Id.* at 36 (quoting *Chevron*, 467 U.S. at 844).

289. *Id.* at 39. (“Specifically, HHS relied upon: (1) Section 340B of the PHSA, 42 U.S.C. § 256b, as amended, (2) Section 215 of the PHSA, 42 U.S.C. § 216, as amended, (3) Section 526 of the FFDCA, 21 U.S.C. § 360bb, as amended, (4) Section 701(a) of the FFDCA, 21 U.S.C. § 371(a); and (5) Section 1927 of the Social Security Act, 42 U.S.C. § 1396r–8, as amended. *See* 78 Fed. Reg. at 44027.”) (explaining that although HHS relied upon several statutory authorizations, none appropriately grant the agency the authority to promulgate the orphan drug rule).

290. *PhRMA I*, 43 F. Supp. at 39–40 (quoting *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013)).

291. *Id.* at 40 (quoting *City of Arlington*, 569 U.S. at 297).

292. *Id.* at 45.

293. *Id.* at 46.

294. *Id.*

the ‘regulatory issuance’ of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions.”²⁹⁵ The court explained that the “rulemaking authority granted HHS by Congress under the 340B program has thus been *specifically limited*, and HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program.”²⁹⁶ Additionally, the court noted, “Congress has limited HHS’s rulemaking authority to creating a system for resolving disputes between covered entities and manufacturers—not to engaging in prophylactic non-adjudicatory rulemaking regarding the 340B program altogether.”²⁹⁷

The court held that Congress did not delegate broad rulemaking authority in HRSA despite vesting the agency with the obligation to oversee and implement the 340B Program. For the newly-added covered entities, the term “covered outpatient drug” did not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition. Therefore, drug manufacturers were not required to provide these entities orphan drugs at 340B prices. Although a manufacturer may, at its sole discretion, offer discounts on orphan drugs to these hospitals.

Despite the court’s ruling, HRSA maintained the decision did not invalidate HHS’s interpretation of the orphan drug exclusion in the Rule.²⁹⁸ In response, HHS issued an interpretive rule identical in substance to the vacated Final Rule in July 2014.²⁹⁹ Again, PhRMA challenged HHS contending that the interpretive rule contravened section 340B’s plain language.³⁰⁰

b. PhRMA II

In October 2014, PhRMA filed suit against HHS and its interpretive rule. HRSA argued (1) “the Interpretive Rule does not constitute a final agency action and, therefore, is not subject to judicial review”; and (2) that, “even if the rule constitutes a final agency action, its interpretation is entitled to *Skidmore* deference.”³⁰¹ PhRMA argued that the Interpretive Rule was a final agency action and that the rule conflicts with the plain language of section 340B(e).³⁰² Ultimately, the court concluded that the Interpretive Rule was a final agency

295. *Id.* at 41.

296. *Id.* at 42 (emphasis added).

297. *Id.* at 42–43.

298. Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 79 Fed. Reg. 42,801, 42,801 (July 23, 2014).

299. *PhRMA I*, 138 F. Supp. 3d at 32; Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 79 Fed. Reg. at 42,801.

300. *PhRMA II*, 138 F. Supp. 3d 31, 32 (D.D.C. 2015).

301. *Id.* at 38.

302. *Id.*

action and that the Interpretive Rule contravened the plain language of section 340B(e).³⁰³

HHS maintained that “interpreting the statutory language to exclude all indications for a drug that has an orphan drug designation would be contrary to the Congressional intent of section 340B(e) to balance the interests of orphan drug development and the expansion of the 340B Program to new entities.”³⁰⁴ For the same reasoning, HHS determined section 340B(e) to “not exclude drugs that are transferred, prescribed, sold, or otherwise used for conditions or diseases other than for which the drug was designated.”³⁰⁵

Following the Interpretive Rule, HRSA sent letters to drug manufacturers informing them that covered entities were denied 340B discounts on products with an orphan designation.³⁰⁶ HRSA informed the drug manufacturers of its interpretation of the statute—340B(e)—and stated that manufacturers are “*out of compliance with statutory requirements* as described in HRSA’s interpretive rule.”³⁰⁷ HRSA cautioned that “[m]anufacturers that do not offer the 340B price for drugs with an orphan designation when those drugs are used for an indication other than the rare condition or disease for which the drug was designated . . . are violating section 340B(a)(1) of the PHS Act and the terms of their Pharmaceutical Pricing Agreement.”³⁰⁸ HRSA noted that drug manufacturers were required to “refund covered entities charged more than the statutory ceiling price for covered outpatient drugs” and requested the manufacturers to “respond within 30 days to notify HRSA of your plan to repay affected covered entities and to institute the offer of the discounted price in the future.”³⁰⁹ On its website, HRSA also stated that “failure to comply with the statutory requirements could subject a manufacturer or covered entity to an enforcement action” which included termination of a PPA.³¹⁰

The court noted that PhRMA did not directly challenge HHS’s authority to issue an Interpretive Rule.³¹¹ The court conceded that HHS had the authority to advise the public of its interpretation of the statute.³¹² Accordingly, despite fact that the court had previously concluded that HHS lacked the authority to promulgate the rule as a binding statement of law, the court acknowledged HHS was “not forbidden altogether from proffering its interpretation of the statute.”³¹³

303. *Id.* at 33.

304. *Id.* at 37 (citation omitted).

305. *Id.* (citation omitted).

306. *Id.* (citation omitted).

307. *Id.* (citation omitted) (emphasis in original).

308. *Id.* (citation omitted) (emphasis in original).

309. *Id.* (citation omitted).

310. *Id.* at 37–38 (quoting First Am. Compl. Ex. D, ECF No.11–4).

311. *Id.* at 38–39.

312. *Id.* at 39.

313. *Id.*

First, the court had to decide whether the Interpretive Rule was a final agency action subject to judicial review. HHS argued that the Interpretive Rule was not a final agency action until “HHS initiate[d] an enforcement action against a drug manufacturer and impose[d] a penalty for not complying with the statutory provision.”³¹⁴ HHS claimed that the Interpretive Rule in itself did not “alter the legal obligations of the program participants,” and thus, had no legal force “independent of any binding effect that the statute itself.”³¹⁵ Put differently, HHS argued “that the statute—and not the Interpretive Rule, itself—is binding on the parties.”³¹⁶

The court conceded that interpretive rules that lack “the force of law ‘generally do not qualify’ as a final agency action.”³¹⁷ However, the court continued, “‘an agency’s other pronouncements’—beyond legislative rules—‘can, as a practical matter, have a binding effect’ which contributes to a finding that the action is ‘final.’”³¹⁸ The court found that the Interpretive Rule “represents a definitive and purely legal determination that puts pharmaceutical manufacturers to the painful choice of complying with HHS’s interpretation or risking the possibility of an enforcement action at an uncertain point in the future.”³¹⁹

The court determined that, “regardless of classification, the burdens posed by HHS’s Interpretive Rule” were “sufficiently significant to rise to the level of a final agency action.”³²⁰ Ultimately, the court concluded that the Interpretive Rule constituted a final agency action within the ambit of an agency action under 5 U.S.C. § 704.³²¹

The court held that HRSA lacks the authority to promulgate a binding statement of law.³²² The court acknowledged HHS’s argument, but found that it is, “not for [this Court] to rewrite the statute.”³²³ The impact of the decision is the orphan drug interpretive rule was invalid and calls into question HRSA’s legal authority to issue a binding guidance. The court concluded by stating “Congress remains free to amend section 340B(e) if it determines that, in practice, the scheme it has set up is not a workable one or does not provide the hoped-for benefits to the extent envisioned.”³²⁴

314. *Id.* at 40.

315. *Id.* at 44.

316. *Id.*

317. *Id.* at 41 (quoting *Am. Tort Reform Ass’n v. Occupational Safety & Health Admin.*, 738 F.3d 387, 395 (D.C. Cir. 2013)).

318. *Id.* at 41 (quoting *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021–22 (D.C. Cir. 2000)).

319. *Id.* at 43.

320. *Id.* at 46–47.

321. *Id.* at 47.

322. *Id.* at 39.

323. *Id.* at 53.

324. *Id.*

c. Orphan Drugs Post-PhRMA

After *PhRMA II*, “[f]or rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals participating in the 340B Program, the term ‘covered outpatient drug’ does not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.”³²⁵ Therefore, drug “manufacturers are not required to provide these covered entities orphan drugs under the 340B Program.”³²⁶ Although “[a] manufacturer may, at its sole discretion, offer discounts on orphan drugs to these hospitals.”³²⁷

D. The Mega-Reg and Mega-Guidance Withdrawals

In 2014, HRSA intended to issue comprehensive regulations in an effort to provide better clarity and guidance for both covered entities and drug manufacturers.³²⁸ Nicknamed the “Mega-Reg” or “Mega-Regs,” these regulations were expected to cover the 340B definition of a patient, compliance requirements for contract pharmacy arrangements, hospital eligibility requirements, and eligibility of hospital offsite facilities.³²⁹ However, the decision in *PhRMA I* called into question HRSA’s ability to issue binding legislative regulations for 340B and forced HRSA to retract the guidance in November 2014.³³⁰ In its place, HRSA published proposed Omnibus Guidance in the Federal Register on August 28, 2015.³³¹

Intended to replace the Mega-Reg, the Omnibus Guidance—often called “MegaGuidance”—would have included several significant updates to the 340B Program.³³² Some of the key issues the proposed guidance addressed included the definition of an eligible patient, DSH and child sites³³³ eligibility, and contract pharmacy arrangements.³³⁴ The redefining of patient eligibility would have likely limited the program’s scope. However, on January 30, 2017, the

325. *340B Drug Pricing Program, Orphan Drugs*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/opa/program-requirements/orphan-drug-exclusion/> (last updated June 2018).

326. *Id.*

327. *Id.*

328. Kara Stencel, *The 340B Drug Discount Program*, HEALTH AFF. (Nov. 17, 2014), https://www.healthaffairs.org/doi/10.1377/hpb20141117.14335/full/healthpolicybrief_130.pdf/.

329. *Id.*

330. *Id.*

331. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,300–02, 52,306 (Aug. 28, 2015).

332. Todd A. Nova et al., *340B “Mega-Guidance” Withdrawn – Next Steps Unclear*, HALL RENDER: HEALTH L. NEWS (Feb. 1, 2017), <http://www.hallrender.com/2017/02/01/340b-mega-guidance-withdrawn-next-steps-unclear/>.

333. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. at 52,301. Child sites are eligible outpatient facilities which may include offsite clinics, departments, or services that are an integral part of the 340B hospital. *Id.*

334. *Id.* at 52,301–03.

340B Mega-Guidance was withdrawn 10 days following the Trump administration directed agencies to temporarily postpone the effective date of regulations that had been published in the Federal Register but had not yet taken effect.³³⁵

IV. RETHINKING 340B

The growth of the 340B Program shows no signs of slowing down. HRSA's anticipated release of the Mega-Guidance would have likely limited the scope of the program. However, as discussed, HRSA withdrew the Guidance in January 2017—suffering the same fate as the MegaReg. Still, the 340B Program is anticipated to keep growing at a rapid pace. Contributing to the growth is the expansion of practice acquisition, physician practice affiliations, patient referrals, and contract pharmacies. In 2015, over 390 hospitals enrolled in the program for the first time—a trend that is expected to continue for the next two to three years.³³⁶ In 2016, over 68 percent of hospitals have at least one contract pharmacy—up from 13 percent from March 2010.³³⁷

Presently, drug manufacturers and qualifying health care providers seems to be locked in a zero-sum game. While manufacturers desire changes to the program, qualifying providers want the program protected. Manufacturers seek to narrow the scope of the program and desire for a more direct link in between drug discounts and indigent patient care. In contrast, 340B providers prefer the program's current form—albeit hospitals would likely appreciate clarity in certain areas—and desire the continuation in the ability to use revenue generated from the discounts without restrictions.

At the beginning of this paper, I pointed out that the 340B Program is designed to help uninsured, indigent patients by giving qualifying health care facilities access to discounts for outpatient drugs. Specifically, covered entities would be granted access to the discounts to enable the entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”³³⁸ Although hospitals are benefiting financially from the program, it may be inconsistent with the design of the program.

The issue seems not to be that hospitals are generating revenue from the 340B Program, rather critics contend that covered entities are exploiting the program to generate revenue at the expense of drug manufacturers and patients. However, drug manufacturers cannot play the role of a helpless victim.

335. Memorandum for the Heads of Executive Departments and Agencies; Regulatory Freeze Pending Review, 82 Fed. Reg. 8346, 8346 (Jan. 24, 2017).

336. AARON VANDERVELDE & ELEANOR BLALOCK, 340B PROGRAM SALES FORECAST: 2016-2021 4 (2016), <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf>.

337. *Id.*

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

Manufacturers have found loopholes in the program as well. For example, given the orphan drug ruling, drug manufacturers have huge incentives to exclude all specialty drugs, often biologics, and other high-cost drugs including oncology drugs from the 340B Program. Manufacturers exploit the program by claiming orphan status and then market the drug for more common conditions.

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.

Despite the fundamental challenges plaguing the 340B Program, it may also face an existential challenge with the Trump administration. President Donald Trump campaigned on repealing and replacing the ACA. Although a full repeal is unlikely, the 340B Program could be affected indirectly under a partial repeal. As discussed, the ACA made several notable changes to the 340B Program. A repeal of the ACA would possibly impact the eligibility of qualifying children's hospitals, critical access hospitals, free standing cancer hospitals, sole community hospitals, and rural referral centers—stripping these entities of 340B eligibility. The ACA also expanded Medicaid, although, under *Sebelius*,³³⁹ the Supreme Court held states could opt out of the expansion. More Medicaid patients means more hospitals would qualify for the 340B Program. However, block grants for Medicaid would likely have an impact on 340B. The ACA also added language excluding orphan drugs from 340B discounts leading to *PhRMA I* and *PhRMA II*. A full or partial repeal could potentially mean orphan drugs would fall under outpatient covered drugs eligible for 340B pricing. Lastly, the Trump administration has raised concerns about the rise in the cost of drugs. Congress may be inclined to target programs such as 340B as a way to reform drug price regulation. Generally, a change in administration can create uncertainty, but only time will tell.

The 340B Program faces several internal challenges due to its nuanced and cumbersome nature. Rarely is there a simple solution for a complex problem. However, updating a few areas of the program would have a huge impact. First and foremost, Congress must grant HRSA more oversight. Second, the program needs an updated definition of patient. Third, contract pharmacies require more attention. Fourth, an increase in auditing will help curb drug diversion and duplicate discounts. And finally, greater transparency should be mandated to ensure the program is being used to help indigent patients.

339. See Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 585 (2012) (holding that the states could opt out of the expansion).

A. Congressional Action Is Needed for Greater Oversight

The holdings in *PhRMA I* and *PhRMA II* are problematic for HRSA and the 340B Program. The ruling in *PhRMA I* held that Congress had only granted HRSA authority to issue legislative rules regarding the 340B program in three very limited circumstances.³⁴⁰ Thus, HRSA does not have “broad rulemaking authority to carry out all the provisions of the 340B program.”³⁴¹ In *PhRMA II*, the court held that HRSA lacks the authority to promulgate a binding statement of law.³⁴² The ruling calls into question HRSA’s legal authority to issue a binding guidance and leaves HRSA’s authority to administer the 340B Program on shaky grounds. PhRMA’s success in litigation has provided a blueprint and precedent for future challenges when a guidance runs contrary manufacturers’ interests.

Statutory authority is a requirement for HRSA to properly implement the program. HRSA takes much criticism for the 340B Program’s shortcomings. However, as confirmed by *PhRMA I*, HRSA lacks the general rulemaking authority needed to resolve many issues facing the 340B Program. Congress vested HRSA with the responsibility to administer the program, but failed to give HRSA the authority to enforce the program. Thus, congressional action is required. As the court held in *PhRMA II*, “Congress remains free to amend section 340B(e) if it determines that, in practice, the scheme it has set up is not a workable one or does not provide the hoped-for benefits to the extent envisioned.”³⁴³ Agency guidance no matter how significant, is insufficient to fix 340B.

B. HRSA Must Update the Definition of Patient

Ambiguity in the definition of patient is problematic. The current definition of patient eligibility comes from a guidance released in 1996—prior to contract pharmacies and the ACA. In the now defunct Mega-Guidance, HRSA proposed an updated definition to “address the diverse set of 340B covered entities.”³⁴⁴ However, given the Mega-Guidance suffered the same fate as the Mega-Reg, it is unlikely that this definition will come to fruition. Until HRSA issues a final guidance, for the foreseeable future, the same issues will remain.

340. See *PhRMA I*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) (holding that Congress had only granted HRSA authority to issue legislative rules regarding the 340B program while establishing an administrative dispute resolution process, regulating the precise standards for calculating 340B ceiling prices, and imposing monetary civil sanctions).

341. *Id.* at 42.

342. See *PhRMA II*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015) (holding that HHS lacks the authority to promulgate the rule as a binding statement of law; HHS is not forbidden altogether from proffering its interpretation of the statute).

343. *Id.* at 53.

344. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015).

As noted by the GAO, the lack of specificity for who is an eligible patient leads to covered entities interpreting the term either too broadly or too narrowly. Currently, covered entities are incentivized to favor a broader, more liberal definition of patient in order to obtain 340B discounts on drugs. The definition allows anyone, regardless of wealth or insurance, to qualify for 340B discounted drugs. Essentially, all patients qualify so long as the covered entity qualifies for the program. Remember, the revenue generated is not restricted by the 340B statute.

To reiterate, an individual is a “patient” of a hospital if: (1) “the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care;” and (2) “the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements—e.g. referral for consultation—such that responsibility for the care provided remains with the covered entity.”³⁴⁵ Simply put, the definition of a patient requires that the hospital maintains records of the individual’s health care and receives care by a professional affiliated with the hospital.³⁴⁶ With advances in technology, maintaining records of the individual’s health care is hollow and sets a low bar. Digital records can be maintained on or off-site and accessed by any care provider or third-parties that are given access. Furthermore, “other arrangements” has not been defined. Thus, the lack in specificity leads to questionable “arrangements” including providers who use the entity for administrative functions rather than actually having a responsibility for care.³⁴⁷

It can be argued that Congress intentionally created a broad program which would allow for covered entities to take advantage of the drug discount without regard to the patient’s income or insurance. Others may argue that the Congress’s intent was clear and that the intention of the 340B Program is to pass the drug discounts directly to indigent patients. However, a clear definition should benefit both drug manufacturers and covered entities. For drug manufacturers, an updated definition should cut down on drug diversion. For covered entities, an updated definition would enable an entity to ensure program compliance.

The current definition only exacerbates the issues with the 340B Program. The definition is not only fundamentally flawed through lack of specificity, it is antiquated. If an entity interprets the definition too broadly, then it may lead to unintended diversion. However, if an entity interprets the definition too narrowly, then it may lead to entities limiting the benefit of the 340B Program in fear of noncompliance. Moreover, the definition does not account for the

345. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157–58 (Oct. 24, 1996).

346. *Id.*

347. See GAO, DRUG PRICING, *supra* note 9, at 23 (explaining the confusion surrounding and need for clarification of the definition of “other arrangements”).

complex organizational structures of hospitals or account for the convoluted contracting arrangements of contract pharmacies.

Under the Mega-Guidance, HRSA recommended a “prescription-by-prescription or order-by-order basis” rather than the broad application, and discussed additional criteria for eligibility.³⁴⁸ However, the additional criteria would only alleviate some issues with the definition. One option is for the definition to allow the discount to be available only for indigent patients of a covered entity. Another option is to require multiple interactions or visits to ensure the patient is really a patient of the covered entity. Still, another option is to require a physician to write a prescription at the time the patient is at a qualifying entity in order to ensure billing.

Regardless of what HRSA chooses to implement, an updated guidance regarding patient eligibility is necessary. The definition of patient is such an integral part of the 340B Program. Despite repeated calls and failed attempts to update the definition, however, the 1996 definition remains. Without a clear definition, interpretations will continue to vary and compliance is at risk. HRSA will likely issue a formal guidance addressing the issue at some point in the future, until then, the 1996 patient definition remains in effect.

C. Contract Pharmacies

The use of contract pharmacies represents a dramatic growth in the 340B Program. The 2010 guidance allowed all covered entities to contract with multiple outside pharmacies.³⁴⁹ Between March 2010 and May 2013, the number of unique pharmacies serving as 340B contract pharmacies grew by 770 percent, and the total number of contract pharmacy arrangements grew by 1,245 percent.³⁵⁰ In 2016, over 68 percent of hospitals had at least one contract pharmacy.³⁵¹

Contract pharmacy arrangements are beneficial for multiple reasons including allowing patients to fill prescriptions somewhere other than the covered entity. However, the increased use of contract pharmacies may result in greater risk of drug diversion.³⁵² Likewise, contract pharmacies may result in a greater risk for duplicate discounts given the complexity of the arrangements.³⁵³

348. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,319 (Aug. 28, 2015).

349. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

350. Wakefield, *supra* note 81, at 2.

351. AARON VANDERVELDE & ELEANOR BLALOCK, 340B PROGRAM SALES FORECAST: 2016-2021 4 (2016), <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf>.

352. See GAO, DRUG PRICING, *supra* note 9, at 28 (explaining why contract pharmacies, as opposed to in-house pharmacies, increases the likelihood of drug diversion).

353. See SUZANNE MURRIN, OFFICE OF INSPECTOR GENERAL, HEALTH & HUM. SERVS., STATE EFFORTS TO EXCLUDE 340B DRUGS FROM MEDICAID MANAGED CARE REBATES, 1, 6, 14, 15 (2016), <https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf> (discussing how the structure of many contract

Although the duplicate discount prohibition applies to contract pharmacies, sophisticated inventory tracking systems and third-party administrators (TPAs) are costly and may require greater effort and involvement.

Covered entities that establish a contract pharmacy are required to oversee these arrangements to prevent diversion of 340B drugs and duplicate discounts through Medicaid.³⁵⁴ In 2014, HHS Office of Inspector General (OIG) conducted an audit of the 340B Program and reported that many contract pharmacy arrangements created complications in preventing diversion and duplicate discounts.³⁵⁵ The report found that most covered entities in the study did not conduct recommended oversight and only a few entities reported retaining independent auditors, which was also recommended.³⁵⁶

Covered entities should not dispense 340B-purchased drugs to Medicaid patients through their contract pharmacies, unless they have an arrangement to prevent duplicate discounts.³⁵⁷ In order for states to collect rebates and avoid duplicate discounts, 340B drug claims must be identified and excluded. The OIG report found that covered entities use different methods to identify 340B-eligible prescriptions in order to prevent diversion.³⁵⁸ The inconsistency results in similar types of prescriptions categorized in different ways.³⁵⁹ The inconsistency leads to greater diversion, causing states to forego proper drug rebates, through the MDRP, and manufacturers to sell a drug at 340B prices while paying a Medicaid rebate. As a result, manufacturers pay too much in rebates under duplicate discounts and States pay too much for drugs under missed rebates.

In 2016, the OIG recommended the use of claim-level methods to accurately identify 340B claims and prevent duplicate discounts. To prevent duplicate discounts, HRSA should follow the OIG's recommendation and instruct contract pharmacies to regularly submit reports that identify 340B claims to the states. States can then remove all 340B claims and prevent duplicate discounts. Another option is to require covered entities to avoid dispensing 340B

pharmacy arrangements creates technical challenges regarding 340B applications leading to duplicate discounts).

354. See Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273–78 (Mar. 5, 2010) (responding to comments questioning the duty of covered entities to prevent 340B drug diversion and outlining possible strategies for covered entities to monitor contract pharmacy arrangements).

355. Wakefield, *supra* note 81, at 16.

356. See *id.* at 2, 7, 14, 15 (reporting that few covered entities in study of 30 complete oversight activities recommended by HRSA, and only 7 of 30 covered entities in study had reported using an auditor for contract pharmacy arrangements).

357. 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. at 10,278.

358. Wakefield, *supra* note 81, at 9.

359. See generally Wakefield, *supra* note 81 (reporting that covered entities in the study used different methods to identify 340B prescriptions, resulting in some covered entities identifying a prescription as 340B eligible while other covered entities did not).

drugs to any Medicaid beneficiaries through contract pharmacies. However, that would limit contract pharmacies providing 340B drugs to indigent patients.

Overall, effective methods for identifying 340B claims are needed to ensure compliance with the statutory prohibition on drug diversion and duplicate discounts. The complexity of the contract pharmacy arrangements requires updated guidelines to ensure uniformity. As the OIG report indicated contract pharmacies follow different methods in identifying 340B claims. A universal process, such as a claim-level method, would reduce the risk of diversion and duplicate discounts.

D. Increased Audits

HRSA needs to increase auditing. All 340B covered entities are required to ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements. Statutorily, HRSA has the authority to audit covered entities to ensure compliance with the 340B Program requirements.³⁶⁰

Despite this ability, for nearly the first 20 years of the 340B Program, HRSA relied heavily on self-policing. By 2011, HRSA had not conducted a single audit.³⁶¹ The GAO deemed self-policing problematic because participants in the 340B Program had “little incentive to comply with program requirements, because few have faced sanctions for non-compliance.”³⁶² After the GAO recommended that HRSA conduct selective audits of 340B covered entities, HRSA implemented a risk-based and targeted approach to conducting audits on covered entities in 2012.³⁶³ HRSA has continued to audit covered entities and posts the results of each year’s audit on its website.³⁶⁴

Covered entities are required to permit HRSA and manufacturers to audit records that directly pertain to compliance with the prohibition of resale/transfer or double discounts.³⁶⁵ HRSA may terminate the manufacturer’s PPA if found to be overcharging a covered entity, which would also terminate the manufacturer’s eligibility for Medicaid coverage.³⁶⁶

360. See generally 42 U.S.C. § 256b(a)(5)(C) (2010) (outlining the requirements for agreements between the Secretary and the manufacturers and suppliers of 340B drugs).

361. GAO, DRUG PRICING, *supra* note 9, at 25.

362. *Id.* at 33.

363. *340B Drug Pricing Program: Important Benefit, Significant Responsibility*, HEALTH RES. AND SERVS. ADMIN., <https://www.hrsa.gov/opa/updates/update.html> (last updated Apr. 2017).

364. See 42 U.S.C. § 256b(d)(2)(B)(i) (2012) (establishing that manufacturers are subject to auditing by HRSA to ensure compliance with the 340B Program, pursuant to section 42 U.S.C. § 256b(d)(1)(B)(ii-v) of the Public Health Service Act. Failure to comply with 340B pricing requirements may make the manufacturer liable to covered entities for refunds of overpriced 340B drugs).

365. *Id.* § 256b(a)(5)(C).

366. *Overview of the 340B Drug Pricing Program*, 340B HEALTH, <https://www.340bhealth.org/members/340b-program/overview/> (last visited Oct. 28, 2018).

Despite the increase in audits since 2012, more auditing should be mandated. By increasing auditing, covered entities have greater incentive to ensure compliance with 340B requirements. Drug manufacturers, who also may audit covered entities, should increase auditing to ensure 340B requirements. In addition, if HRSA would authorize state Medicaid programs to have access to 340B prices, then Medicaid programs can better audit for compliance with 340B billing.

Unfortunately, auditing is complex, time consuming, and expensive. Until 2009, HRSA relied on discretionary spending to staff the OPA.³⁶⁷ In 2016, the OPA operated on an annual budget of approximately \$10 million.³⁶⁸ Moreover, auditing may be deemed inefficient considering the flexibility of some of the program requirements—consider the definition of patient for example. Nevertheless, all 340B covered entities are required to ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements. Although HRSA has increased auditing in the last few years, much more is required to ensure program compliance.

E. Greater Transparency

Hospitals are using the 340B Program to generate revenue. However, exactly where that revenue is going in not always apparent. To be clear, covered entities are under no obligation to pass on the savings to patients directly. The 340B statute does not restrict how covered entities can use revenue. Thus, covered entities are within their right to generate revenue and “use the funds to expand the number of patients served, increase the scope of services offered to low-income and other patients, invest in capital, cover administrative costs, or for any other purpose.”³⁶⁹

In 2013, 340B hospitals provided \$28.6 billion in uncompensated care, which was four times the amount of drugs purchased through the 340B program.³⁷⁰ However, a May 2016 report from Alliance for Integrity and Reform of 340B claimed a dramatic decline in the charity care provided by 340B hospitals.³⁷¹ The report indicated that in total, 64 percent of 340B hospitals

367. *See generally* Omnibus Appropriations Act of 2009, Pub. L. No. 111-8, 123 Stat. 524.

368. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH RESOURCES AND SERVICES ADMINISTRATION, JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 325 (2017), <http://www.hrsa.gov/about/budget/budgetjustification2017.pdf>.

369. MEDPAC, *supra* note 12, at 8.

370. *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. On Energy and Commerce*, 114th Cong. 2 (2015) (statement of the American Hospital Association), <https://www.aha.org/sites/default/files/aha-statement-to-the-house-ec-health-subcommittee-re-examining-the-340b-drug-pricing-program.pdf>.

371. *See* ALLIANCE FOR INTEGRITY AND REFORM OF 340B, BENEFITING HOSPITALS, NOT PATIENTS: AN ANALYSIS OF CHARITY CARE PROVIDED BY HOSPITALS ENROLLED IN THE 340B DISCOUNT PROGRAM 9–10 (2016), <http://340breform.org/userfiles/May%202016%20AIR340B%20Avalere%20Charity>

provided less charity care than the national average for all hospitals, including for-profit hospitals.³⁷² Furthermore, in more than one-third—37 percent—of 340B hospitals, charity care represented less than 1 percent of total patient costs.³⁷³

Greater transparency should be mandated to ensure the program is being used to help indigent patients. Mandating increased transparency in revenue generated by a 340B covered entity will help illuminate exactly what the entity does with the profits. Currently, HRSA does not have the statutory authority to track how entities revenue generated from the program.³⁷⁴ However, congressional action should give HRSA this authority. Transparency would allow others to see if a covered entity is passing on any revenue to the community, or if the covered entity is developing services to better serve the indigent—as the program was intended.

IV. CONCLUSION

Created in 1992, the 340B Program was set up to provide “protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans.”³⁷⁵ The program was to extend drug discounts to the most vulnerable patients, the “medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services.”³⁷⁶ However, after nearly two-and-a-half decades since its signing, it is unclear whether the program operates in accordance to its statutory foundation.

This paper has highlighted the history of the 340B Program, the rapid expansion after the ACA, and the fundamental issues plaguing the program. Although many issues troubling the 340B Program could not have been foreseen in 1992, the program is in desperate need of a revision. Specifically, this paper concludes that the program needs Congressional action to grant HRSA more oversight, an updated definition of patient, more regulation on contract pharmacies, an increase in auditing, and greater transparency to better serve all the parties involved.

Critics of the 340B Program argue that Congress could have ensured covered entities would pass the savings on to patients by simply stating it. Critics have also questioned whether covered entities even need discounts given the

%20Care%20Study.pdf (emphasizing that 64% of 340B hospitals provide charity care at rates below the national average).

372. *Id.* at 9.

373. *Id.* at 9.

374. MEDPAC, *supra* note 12, at 8.

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

376. S. REP. NO. 102-259, at 6 (1992).

ACA has increased health insurance coverage to more Americans.³⁷⁷ Despite the critics, this paper argues that the 340B Program has helped indigent patients.

As indicated above, rarely is there a simple solution for a complex problem. The 340B Program faces several internal challenges due to its nuanced and cumbersome nature. However, this paper has highlighted several key areas of the program, if updated, would have a huge impact. In the words of Ann Maxwell, “[w]ithout clear rules, HRSA oversight is compromised, interpretations of program rules vary, and vulnerabilities in 340B program integrity will persist.”³⁷⁸

Tradeoffs are inevitable. However, any substantial change to the 340B Program should protect the original intent. Currently, competing incentives between drug manufacturers and covered entities have turned this well-intended program into a revenue generating arrangement. Still, the 340B Program has enabled covered entities to increase services provided. For some patients, these services may be the difference between life and death.

377. GAO, DRUG PRICING, *supra* note 9, at 4.

378. *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health before the H. Comm. on Energy and Commerce: Subcomm. on Health*, 114th Cong. 7–8 (2015) (testimony of Anne Maxwell, Assistant Inspector General, Office of Inspector General).