IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC.,
800 Scudders Mill Road,
Plainsboro, NJ 08536

NOVO NORDISK PHARMA, INC.,
800 Scudders Mill Road, Suite 1A-108
Plainsboro, NJ 08536

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington D.C. 20201,

XAVIER BECERRA,
in his official capacity as
Secretary of Health & Human Services
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

DANIEL J. BARRY,
in his official capacity as
Acting General Counsel of the United States Department of Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20852,

DIANA ESPINOSA, in her official capacity as Acting Administrator of the Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20852,

Defendants.

No. 3:21-cv-00806-FLW-LHG

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF[1]

Plaintiff Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Novo"), by and through their undersigned attorneys, allege as follows:

PRELIMINARY STATEMENT

1. This case challenges a final decision by the U.S. Department of Health and Human Services ("HHS") that purports to impose new binding obligations on drug manufacturers, on threat of significant penalties, but exceeds the agency's statutory authority and does not comply with the requirements of reasoned decision-making under the Administrative Procedure Act ("APA").

2. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to offer their outpatient drugs at deeply discounted prices to an enumerated list of "covered" entities" for the purpose of ensuring that vulnerable and low-income patients have better access to prescription medications. Manufacturers that fail to comply with the statute's mandate face enforcement action, significant civil monetary penalties, and potential revocation of the manufacturer's ability to participate in the federal Medicare and Medicaid programs.

3. Under the terms of the statute, and consistent with constitutional limits on forcing private parties to subsidize other private parties, Congress provided that *only* covered entities that meet the statute's requirements are entitled to purchase manufacturers' drugs at discounted prices. *See* 42 U.S.C. § 256b(a)(4). Congress also made clear that covered entities are prohibited from transferring manufacturers' drugs to anyone other than their own patients. *See id.* § 256b(a)(5)(B).

[1] On May 24, 2021, the Court directed Novo "to file an amended complaint to add additional factual allegations related to Defendants' recent agency action taken against Plaintiffs" by May 25, 2021. Novo is filing this Amended Complaint pursuant to the Court's Order and reserves its right to move for leave to further amend its complaint if claims are filed against Novo seeking to initiate administrative proceedings to enforce HHS's December 30 decision or if HHS attempts to take further actions to enforce that decision or the extra-statutory obligations that it seeks to impose.

This prohibition on "diversion" is essential to ensuring that the program remains within constitutional bounds and serves the statutory purpose of aiding needy patients, not enriching covered entities or commercial third parties at manufacturers' expense.

4. Despite these statutory prohibitions, many covered entities have entered into arm's-length agreements with for-profit, commercial pharmacies—known as "contract pharmacies"—that allow the pharmacies to acquire and dispense manufacturers' discounted drugs and to share in the profits resulting from selling manufacturers' discounted drugs at the full market price to patients who are not uninsured or needy. These contractual arrangements have dramatically increased the size of the 340B program, allowing covered entities and their contract pharmacies to make substantial profits at the expense of manufacturers. It has also made it much harder to ensure compliance with the 340B statute, increasing the risk of 340B drugs being sold to non-patients and the problem of "duplicate discounting," which occurs when the same drug is subject to both a 340B discount and a Medicaid rebate. The systemic abuses resulting from this massive expansion in the use of contract pharmacies is directly contrary to Congress's intent.

5. To address these concerns, Novo announced a new initiative, which took effect January 2021, that it will no longer accept covered entity requests that Novo transfer its covered outpatient drugs (or cause its covered outpatient drugs to be transferred) to an unlimited number of commercial contract pharmacies servicing hospitals. Novo made clear that it will fully comply with the 340B statute by still offering its outpatient drugs at 340B discounted prices to all eligible covered entities. It also made numerous exceptions in its discretion—going beyond what the statute requires—to ensure that federal grantee covered entities are able to purchase Novo's outpatient drugs at the discounted price and dispense them through contract pharmacies. But Novo

is no longer willing to allow hospital covered entities and commercial contract pharmacies to abuse the 340B program.

6. Nothing in the statute or any regulation requires manufacturers to facilitate the transfer of their covered outpatient drugs to third parties at a covered entity's request. The statute requires only that manufacturers "offer" their covered outpatient drugs "for purchase" at discounted prices to eligible "covered entities." 42 U.S.C. § 256b(a)(1). Moreover, although HHS has previously issued guidance permitting covered entities to use contract pharmacies, it repeatedly emphasized that its guidance was non-binding and that the statute itself did not address contract pharmacy arrangements. Under the law, manufacturers have discretion to decide when or whether to honor covered entity requests that their discounted drugs be transferred to third parties, including to for-profit, commercial pharmacies.

7. On December 30, 2020, HHS's Office of General Counsel issued what it labeled an "advisory opinion" but in fact constitutes a final rule that seeks to change the legal requirements that the 340B program imposes on manufacturers. Without textual support, the agency's decision announces finally and unequivocally that the agency has concluded that drug manufacturers are legally obligated to facilitate the transfer of their discounted drugs to contract pharmacies, which HHS assumed are acting as agents of 340B covered entities. *See* HHS, Office of the Gen. Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020) (Ex. A) (the "December 30 decision"). According to HHS, because the statute requires manufacturers to offer their drugs for purchase at discounted prices, the agency also has authority to require manufacturers to transfer their drugs to wherever covered entities may demand, "be it the lunar surface, low-earth orbit, or a neighborhood pharmacy." Ex. A at 3.

8. HHS's decision is wrong, contrary to the statute, and inconsistent with the requirements of reasoned decision-making. The 340B statute requires manufacturers to "offer" their covered outpatient drugs to covered entities at 340B prices, and Novo's initiative fully complies with that statutory requirement. Nothing in the 340B statute requires manufacturers to facilitate the transfer of their deeply discounted drugs to an unlimited number of contract pharmacies. Nor does anything in the statute establish that Congress intended to impose such a significant burden on manufacturers or to allow the 340B program to be abused for commercial gain.

9. As a result of HHS's decision, Novo is exposed to enforcement action, severe and accumulating monetary penalties, and potential revocation of its ability to participate in the Medicare and Medicaid programs. Unless and until HHS's decision is struck down, Novo is exposed to the threat of accumulating greater and greater liability.

10. On May 17, 2021, with no notice to Novo or its counsel, defendant Diane Espinosa on behalf of defendant Health Resources and Services Administration, an agency within HHS, sent a letter to Novo threatening to impose massive penalties on the company unless it accedes to HHS's position set forth in its December 30 decision and complies with the extra-statutory obligations that HHS's December 30 decision seeks to impose on manufacturers. *See* Letter from D. Espinosa to Novo Nordisk (May 17, 2021) (Ex. B) ("May 17 letter"). The letter states that Novo has violated the 340B statute by not accepting covered entity demands that Novo transfer its discounted drugs to commercial contract pharmacies without limitation. It directs Novo to respond by June 1, 2021, and threatens Novo that if it does not "immediately" capitulate and begin transferring "its covered outpatient drugs at the 340B ceiling price" to commercial pharmacies—in other words, if it does

not surrender on the ultimate issues raised in this litigation—HHS may seek to impose substantial monetary penalties. Ex. B at 2.

11. HHS's May 17 letter seeking to enforce the obligations against Novo set forth in HHS's December 30 decision is substantively and procedurally invalid for the same reason HHS's December 30 letter is unlawful. In addition, HHS's May 17 letter fails to offer any sufficiently reasoned explanation for its conclusions, which are inconsistent with HHS's past guidance, relies on justifications that are inconsistent with its December 30 decision, and is not supported by evidence in the record.

12. Novo is therefore bringing this action to seek an order (1) declaring that HHS's December 30 decision and its recent letter seeking to enforce that decision violate the Administrative Procedure Act because they are in excess of HHS's statutory authority, were issued without following proper procedure, and are not otherwise in accordance with law, (2) declaring that Novo is not required to facilitate the transfer of 340B discounted drugs to contract pharmacies, and (3) enjoining enforcement of HHS's decision and all actions by HHS inconsistent with that declaratory relief, including preventing HHS from taking any enforcement or other action in any administrative proceeding or pursuant to its May 17 letter.

THE PARTIES

13. Novo Nordisk Inc. is the United States based affiliate of a global healthcare company, founded in 1923, with the purpose to drive change to defeat diabetes and other serious chronic diseases, such as obesity, and rare blood and rare endocrine diseases. Novo Nordisk Inc.'s headquarters are located in Plainsboro, New Jersey.

14. Novo Nordisk Pharma, Inc. supplies unbranded biologic versions of Novo Nordisk insulin products at a reduced list price to individuals facing affordability challenges. Novo Nordisk Pharma, Inc.'s headquarters are located in in Plainsboro, New Jersey.

15. Defendant United States Department of Health and Human Services ("HHS") is an executive branch department in the United States government. It is headquartered in the District of Columbia.

16. Defendant Health Resources and Services Administration ("HRSA") is an administrative agency within HHS that is responsible for administering the 340B program. It is headquartered in Rockville, Maryland.

17. Defendant Xavier Becerra is the Secretary of HHS. His official address is in the District of Columbia. He has ultimately responsibility for overseeing HRSA's activities, including with regard to administering he 340B program. Secretary Azar is sued in his official capacity.

18. Defendant Daniel J. Barry is Acting General Counsel of HHS. His official address is in the District of Columbia. Acting General Counsel Barry is sued in his official capacity.

19. Defendant Diana Espinosa is the Acting Administrator of HRSA. Her official address is in Rockville, Maryland. Acting Administrator Espinsoa is responsible for administering the 340B program. She is sued in his official capacity.

JURISDICTION AND VENUE

20. Novo brings this action under the Administrative Procedure Act, 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

21. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1361.

22. Defendants' issuance of the December 30 decision constitutes final agency action that is reviewable under the Administrative Procedure Act. *See* 5 U.S.C. §§ 704–706.

23. Defendants' issuance of the May 17 letter seeking to enforce its December 30 decision constitutes final agency action that is reviewable under the Administrative Procedure Act. *See* 5 U.S.C. §§ 704–706.

24. The Court has authority to grant injunctive and declaratory relief and to vacate and set aside the December 30 decision under the Administrative Procedure Act, 5 U.S.C. §§ 701–706, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the Court's inherent equitable powers.

25. The Court also has authority to enjoin enforcement of HHS's December 30 decision and all actions by HHS that are inconsistent with the declaratory relief sought, including preventing HHS from taking enforcement or other action pursuant to its May 17 letter.

26. The Court has inherent authority to prevent HHS or any of the defendants from interfering with this litigation, disrupting the briefing schedule, or otherwise interfering with the Court's rightful exercise of jurisdiction.

27. Venue is proper in this district under 28 U.S.C. § 1391(e) and 5 U.S.C. § 703 because this action seeks relief against federal agencies and officials acting in their official capacities, Novo resides in this district, and no real property is involved in his action.

GENERAL ALLEGATIONS

A. The 340B Drug Pricing Program

28. This case concerns section 340B of the Public Health Service Act, which created the "340B program" as part of the authority granted in the Veterans Health Care Act of 1992. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

29. Before Congress created the 340B program, individual manufacturers helped vulnerable patients by voluntarily providing their drugs at significantly reduced prices to institutions that serve the needy. Turning this voluntary support into a legal mandate, the statute requires that any manufacturer that participates in the Medicaid Drug Rebate Program must "offer" its covered outpatient drugs "for purchase" at deeply discounted prices to eligible "covered

entities"—disproportionate share hospitals and other service providers that are expected to serve predominantly low-income and vulnerable patients. 42 U.S.C. § 256b(a)(1).

30. The discounted 340B price is calculated by determining the difference between the manufacturers Average Manufacturer Price and its Medicaid unit rebate amount, as determined under the Medicaid Drug Rebate Program statute, codified at section 1927 of the Social Security Act. *Id.* § 256b(a)(1)–(2) & (b). The resulting prices, referred to as 340B "ceiling prices," are significantly lower than the price at which manufacturers sell their products to other purchasers. For the vast majority of innovator drugs, the mandatory discounts range from at least 23.1% to more than 99.9% of the average price in the market. *See* 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1). Some mandatory 340B ceiling prices are as little as a penny a unit or dose.

31. The purpose of the 340B program is to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by creating "a low-cost source of pharmaceutical medication for the indigent patients themselves." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

32. Although participation in the 340B program is optional, as a practical matter most manufacturers have no choice. If they do not participate in the program, they cannot receive coverage or reimbursement of their products under Medicaid or Medicare Part B. 42 U.S.C. § 1396r-8(a)(1), (5).

33. To indicate their agreement to participate in the 340B program, manufacturers sign a form contract with HHS, referred to as the Pharmaceutical Pricing Agreement. Those agreements are drafted by HHS, they have "no negotiable terms," and they "simply incorporate the statutory

obligations and record the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 117–18 (2011).

34. The Pharmaceutical Pricing Agreement does not impose any obligation on participating manufacturers to sell discounted drugs to contract pharmacies, or to cause their discounted drugs to be transferred to contract pharmacies at 340B discounted prices. The Pharmaceutical Pricing Agreement does not contain the term "contract pharmacy," let alone establish legal obligations on manufacturers with respect to contract pharmacies.

35. Failure to comply with the statutory requirements under the 340B program may result in termination of the Pharmaceutical Pricing Agreement (and the manufacturer's ability to participate in Medicare and Medicaid), as well as enforcement action and potentially the imposition of large civil penalties.

36. Under the 340B statute (and the terms of the Pharmaceutical Pricing Agreement), any manufacturer that participates in the 340B program must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

37. Only "covered entities" are eligible to participate in the 340B program, and only "covered entities" and their patients are entitled to receive manufacturers' prescription drugs at the deeply discounted prices that the statute requires.

38. The 340B program does not require covered entities to treat only needy patients with the drugs that manufacturers make available to them at discounted prices, or even (in the case of hospital covered entities) to offer the discounts they receive to needy patients. In short, the discounts that covered entities receive do not have to be, and are typically not, passed on to the patients. Instead, covered entities are permitted to use the 340B drugs to treat any of the patients

they serve. By charging the full price of the discounted 340B outpatient drugs to non-needy patients and their insurance companies (and, in the case of hospital covered entities, by charging the full price even to the needy), covered entities are able to obtain significant profits.

39. These profits—the "spread" between the discounted price and the full market price—are not supposed to be used to enrich the covered entities or to benefit other commercial parties. Instead, Congress intended that covered entities would invest the profits to provide care and services to uninsured and underinsured patients.

40. The 340B program raises obvious concerns because the Constitution prohibits the government from forcing the transfer of property at confiscatory prices from one group to another for private benefit. *See* U.S. Const. amend. V. Congress designed the 340B program with the intent that there would be a close nexus between the program and its only valid public purpose (helping needy patients). Consistent with that intent, the statute is structured to prevent covered entities from using manufacturers' drugs to generate commercial profits or to allow the drugs to be transferred or sold for the financial benefit of entities outside the program.

41. The statute expressly limits which entities—"covered entities"—are entitled to participate in the program and obtain access to 340B covered outpatient drugs at discounted prices. *See* 42 U.S.C. § 256b(a)(4). Consistent with its objective of helping vulnerable and low-income patients gain lower-cost access to life-saving medications, the statute defines "covered entities" to include only organizations that predominantly serve low-income patients. The definition includes, for example, federally qualified health centers, children's hospitals, rural hospitals, and clinics that serve vulnerable patients. *Id.*

42. For-profit third-party pharmacies are not included in the statutory list of "covered entities." *See id.*

43. The statute expressly forbids "diversion" by prohibiting covered entities from selling or otherwise transferring any manufacturer's discounted drugs "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity").

44. The statute also prohibits covered entities from receiving or causing "duplicate discounts or rebates," which means that they may not obtain a 340B discount and also cause a Medicaid rebate to be issued for the same unit of drug. *Id*. § 256(a)(5)(A).

45. In addition to these express prohibitions, the statute imposes an affirmative obligation on the Secretary of HHS—authority that has been delegated to HRSA—to protect the program's integrity by "provid[ing] for improvements in compliance by covered entities … in order to prevent diversion" and violations of the duplicate discount prohibition. *Id.* § 256b(d)(2)(A).

B. The Growth in Contract Pharmacy Arrangements

46. In 1996, HRSA issued non-binding guidance stating that the agency would not prevent covered entities that lacked an in-house pharmacy from entering into a contractual relationship with a single outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996). HRSA justified this modest expansion of the program on grounds that some covered entities lacked in-house pharmacies and any contract pharmacy would function as an "agent" of a covered entity. *See id.* at 43,549–50. The guidance made clear that it "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550.

47. In 2010, HRSA issued new non-binding guidance that radically changed how covered entities operated under the 340B program. The guidance stated for the first time stated

that the agency would allow covered entities to enter into contractual relationships with an *unlimited* number of "contract pharmacies." 75 Fed. Reg. 10,272 (Mar. 5, 2010).

48. The 2010 guidance did not purport to impose binding obligations on manufacturers. HRSA did not attempt to promulgate a "contract pharmacy rule" through proper notice-and-comment procedures. Instead, as with the 1996 guidance, HRSA made clear that the non-binding guidance did not create any new rights or impose any new obligations. *See id.* at 10,273 ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law").

49. Following issuance of the 2010 guidance, covered entities have dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 4,228% between 2010 and today. *See* Aaron Vandervelde et al., For-Profit Pharmacy Participation in the 340B Program, at 4 (2020) (Ex. C). This explosion in the use of contract pharmacies has been driven by the prospect of sharing in the outsized profit margins on the deeply discounted 340B drugs.

50. Contract pharmacies, which are predominantly large commercial pharmacy chains, do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe a fiduciary obligation to the covered entities. The relationships between covered entities and the for-profit, commercial pharmacies are governed by arm's-length contracts.

51. Under these arrangements, covered entities direct manufacturers to ship 340B-covered outpatient drugs purchased at the 340B discount to contract pharmacies, which then share in the "spread" generated by selling the drugs at higher prices to patients and/or seeking full commercial reimbursement from the patients' insurance plans. As a result, for-profit pharmacies

are able to obtain significant profits from the covered outpatient drugs that manufacturers are required to offer covered entities at deeply discounted prices.

52. By dramatically expanding the pool of individuals that have access to the drugs that covered entities are able to purchase at discounted prices—including individuals who would not otherwise qualify as patients of the covered entity—covered entities are able to obtain profits that extend far beyond Congress's intent when it created the 340B program.

53. One study found that in 2018 alone, covered entities and their contract pharmacies have generated more than $13 billion in estimated gross profits from the purchase of manufacturers' drugs at mandated 340B prices. *See* Vadervelde Report, Ex. B at 7.

54. By bringing commercial pharmacies into the program, there is a significantly greater risk that the covered outpatient drugs will be dispensed to individuals who are not properly classified as "patients" of the covered entity. As HHS has found, contract pharmacy arrangements "create complications in preventing diversion" (for example, contract pharmacies cannot verify patient eligibility in real-time like a covered entity can). HHS, OEI-05-13-00431, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, at 1, 16 (Feb. 4, 2014) (Ex. D) ("HHS Report"). Indeed, because contract pharmacies often dispense 340B-covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit. *See* GAO, GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, at 28 (2011) (Ex. E) (noting that approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies).

55. Contract pharmacy arrangements also "create complications in preventing duplicate discounts." HHS Report, Ex. D at 2, 16. Because HRSA has only partial insight into which covered entities use which contract pharmacies, and only incomplete information on which covered entities use 340B-discounted drugs for Medicaid-insured patients, there is no effective or comprehensive way to know where a contract pharmacy's prescriptions are being submitted for duplicate discounts—that is, for both a 340B discount (under the covered entity's name) and a Medicaid rebate (under the pharmacy's name).

56. Although covered entities and commercial pharmacies are reaping windfalls as a result of being able to obtain access to manufacturers drugs at discounted prices, uninsured and underinsured patients are not benefitting. *See* HHS Report, Ex. D at 2 (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program That Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020) (Ex. F) (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which was designed as a narrow support to certain hospitals," while patients "don't benefit," even though manufacturers have "practically given the product away").

57. In fact, while commercial pharmacies are driving massive growth in the 340B program—at double-digit rates—charity care by hospitals has decreased. Commentators have noted, for example, that while the 340B program has grown at a remarkable rate, the total value of hospitals' uncompensated care has significantly declined. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing program (Oct. 30, 2020) (Ex. G); Adam J. Fein, *340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019) (Ex. H).

58. HRSA has failed to protect the 340B program's integrity. It has refused to address significant and widespread abuses despite repeated reports and concerns raised by other government entities. *See* GAO, GAO-18-480, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* (2018) (Ex. I); H. Comm. on Energy & Commerce, *Review of the 340B Drug Pricing Program*, 114th Cong., at 30–41 (Jan. 11, 2018) (Ex. J); HHS Report, Ex. D.

59. HRSA has also neglected to enforce the statutory prohibitions on diversion, despite serious concerns that commercial contract pharmacies are profiting from the 340B program and that covered outpatient drugs are being unlawfully diverted to individuals who are not patients of the covered entities.

C. Novo's Initiative to Address Contract Pharmacy Abuses

60. Novo and other manufacturers have exercised their lawful right to decline covered entity requests that they cause discounted covered outpatient drugs to be transferred to an unlimited number of commercial pharmacies.

61. Novo has thus implemented a new initiative—which took effect in January 2021—making clear that it will no longer indiscriminately accept covered entity requests that it transfer 340B-covered outpatient drugs to an unlimited number of third-party commercial contract pharmacies servicing hospital covered entities.

62. In implementing this initiative, Novo has confirmed that it will continue to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute. 42 U.S.C. § 256b(a)(1).

63. Novo's initiative thus ensures that, as the statute requires, each covered entity is able to purchase Novo's 340B cover outpatient drugs at discounted prices. If a hospital covered entity does not have an on-site pharmacy capable of dispensing to outpatients, Novo will allow the

hospital covered entity to designate a single outside contract pharmacy to dispense the product to the covered entity's patients, and Novo will facilitate shipment to that single contract pharmacy.

64. Novo's initiative is tailored to address systemic abuses and, going beyond what the statute requires, includes exceptions for the benefit of covered entities and their patients. Under its new initiative, Novo has made an exception whereby it will facilitate shipment of covered outpatient drugs to an unrestricted number of contract pharmacies that are *wholly owned* by the covered entity. Novo also exempts all federal grantee covered entity types (safety net clinics) from its new initiative, enabling them to continue to use an unlimited number of contract pharmacies.

65. There are no legal requirements—no obligation imposed by any statute or regulation—that requires Novo to transfer and ship its drugs to an unlimited number of for-profit commercial pharmacies. Contract pharmacies are not supposed to benefit from the 340B program because they are neither covered entities nor patients.

D. HHS's December 30, 2020 Decision

66. Manufacturers have been transparent with the government about their policies and decisions not to continue honoring covered entity requests to have manufacturers' drugs transferred to third parties.

67. HRSA repeatedly informed manufacturers that agency guidance was not binding or legally enforceable. *See* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020) (Ex. K).

68. Despite knowing that manufacturers intended to implement policies designed to curb contract pharmacy abuses, HRSA did not identify any statutory provision or other legal requirement that would prevent manufacturers from implementing those policies.

69. Novo alerted HRSA to its intent to adopt its initiative on December 1, 2020.

70. HRSA has never contacted Novo to express any concern over Novo's initiative.

71. Covered entities have asked HHS to take enforcement action against manufacturers, including assessing civil monetary penalties, on the view that the statute requires manufacturers to cause their drugs to be transferred to commercial contract pharmacies. They also filed lawsuits seeking to compel HHS to establish a process for adjudicating disputes and to take enforcement action that would require manufacturers to cause their drugs to be transferred to commercial contract pharmacies and pay penalties if they failed to do so. *See Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C.); *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal.). (Because Novo was referenced in the covered entities' complaint in the case filed in the Northern District of California, it filed a motion to intervene, and a proposed motion to dismiss the complaint.)

72. In December 2020, the GAO released a report re-affirming that "the 340B statute does not address contract pharmacy use." GAO, GAO-21-107, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, at 15–16 (2020) (Ex. L).

73. In response to the litigation filed by covered entities, counsel for HHS and HRSA described efforts to compel "participation through contract pharmacies" as improper attempts to foist "wholesale changes to an agency program" on the government. *See* Memo. in Support of Mot. to Dismiss for Lack of Jurisdiction, at 19–20, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Dec. 14, 2020) (Dkt. 41-1).

74. ***The ADR Rule.*** On December 14, 2020, in a rushed response to the litigation filed by covered entities, HHS promulgated regulations establishing an administrative process for resolving (a) claims by covered entities that they have been overcharged for drugs purchased under the 340B program, and (b) claims by manufacturers, after conducting an audit, that a covered entity has violated the prohibitions on duplicate discounts and diversion. *See id*. § 256b(d)(3)(A). The

regulations took effect January 13, 2021. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,632 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10) (the "ADR rule").

75. Claims brought under the ADR rule are to be adjudicated by a panel consisting of representatives in equal numbers from the HHS Office of General Counsel, HRSA, and the Centers for Medicare & Medicaid Services ("CMS"). *Id.* at 80,634. The panel is charged with reviewing "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." *Id*. § 10.21(c)(1), 85 Fed. Reg. at 80,645.

76. The HHS Office of General Counsel "supervises all legal activities of the Department and its operating agencies," including HRSA and CMS, and furnishes "all legal services and advice to the Secretary, Deputy Secretary, and all offices, branches, or units of the Department in connection with the operations and administration of the Department and its programs." Statement of Organization, Functions, and Delegations of Authority, 85 Fed. Reg. 47,228, 47,230 (Aug. 4, 2020).

77. The ADR rule is not a lawful exercise of HHS's authority and does not allow for the fair and unbiased adjudication of claims. HHS failed to respond to serious objections that the ADR process could not work until HHS established a fair and reliable audit process. It failed to address abuses in the program and delegated improper authority to the ADR panels. HHS failed to undertake an adequate notice and comment process. It also states that ADR panels would be able to resolve "legal questions," including "whether a pharmacy is part of a 'covered entity.'" 85 Fed. Reg. at 80,633, 80,640.

78. ***HHS's December 30 Decision.*** Two weeks after the publication of the final ADR rule, on December 30, 2020, HHS's General Counsel issued an "Advisory Opinion" asserting that manufacturers are "obligated" to deliver their "covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs" whenever a contract pharmacy acts as a covered entity's "agent." HHS Advisory Opinion, Ex. A at 1.

79. HHS's decision announces the agency's definitive position that manufacturers are prohibited from limiting the transfer of discounted drugs to contract pharmacies, suggesting that "private actor[s]" are not "authorized by section 340B to add requirements to the statute." *Id*. at 2. According to the decision, "[i]f a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see id.* § 256b(d)(3)(A)." *Id.* at 5.

80. HHS did not identify any statutory provision that requires manufacturers to cause their discounted drugs to be transferred to commercial contract pharmacies. Its decision's entire textual analysis turns on its unreasoned (and unreasonable) conclusion that because the 340B statute requires manufacturers to "offer" their drugs to covered entities for "purchase" at discounted prices, "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." *Id.* at 3. But that conclusion has no basis in the statutory text. As noted above, the statute requires only that manufacturers "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

81. Although the statute expressly prohibits covered entities from selling or transferring covered outpatient drugs to non-patient third parties, HHS assumed that covered entities and contract pharmacies "are not distinct, but function as principal-agent." Ex. A at 6. But HHS did not explain why agency principles are relevant under the statute. It also never explained the basis for its assumption, providing no reason for concluding that a fiduciary obligation exists between covered entities and contract pharmacies or that covered entities have the right to control contract pharmacies—all standard criteria for establishing a principal-agent relationship.

82. HHS also compared transferring drugs to contract pharmacies as akin to using a "courier service" to deliver drugs to patients, but it never explained why that analogy is accurate or appropriate. In particular, it never addressed the reality that contract pharmacies share in the profits received from the sale of manufacturers' drugs obtained at discounted prices, or that the use of contract pharmacies has caused the 340B program to swell by billions of dollars.

83. HHS's December 30 decision exposes Novo to government enforcement actions for alleged noncompliance, including civil monetary penalties in the amount of $5,000 for *each instance* of noncompliance, *see* 42 U.S.C. § 256b(d)(1)(B)(vi)(II), and the revocation of its ability to participate in Medicare and Medicaid.

84. HHS's December 30 decision also subjects Novo to a substantial threat that covered entities will assert claims through the ADR process to challenge Novo's initiative under the terms of HHS's decision—and that ADR panels will rule against and seek to sanction Novo. The ADR panel will consist of representatives from HHS Office of General Counsel, which issued the December 30 decision, and from HRSA and CMS, both of which are HHS agencies subject to the Office of General Counsel's oversight. The Office of the General Counsel serves as the legal team for all of HHS. It supports the development and implementation of HHS's rules and programs by

providing legal services to both the Secretary of the HHS and HHS's various agencies and divisions, including HRSA.

85. HHS has made clear that it intends to use the ADR process to impose liability on manufacturers for failing to follow the position taken by HHS in its December 30 decision. Because the December 30 decision conclusively and unequivocally announces HHS's legal position on the contract pharmacy issue, any attempt by a manufacturer to contest the December 30 decision before an ADR panel would be futile. Nothing produced in the administrative record during a specific ADR proceeding would change HHS's legal interpretation.

86. Counsel for covered entities have taken the position that HHS's December 30 decision establishes that the statute requires manufacturers to cause their drugs to be transferred to commercial contract pharmacies. Even though Novo's initiative places *no* limits on the amount of 340B drugs that the covered entity itself is able to purchase at the 340B ceiling price, delivered to the covered entity itself, counsel for the covered entities have threatened that if Novo does not "immediately discontinue" its initiative, they will "seek to require that HHS enforce the 340B statute, covered entities are reimbursed for damages caused by the [allegedly] illegal policy, and the matter is referred to the HHS Inspector General for the imposition of civil money penalties." Ltr. William B. Shultz to D. Langa, at 2 (Jan. 7, 2021) (Ex. L).

87. Given the threats that have been made by covered entities, it is almost certain that covered entities will file claims against Novo now that the ADR Rule has taken effect. It is also almost certain that, because of its composition and because of HHS's December 30 decision, an ADR panel will treat HHS's December 30 decision as binding in any ADR proceeding and find that Novo's contract-pharmacy initiative violates the statute as interpreted by HHS.

88. ***HHS's May 17 Letter***. HHS and the other defendants filed their motion to dismiss and motion for summary judgment on May 11, 2021, consistent with the briefing schedule agreed upon by the parties and approved by the Court on April 19, 2021. A few days later, HHS through HRSA issued its May 17 letter threatening to enforce the new position and new rule announced in its December 30 decision. The letter's demands are imminent and authoritative. It directs Novo to respond by June 1, 2021, and threatens Novo that if it does not "immediately" capitulate and begin transferring "its covered outpatient drugs at the 340B ceiling price" to commercial pharmacies, HRSA may seek to impose substantial civil monetary penalties.

89. HHS's May 17 letter—like its December 30 decision—does not identify any statutory provision that requires manufacturers to cause their discounted drugs to be transferred to commercial contract pharmacies. The May 17 letter's entire textual analysis turns on its unreasoned (and unreasonable) conclusion that the requirement that Novo "offer" covered entities "covered outpatient drugs for purchase at or below the applicable ceiling price," imposes an additional obligation on manufacturers to transfer their drugs to for-profit commercial pharmacies at the direction of covered entities. Ex. B at 1.

90. HHS's May 17 letter is an improper, unreasonable, and arbitrary and capricious attempt to disrupt and interfere with this Court's ongoing judicial proceedings. The conclusion reached by HHS in its May 17 letter—that Novo's decision not to transfer its discounted drugs to an unlimited number of commercial pharmacies is a violation of the 340B statute—is the central legal issued raised in this case. Instead of waiting for the Court to resolve that important legal issue under the schedule approved by the Court, HHS seeks to undermine that schedule by pressuring Novo into abandoning its litigation position. Its May 17 letter is both unreasonable and unreasoned.

STANDING

91. Novo is injured by HHS's December 30 decision and its May 17 letter because the decision requires Novo to ship its discounted drugs to contract pharmacies and exposes Novo to enforcement actions and civil penalties that are certainly impending if Novo fails to comply with HHS's new rule.

92. Novo's injuries are fairly traceable to HHS's December 30 decision because it seeks to impose new substantive obligations on drug manufacturers by interpreting the statute as imposing a binding legal requirement that manufacturers must ship their discounted drugs to third parties, such as contract pharmacies, when requested by covered entities. Neither section 340B, nor any existing regulation, nor the Pharmaceutical Pricing Agreement, contains these binding legal requirements.

93. Through its December 30 decision, HHS has taken the position that Novo has no right to limit shipments of its covered outpatient drugs to non-covered entities. As a result of the December 30 decision, Novo is exposed to enforcement actions and accumulating liability and civil monetary penalties, as well as the revocation of its participation in the Medicare and Medicaid programs, if it fails to comply with the new substantive obligations imposed as a result of the December 30 decision.

94. HHS's May 17 letter makes clear that HHS intends to enforce the requirements imposed by its December 30 decision and threatens Novo that HHS may impose civil monetary penalties if Novo does not "immediately" surrender and comply with the obligations that HHS seeks to impose through its December 30 decision. The May 17 letter confirms that Novo is injured because Novo faces substantial monetary penalties and reputational harms if it does not immediately comply with the new rule set forth in HHS's December 30 decision.

95. A favorable ruling is likely to address Novo's injuries. Vacating the December 30 decision, preventing HHS from enforcing its decision through its May 17 letter, and granting declaratory relief would redress Novo's injuries because Novo would not be required to cause its deeply discounted drugs to be shipped to contract pharmacies. Similarly, a declaratory judgment would redress Novo's injuries because Novo would not be exposed to enforcement actions, accumulating liability and civil monetary penalties, or revocation of its participation in Medicare and Medicaid for continuing to limit shipments to third parties that do not qualify as covered entities under the statute.

FINAL AGENCY ACTION

96. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

97. The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

98. The APA also provides that "final agency action for which there is no other adequate remedy in a court" is "subject to judicial review." 5 U.S.C. § 704.

99. Although HHS's December 30 decision claims that it "is not final agency action" and "does not have the force or effect of law," the decision is in fact "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Novo has exhausted all of its available administrative remedies and the pursuit of any further administrative remedies would be futile. Novo does not have any other adequate remedy. *See Army Corps. of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815–16 (2016).

100. HHS's December 30 decision represents the consummation of HHS's decision-making process that drug manufacturers must provide drugs covered under the 340B program to contract pharmacies. HHS reached this decision after years of studying the issues and after reviewing complaints filed by covered entities concerning Novo's and other manufacturers' compliance with the 340B statute. The December 30 decision was issued by HHS's chief legal officer, who has delegated authority to interpret the 340B statute, and the decision is not subject to further review or appeal within HHS.

101. HHS's December 30 decision imposes substantive rights and obligations under the 340B program that do not otherwise exist as a matter of law. Direct and appreciable legal consequences will inevitably flow from the decision if it is not vacated. In particular, if HHS's decision is not enjoined and the statute enforced, Novo will be prevented from exercising its right to limit shipments of its own discounted covered outpatient drugs to non-covered entities. In addition, Novo will be exposed to enforcement actions, potential allegations of overcharging, and accumulating civil monetary penalties, as well as the possible revocation of its participation in the Medicare and Medicaid programs.

102. Novo need not wait for enforcement to occur to challenge HHS's erroneous decision. *See Hawkes*, 136 S. Ct. at 1815; *Pharm. Research & Mfrs. of Am. v. HHS.*, 138 F. Supp. 3d 31, 43 (D.D.C. 2015) (party does not have to wait to file litigation when put to the "painful choice" of either complying with incorrect obligations resulting from agency's statutory interpretation or "risking the possibility of an enforcement action at an uncertain point in the future").

103. HHS has already attempted to enforce its December 30 decision, threatening Novo in its May 17 letter that if Novo does not immediately comply with the obligations that the

December 30 decision seeks to impose on manufacturers, HHS may seek civil monetary penalties. This threatened enforcement confirms that the December 30 decision represents the consummation of HHS's decision-making process and that the decision seeks to impose substantive obligations on manufacturers.

104. By attempting to enforce the December 30 decision before this Court rules on its lawfulness, HHS is impermissibly interfering with the briefing schedule approved by the Court and, more broadly, with the Court's authority to resolve this dispute on its merits. By its own terms, HHS's May 17 letter reflects a final determination that, under the final rule set forth in HHS's December 30 decision, Novo's decision not to transfer its 340B discounted drugs to commercial pharmacies is contrary to the HHS's view of the statutory requirements. If the Court does not grant declaratory and injunctive relief, legal consequences will flow from the May 17 letter, including threatening Novo with further enforcement action and subjecting Novo to substantial civil monetary penalties.

105. The consequences threatened by HHS's December 30 decision and its recent May 17 letter could be devastating to Novo's business and contrary to the public interest. HHS's December 30 decision has put Novo in the untenable position of either causing deeply discounted drugs to be shipped to ineligible, commercial third parties, or else face crippling financial sanctions for asserting its right to comply with the obligations that are actually in the statute. HHS's May 17 letter similarly puts Novo in the untenable position of either surrendering to HHS's attempt to rewrite the 340B statute in its December 30 decision or face crippling financial sanctions for pursuing this litigation to conclusion.

106. Any delay in addressing this dispute would be inappropriate because each day that Novo "wait[s] for the Agency to drop the hammer," it risks potential "accru[ing]" significant

"penalties." *Sackett v. EPA*, 566 U.S. 120, 126–27 (2012). The "direct and immediate" burdens imposed by HHS's December 30 decision mean that the decision warrants immediate judicial review.

107. The need for immediate review is particularly important because, in addition to putting Novo in the untenable position of exercising its rights under the statute or facing severe penalties, HHS's December 30 decision effectuates an unconstitutional taking of property by forcing Novo to transfer its own property (its covered outpatient drugs) to for-profit entities for their private benefit. The Fifth Amendment of the U.S. Constitution forbids this unconstitutional taking, which does not serve any valid public purpose under the 340B statute.

108. Moreover, it is well settled that government may not condition a benefit, such as participating in Medicare Part B and Medicaid, on the relinquishment of a constitutional right. HHS's December 30 decision violates this basic constitutional principle. In order to receive reimbursement and coverage from the federal government—the nation's largest insurance provider—the December 30 decision forces Novo and the rest of the pharmaceutical industry to improperly transfer billions of dollars for the financial benefit of covered entities and large commercial pharmacies, and not the needy patients the 340B program was designed to serve.

CLAIMS FOR RELIEF

COUNT I
(Violation of the Administrative Procedure Act — Contrary to Law and in Excess of Statutory Authority)

109. Novo re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

110. Under the APA, a reviewing court must "hold unlawful and set aside agency action" that is "not in accordance with law" as well as agency action "in excess of statutory … authority." 5 U.S.C. § 706(2)(A), (C).

111. The 340B statute does not confer on HHS (or any of the other defendants) any authority to require drug manufacturers to provide drugs subject to pricing under the 340B statute to contract pharmacies. Contract pharmacies are not covered entities as defined by the 340B statue and the statute does not authorize HHS to require manufacturers to offer discounts to any other type of entity.

112. HHS has no authority to create, through guidance or otherwise, an exception to the statutory prohibition that covered entities may not divert manufacturers' covered outpatient drugs to any entity that is not a patient of the 340B covered entity under the 340B statute.

113. Nor does HHS have any authority to require manufacturers to transfer their deeply discounted covered outpatient drugs to third parties that do not qualify as either covered entities or patients.

114. HHS's December 30 decision is not entitled to *Chevron* or *Skidmore* deference. *See generally Chevron U.S.A., Inc. v. Nat. Res. Def. Council*, *Inc.,* 467 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). HHS's decision violates the text of the statute, and Congress has not delegated authority to HHS to expand the 340B program to require manufacturers to facilitate transferring discounted drugs to third parties, such as contract pharmacies. HHS's position also has no persuasive authority because HHS has not reasonably or rationally explained its position.

115. Because HHS's December 30 decision is contrary to law and in excess of statutory authority, it should be set aside. 5 U.S.C. § 706(2)(A).

116. All of the flaws that render HHS's December 30 decision contrary to law and in excess of statutory authority also render unlawful HHS's attempt in its May 17 letter to enforce the obligations that its December 30 decision seeks to impose on manufacturers. As a result, and

for the same reasons, HHS's May 17 letter is contrary to law and in excess of statutory authority, and it should be set aside. 5 U.S.C. § 706(2)(A).

COUNT II
(Violation of the Administrative Procedure Act —
Failure to Observe Notice and Comment Procedures Required by Law)

117. Novo re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

118. A court must "hold unlawful and set aside agency action, findings, and conclusions found to be … without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

119. The APA requires agencies to issue rules through a notice-and-comment process. *See* 5 U.S.C. § 553.

120. The APA defines a "rule" as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4).

121. To issue a valid rule, an agency "shall [ ] publish[]" "[g]eneral notice of proposed rule making" "in the Federal Register," and shall include in that notice "either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id*. § 553(b). After providing notice of a proposed rule, the agency is required to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(c).

122. HHS's December 30 decision is a "rule" within the meaning of the APA because it is an agency statement of general applicability to all drug manufacturers, applies prospectively, and implements, interprets, or prescribes HHS's law or policy with respect to drug manufacturers' obligations under the 340B statute.

123. HHS's decision is not exempt from the APA's notice-and-comment requirements under 5 U.S.C. § 553(b)(A), because it is not an "interpretive rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." It is a legislative rule because it creates rights and imposes obligations on manufacturers with which they must comply, on threat of civil sanction and expulsion from the 340B program.

124. HHS's decision has the force and effect of law because it imposes binding obligations that exceed existing law. Neither the 340B statute nor any regulation requires drug manufactures to provide discounted drugs to contract pharmacies.

125. Novo and other manufacturers are exposed to enforcement actions and civil monetary penalties if they fail to comply with HHS's decision. Noncompliance with HHS's decision also puts at risk manufacturers' participation in Medicare and Medicaid.

126. HHS issued its decision without complying with required notice-and-comment procedures.

127. Because HHS's decision was issued "without observance of procedure required by law," it should be set aside. 5 U.S.C. § 706(2)(D).

128. Because HHS's May 17 letter seeks to enforce the obligations that HHS's December 30 decision seeks to impose on manufacturers, it is also procedurally invalid. HHS may not enforce a rule that has been issued "without observance of procedure required by law" and its May 17 letter should therefore be set aside.

COUNT III
(Violation of the Administrative Procedure Act —
Arbitrary and Capricious)

129. Novo re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

130. Under the APA, a reviewing court must "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

131. Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted). An agency rule is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

132. Any change to an agency's policy must be adequately explained. The agency must "display awareness that it *is* changing position," "show that there are good reasons for the new policy," and be aware that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

133. HHS's December 30 decision is arbitrary and capricious because HHS failed to reasonably explain its position or give adequate consideration to the text of the 340B statute, which precludes HHS from imposing an obligation on manufacturers to offer discounts to any entity other than the covered entities Congress specifically enumerated, or to cause its discounted products to be shipped to commercial entities shown to facilitate diversion and duplicate discounting.

134. HHS's decision is arbitrary and capricious because HHS failed to give sufficient consideration to the myriad and far-ranging abuses contract pharmacy arrangements have facilitated.

135. HHS's decision is arbitrary and capricious because HHS did not attempt to reconcile the "obligation" imposed by its decision with the agency's earlier pronouncements that manufacturers were under no legally enforceable obligation to offer 340B prices to contract pharmacies. The December 30 decision fails to explain HHS's dramatic change in policy.

136. HHS's decision is contrary to the requirements of its "good guidance rule." 85 Fed. Reg. 78,770 (Dec. 7, 2020).

137. HHS's decision relies on irrational and illogical reasoning, citing inapt analogies and suggesting that the statute gives HHS authority to force manufacturers to deliver their covered outpatient drugs to any location, even though the statute only requires manufacturers to offer their drugs to covered entities for purchase at the discounted price.

138. Because HHS's December 30 decision is unexplained and irrational, and because it does not consider the relevant factors, it is arbitrary and capricious and should be set aside. 5 U.S.C. § 706(2)(A).

139. Because HHS's December 30 decision is arbitrary and capricious, HHS's May 17 letter seeking to enforce the obligations that HHS's December 30 decision seeks to impose is also arbitrary and capricious, an abuse of discretion, and not in accordance with law, and should be set aside. 5 U.S.C. § 706(2)(A).

140. HHS's May 17 letter confirms that HHS's December 30 decision is arbitrary and capricious because it also was not issued in compliance with the requirements of HHS's "good guidance rule," 85 Fed. Reg. 78,770 (Dec. 7, 2020), and it relies on reasoning that is inconsistent with the rationale set forth in its December 30 decision.

141. It is arbitrary and capricious, and abuse of discretion, and not in accordance with law for an agency, without reasoned explanation or justification, to threaten to enforce statutory

requirements that are subject to pending litigation under an agreed-upon briefing schedule. It is similarly arbitrary and capricious, an abuse of discretion, and not in accordance with law for an agency to threaten a litigant with civil monetary penalties if it does not immediately accede to the government's position and give up its legal rights. For these additional reasons, HHS's May 17 letter seeking to seeking to enforce the obligations that HHS's December 30 decision seeks to impose is also arbitrary and capricious, an abuse of discretion, and not in accordance with law, and should be set aside. 5 U.S.C. § 706(2)(A).

COUNT IV
(Violation of the Administrative Procedure Act —
Contrary to the U.S. Constitution)

142. Novo re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

143. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, … found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

144. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.

145. The Takings Clause is not limited to instances when government physically appropriates property for its own use through eminent domain. A taking can occur through legislation and regulation that sufficiently deprives a user of its property rights. *See E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998). The Takings Clause extends to both real and personal property. *Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015).

146. HHS's December 30 decision raises substantial constitutional concerns because it imposes a new and unexpected obligations on manufacturers that do not serve any valid public purpose. *See E. Enters.*, 524 U.S. at 528–29. These constitutional concerns are heightened by

HHS's May 17 letter seeking to enforce the new and unexpected obligations that HHS's December 30 decision seeks to impose.

147. Confiscatory regulations that mandate the transfer of personal property from one private party to another private party amount to an unconstitutional taking with or without just compensation. "[I]t has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005); *Reagan v. Farmers' Loan & Tr. Co.*, 154 U.S. 362, 399, 410 (1894) (similar). Such private takings are always unconstitutional, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) ("[i]t is against all reason and justice" to allow government to "take[] property from A. and give[] it to B").

148. In addition, the unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to obtain a benefit, such as the ability to participate in a government program. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013); *see also Libertarian Party of Ind. v. Packard*, 741 F.2d 981, 988 (7th Cir. 1984) ("The 'unconstitutional conditions' doctrine is premised on the notion that what a government cannot compel, it should not be able to coerce."). That includes the rights to retain one's own personal (or business) property unless properly taken by the government. *See Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994); *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987). The doctrine "forbid[s] the government from engaging in 'out-and-out … extortion' that would thwart the Fifth Amendment" by coercing private parties, on pain of losing

a government benefit, into relinquishing their property without proper compensation. *Koontz*, 570 U.S. at 606 (quoting *Nollan*, 483 U.S. at 837).

149. HHS's decision to mandate that manufacturers transfer their drugs to commercial pharmacies is an impermissibly confiscatory regulation that imposes significant financial losses on Novo and other manufacturers.

150. HHS's decision is also constitutionally suspect because there are no assurances that the transferred property will be used for a public use, as required by the Fifth Amendment. Instead, HHS's decision, if it is not struck down, will force Novo and other manufacturers to transfer their property to other private entities, many (if not most) of which are large commercial pharmacies that use the property for their own private benefit. *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 311 (3d Cir. 2008).

151. Moreover, HHS's December 30 decision requires this transfer to occur as a condition for participating in Medicaid and Medicare Part B. HHS's decision thus imposes a previously nonexistent condition that directly contravenes the unconstitutional condition doctrine.

152. The broad reading of the 340B statute that is required for HHS's December 30 decision to be within its statutory authority raises serious constitutional concerns. The canon of constitutional avoidance thus weighs heavily against HHS's stained interpretation. *See INS v. St. Cyr*, 533 U.S. 289, 299–300 (2001).

PRAYER FOR RELIEF

WHEREFORE, Novo prays for the following relief:

a. A declaration, order, and judgment holding unlawful, enjoining, and setting aside HHS's December 30 decision because it is in excess of HHS's statutory authority, was issued without following proper procedure, raises significant constitutional

concerns, and is arbitrary, capricious, and abuse of discretion, and otherwise not in accordance with law;

b. A declaration, order, and judgment holding unlawful, enjoining, and setting aside HHS's May 17 letter seeking to enforce the obligations sought to be imposed by its unlawful December 30 decision because the May 17 letter is in excess of HHS's statutory authority, was issued without following proper procedure, raises significant constitutional concerns, and is arbitrary, capricious, and abuse of discretion, and otherwise notin accordance with law;

c. A declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to transfer or cause their discounted covered outpatient drugs to be transferred to contract pharmacies.

d. A declaration, order, and judgment holding that the 340B statute does not prohibit drug manufacturers from imposing conditions on the provision of covered outpatient drugs at 340B discounted prices to contract pharmacies;

e. A declaration, order, and judgment holding that it is lawful for Novo not to transfer or cause its covered outpatient drugs at 340B discounted prices to be transferred to contract pharmacies;

e. A preliminary and permanent injunction enjoining HHS from enforcing its December 30 decision, including through its May 17 letter or in any administrative proceeding or other enforcement action;

f. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

g. Any other relief that this Court deems just and proper.

Dated: May 25, 2021

Respectfully submitted,

/s/ Israel Dahan
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Novo Nordisk Inc. and Novo Nordisk Pharma, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2021, a copy of Plaintiffs' Amended Complaint was filed with the Clerk of the Court using the CM/ECF system. In addition, I caused a copy of Plaintiffs' Amended Complaint to be served on the following via third-party carrier UPS on this date:

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington D.C. 20201,

XAVIER BECERRA,
Secretary of Health & Human Services
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

DANIEL J. BARRY,
Acting General Counsel of the United States Department of Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20852,

DIANA ESPINOSA,
Acting Administrator of the Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20852

/s/ Israel Dahan
Israel Dahan (NJ Bar No. 042701997)

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM
DECEMBER 30, 2020

The 340B Program, established by section 340B of the Public Health Service Act ("PHSA"), 42 U.S.C. § 256b, imposes limitations on the prices manufacturers may charge for medications sold to specified health care facilities, referred to as "covered entities." Those facilities include public hospitals and community health centers, many of which provide safety-net services to the poor. The 340B Program requires drug manufacturers, as a condition of coverage of their products under Medicaid (*see* Social Security Act ("SSA") § 1902(a)(54)) and Medicare Part B (*see, e.g.*, SSA §§ 1842(o)(1), 1847A), to agree to sell their covered outpatient drugs to covered entities at no more than the statutorily-set "ceiling price." *See* SSA § 1927(a)(1).

Many covered entities enter into written agreements with pharmacies ("contract pharmacies") to distribute their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contact pharmacy has physical possession of the drug, it has been purchased by the covered entity.

Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.

The Office of the General Counsel ("OGC") has received numerous requests from both manufacturers and covered entities to address whether it is proper for a drug manufacturer participating in the 340B Program to refuse to provide covered outpatient drugs at the 340B ceiling price to a covered entity for drugs distributed at the entity's contract pharmacies. For the reasons set forth below, we conclude that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.

I. Analysis

A. The Plain Meaning of Section 340B Requires Manufacturers to Sell Covered Drugs to Covered Entities at or Below the Ceiling Price, Independent of Whether the Entity Opts to Use Contract Pharmacies to Dispense the Drugs

"[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004). Section 340B of the PHSA, entitled "Limitation on prices of drugs purchased by covered entities," states, in relevant part, that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1) (emphasis supplied). Furthermore, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As a result, the obligations placed on manufacturers by 340B are set out in a Pharmaceutical Pricing Agreement ("PPA") between the Secretary and the respective manufacturer. *See generally Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011) (describing role of PPAs in 340B Program). The exemplar PPA provides, in pertinent part, as follows:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following: (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to [the ceiling price].

PPA § II(a). The exemplar PPA Addendum provides that a "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price." PPA Addendum ¶ 2.

Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. *See Radovich v. Nat'l Football League*, 352 U.S. 445, 454 (1957) ("Congress itself has placed the private antitrust litigant in a most favorable position . . . . In the face of such a policy this Court should not add requirements to burden the private litigant beyond what is specifically set forth by Congress in those laws."); *Financial Planning Ass'n v. SEC*, 482 F.3d 481 (D.C. Cir. 2007); *Baker v. Bell Textron, Inc.*, 2020 WL 5513431, at *4 (N.D. Tex. 2020) ("The Court will not add requirements to the law that Congress could have included but did not.").

It is against this backdrop that we examine the 340B phrase "purchased by." It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise. The Court recently cautioned against seeing ambiguity where none exists. For

example, a regulation must be "genuinely ambiguous" before resorting to deference. *Kisor v. Wilkie*, ___U.S.___, 139 S.Ct. 2400, 2415 (2019). Here, as we understand it, the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor. In either event, the arrangement between the manufacturer and covered entity is a straightforward "sale" which "consists of the passing of title from the seller [drug manufacturer] to the buyer [covered entity] for a price." Uniform Commercial Code (U.C.C.) § 2-106.[1] A "buyer" is, by definition, a "purchaser." BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "buyer" as "[s]omeone who makes a purchase"). The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant. *See* U.C.C. § 2-401(2) ("Unless otherwise explicitly agreed title passes to the buyer at the time and place at which the seller completes his performance with reference to the physical delivery of the goods . . . ").

Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive. *Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). This straightforward textual interpretation, aside from dutifully reflecting the plain meaning of the statute, has the added benefit of comporting with the statute's purpose and history.

B. The Purpose and History of the 340B Program Reflect the Provision's Plain Meaning

1. Contract Pharmacies Have Been an Integral Part of the 340B Program Since Its Outset

The 340B Program was created to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rept. No. 102–384(II), at 12 (1992). As the Health Resources and Services Administration ("HRSA")—the agency primarily responsible for administering the 340B Program—has explained in prior guidance, a substantial number of covered entities are practically constrained to rely on contract pharmacies to access the 340B Program; if manufacturers can simply shut off this means of access, the Program's effectiveness will be greatly diminished. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) (OIG proposed rule discussing distribution of pharmaceuticals).[2]

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[1] The U.C.C. can be used for statutory construction, even if it does not directly apply. *See Comm'r of Internal Revenue v. Brown*, 380 U.S. 563, 571 (1965) (interpreting provision of the Internal Revenue Code by pointing to U.C.C. as support for the "ordinary sense" of the word "sale").

[2] The argument that the statute also evinces a purpose to prevent drug diversion or duplicate discounting, and therefore prohibits contract-pharmacy arrangements, is not persuasive. That is like arguing that the main purpose of federal healthcare programs are their antifraud provisions. In the absence of the core 340B discount mechanism, there would be no need for the duplicate-discount or diversion provisions.

This is particularly pertinent given that at the outset of the 340B Program only approximately 500 out of 11,500 covered entities (less than 5 percent) used in-house pharmacies. *See* 61 Fed. Reg. at 43,550. This is not surprising: the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. *See, e.g.*, 42 U.S.C. § 256b(a)(4) (defining covered entities); *Astra USA*, 563 U.S. at 113. These are the poster children of providers that one would expect to lack an in-house pharmacy. To champion a policy, ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with purpose of the Program and common sense. Had Congress intended to reach such a bizarre result, it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel, but it did not. *Doe v. Hesketh*, 828 F.3d 159, 167 (3d Cir. 2016) (the result is "so bizarre that Congress could not have intended it").

2. The Department's Longstanding Interpretation of Section 340B Reflects the Plain Language of the Section by Recognizing the Use of Contract Pharmacies

The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used. In 1996, HRSA issued the aforementioned guidance and stated, "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." 61 Fed. Reg. at 43,549. HRSA's assertion cannot be attacked as impermissible legislative rulemaking,[3] because the guidance only sought to "explain the statutory language by clarifying the meaning given by the Department to particular words or phrases"—it "create[d] no new law and create[d] no new rights or duties" not otherwise present in the statute. *See id.* at 43,550. HRSA reaffirmed its interpretation of the statute in guidance issued in 2010. *See* HRSA, *Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

The Department's consistent position over the past 24-plus years would factor into a court's interpretation of the statute. Courts defer to agency expertise in the interpretation of statutes, especially where they govern complex administrative regimes. *See, e.g., United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). Conversely, a court would be skeptical of an abrupt about-face. *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 577–81 (2009). Courts may also look to agency implementation and the actions of regulated parties to determine the meaning of a statute. *See, e.g., S.D. Warren Co. v. Me. Bd. of Env't Prot.*, 547 U.S. 370, 377–78 (2006) (even though relevant agencies had not "formally settled the definition, or even set out agency reasoning," the "administrative usage of [the disputed term] in this way confirm[ed the Court's]

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[3] *See, generally, Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Within section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions."); *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015) (even if "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").

understanding"); *Bd. of the Trs. of Leland Stanford Jr. Univ. v. Roche Molecular Sys.*, 563 U.S. 776, 792–93 (2011) ("[I]t is worth noting that our construction of the [statute in question] is reflected in the common practice among parties operating under the Act."). Here, contract-pharmacy arrangements have been utilized, and honored by manufacturers, since 1996 and earlier.[4]

C. Manufacturers' Rationale for Precluding the Use of Contract Pharmacies Is Not Supported by the Language of the Statute and Leads to Absurd Results

The primary rationale offered for cutting off contract pharmacies—that such arrangements lead to a heightened risk of diversion and duplicate discounts—makes clear that manufacturers are attempting to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities. *See, e.g.*, *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1984) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.") (emphasis supplied). Not surprisingly, the manufacturers have been unable to point to any language in the statute that would support this hobbling interpretation. If a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see* §256b(d)(3)(A). The PPA even provides that a covered entity's failure to comply with the audit requirement does not "relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement." PPA § IV(d). Moreover, the Department specifically rejected this reasoning when issuing regulations regarding the calculation of the 340B ceiling price. In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017). In addition, "[m]anufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." *Id.* Certain manufacturers' newfound and unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute.[5]

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[4] The fact that Congress has not amended the 340B statute to expressly exclude contract-pharmacy arrangements from coverage can be read as supporting the agency's longstanding construction. *See* Valerie C. Brannon, Cong. Rsch. Serv., R45153, *Statutory Interpretation: Theories, Tools, and Trends* 63 (2018) (discussing "presumption of legislative acquiescence").

[5] For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution. To the extent manufacturers now have sincere concerns about diversion or duplicate discounting, the 340B statute speaks directly to how they should proceed. *See also 340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) ("The purpose of the ADR process is to resolve . . . claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts."). Manufacturers who shut off contract-pharmacy access may have also skipped over any effort to resolve disputes with covered entities in "good faith." PPA § IV(a)(1) ("If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A) . . . [t]he Manufacturer shall attempt in good faith to resolve the matter with the covered entity."); 85 Fed. Reg. at 80,633 ("Historically, HHS has

Relatedly, it has also been argued that the use of contract pharmacies is inconsistent with the 340B statute's prohibition on diversion of discount drugs. We start with the basic proposition that subsection (a)(5)(B) was intended to prohibit the diversion of 340B drugs. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). According to one court, the 340B Program places a "ban on 'diversion,' *i.e.*, a requirement that covered entities refrain from reselling or otherwise transferring covered drugs to non–340B entities[.]" *Cty. of Santa Clara v. Astra USA, Inc.*, 257 F.R.D. 207, 211–12 (N.D. Cal. 2009), *vacated on other grounds*, *Astra USA*, 563 U.S. 110; *see also* 85 Fed. Reg. at 80,636 (subsection (a)(5)(B) prohibits diversion).

Diversion means that, on net, covered outpatient drugs end up in the hands of persons who are not patients of the covered entity. The movement of drugs purchased by the covered entity and ultimately dispensed to the patient by a contract pharmacy can involve complex inventory models. Whether diversion occurs, however, should be independent of the inventory-accounting model contemplated by the agreement between the contract pharmacy and the covered entity. *See Toyota Motor Sales, U.S.A., Inc. v. United States*, 35 Ct. Int'l Trade 1205 (2011) (noting that inventory-accounting methods are authorized to determine tariffs and drawbacks); *Sears, Roebuck & Co. v. King County*, 487 P.2d 221, 223, 5 Wash. App. 273, 276 (1971) (for tax purposes "identification by any reasonable and reliable [inventory-accounting] method [is proper], rather than by a strict tracing method.").

The notion that the legitimate transfer of drugs to contract pharmacies so that they can be dispensed to patients of the covered entity constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct, but function as principal-agent. As explained, the covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy. *See also* 61 Fed. Reg. at 43,550 ("The mechanism does not in any way extend this pricing to entities which do not meet program eligibility."); *id.* (agreeing that "[a]s a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance") (citing Restatement (Second) of Agency § 17 (Am. L. Inst. 1995)); *id.* ("The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy."); *id.* at 43,552 (under "bill to/ship to" arrangement contemplated in guidance, "[t]he contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity" and "the manufacturer is still selling to the covered entities"); *cf. Abramski v. United States*, 573 U.S. 169, 186 (2014) ("[t]he individual who sends a straw [purchaser] to a gun store to buy a firearm is transacting with the dealer, in every way but the most formal" such that "straw arrangements are not a part of the secondary market, separate and apart from the dealer's sale") (emphasis in original).[6]

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encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith.").

[6] Similar reasoning still applies under the so-called "replenishment" model, where the contract pharmacy dispenses medications from a general inventory to the covered entity's patient and "replenishes" its general

In addition, the argument that use of contract pharmacies constitutes an illicit "transfer" leads to absurd results. For instance, if a covered entity uses a courier service to send discount drugs to its patient, this, too, would be appear to be an illegal "transfer" to the shipper. Any arrangement that did not involve a physical hand-off from the employee of a covered entity to the patient him or herself could be an unauthorized "transfer" under the 340B statute. To avoid such absurdities, and under the canon of *noscitur a sociis*,[7] the phrase "otherwise transfer" must be interpreted in conjunction with the word "resell" and the title of that specific provision ("Prohibiting resale of drugs") (emphasis supplied).[8]

This conclusion is reinforced by an understanding of the practical realities of drug distribution. Such distribution often functions through intermediaries. For example, covered entities often purchase 340B discounted drugs from wholesalers, not directly from manufacturers. And yet, the obligations of § 256b(a) are placed on manufacturers. If it were correct that distribution to any entity other than a covered entity freed the manufacturer from the obligation to charge no more than the ceiling price, then there would be no firm basis for the wholesalers to charge-back discounts to the manufacturer. Large portions of the current 340B Program would seem to turn on solely manufacturers' voluntary choice to offer the ceiling price,

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inventory with discount medications purchased by the covered entity. The inventory commingling (drugs purchased by covered entity(ies) under the auspices of 340B, commingled with what the contract pharmacy might otherwise have) does not change the analysis. *Cf. Martin Marietta Corp. v. N.J. Nat'l Bank*, 612 F.2d 745, 749 (3d Cir. 1979) ("identification" of goods for purposes of U.C.C. § 2-501 not broken even if "seller removes some of the fungibles and later replaces them . . . because such conduct is quite natural with fungibles and cannot be taken as an intent to negate the buyer's interest in the goods"); *Apex Oil Co. v. Belcher Co. of N.Y., Inc.*, 855 F.2d 997, 1,003–05 (2d Cir. 1988) ("[W]here fungible goods are concerned, identification is not always an irrevocable act and does not foreclose the possibility of substitution."); *Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp.*, 67 B.R. 557, 588 (D.N.J. 1986) (under U.C.C. § 9-207, "a secured party is allowed to commingle fungible collateral, including certain types of securities, and may sell the collateral and replace it with instruments which are equivalent in kind and value without breaching his duty to exercise reasonable care in the custody and preservation of the pledged collateral"). Nor does the ordering of events. If the contract pharmacy's dispensing of the drugs is event "A" and the contract pharmacy's receipt of the drugs is event "B," the ordering of events does not matter if repeated over time. Whether the series looks like ...BABABA... or ...ABABAB... is simply a function of the reference timeframe. In sum, where the contract pharmacy is replenished by the covered entity and dispenses to the covered entity's patients on a rolling basis, it is still true that the covered entity's patients are receiving the covered entity's drugs—they are not re-sold or "otherwise transfer[red]" to the contract pharmacy.

It also bears mention that the replenishment inventory model is currently an integral part of many patient assistance programs operated by drug manufacturers. *See, e.g., Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005); Merck & Co., Inc. *For Health Care Professionals*, MERCK HELPS, https://www.merckhelps.com/HCPs.aspx (last visited Dec. 21, 2020); Pfizer, Inc., *The Pfizer Institutional Patient Assistance Program (IPAP) At-a-Glance* (April 2019), https://www.pfizerrxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways_IPAP_Factsheet%202019.pdf (last visited Dec. 21, 2020).

[7] "[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps—to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Yates v. United States*, 574 U.S. 528, 543 (2015) (plurality op.) (quotes omitted).

[8] An exact delineation of the scope of the phrase "otherwise transfer" is beyond the scope of the Advisory Opinion. The point here is simply that the phrase must have some limiting principle to avoid sweeping in innocuous conduct that is inevitable in the functioning of the 340B Program.

not a statutory mandate. Thus, manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies.

II. Conclusion and Limitations

For these reasons, the Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.[9]

This Advisory Opinion may be supplemented or modified by the Office of the General Counsel. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.[10] It is not a final agency action or a final order, and it does not have the force or effect of law.

Robert Charrow

Robert P. Charrow
General Counsel
December 30, 2020

[9] This Advisory Opinion is limited to interpretation of the 340B statutory requirements in general and does not opine on the legality of any specific contract-pharmacy model, under either the 340B statute or other laws that may apply (such as the anti-kickback statute, 42 U.S.C. § 1320a-7b).

[10] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).

Exhibit B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

Mr. Farruq Jafery
Vice President, Pricing, Contract Operations & Reimbursement
Novo Nordisk, Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Mr. Jafery:

The Health Resources and Services Administration (HRSA) has completed its review of Novo Nordisk Inc. and Novo Nordisk Pharma, Inc.'s (Novo Nordisk) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Novo Nordisk's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. Novo Nordisk is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

Novo Nordisk purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, Novo Nordisk must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Novo Nordisk must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from Novo Nordisk's policy. Novo Nordisk must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on Novo Nordisk's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Novo Nordisk provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

/Diana Espinosa/

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

Exhibit C

For-Profit Pharmacy Participation in the 340B Program

OCTOBER 2020

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INTELLIGENCE THAT WORKS

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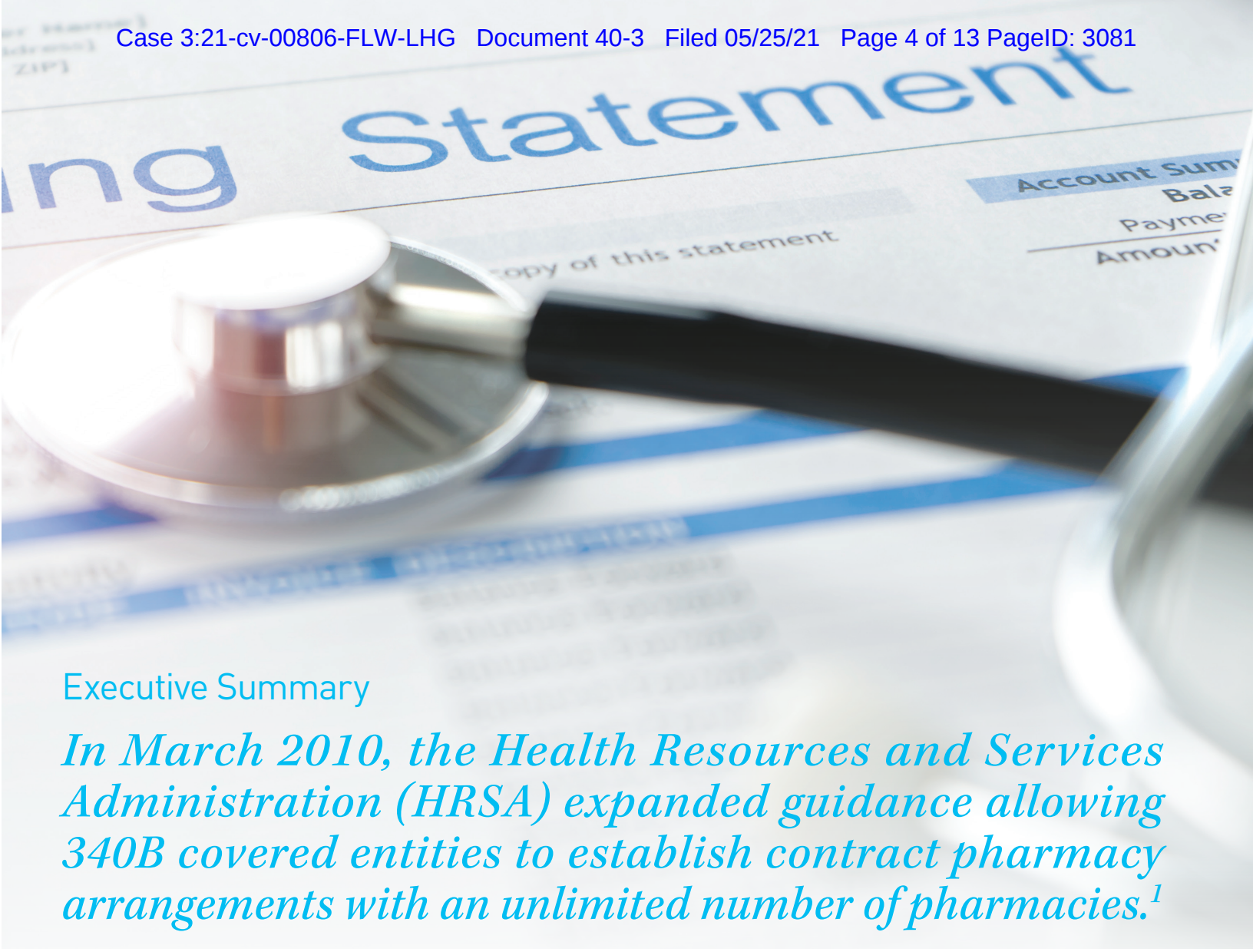

Executive Summary

In March 2010, the Health Resources and Services Administration (HRSA) expanded guidance allowing 340B covered entities to establish contract pharmacy arrangements with an unlimited number of pharmacies.[1]

What started as a well-intentioned effort to provide safety-net providers free or discounted drugs to treat uninsured and vulnerable patients appears to have evolved into a profit-centric corporate initiative that has fundamentally altered the 340B program. Today, half of the twenty largest for-profit corporations in the United States—including Walgreens, Cigna, CVS Health, and Walmart—are active participants in the 340B program through contract pharmacy arrangements.[2] Using vertically integrated supply chains consisting of pharmacies, pharmaceutical benefit managers (PBMs), and health plans, these corporations can leverage their market power to drive growth in the 340B program and capture profits related to 340B sales.

In light of this evolution in the 340B program, BRG professionals conducted this analysis to better understand historical trends in 340B contract pharmacy arrangements, the increased participation of for-profit corporations in the 340B program, average profit margins on 340B purchased medicines dispensed through contract pharmacies, and the potential impact of growth in 340B contract pharmacy participation. Key findings include:

1. Following HRSA's expansion of the contract pharmacy program in March 2010, contract pharmacy participation grew 4,228 percent between April 2010 and April 2020.
2. While over 27,000 distinct pharmacies participate in the 340B program today, we estimate over half of the 340B profits retained by contract pharmacies are concentrated in just three pharmacy chains (Walgreens, Walmart, CVS Health) and Cigna's Accredo specialty pharmacy.
3. The average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies.
4. 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018, which represents over 25 percent of the total gross profits on brand medicines realized by all providers that dispense or administer medicines.

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1 Federal Register, "Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services," Vol. 75, No. 43 (March 5, 2010), available at: https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

2 Based on BRG analysis of the 340B contract pharmacy database.

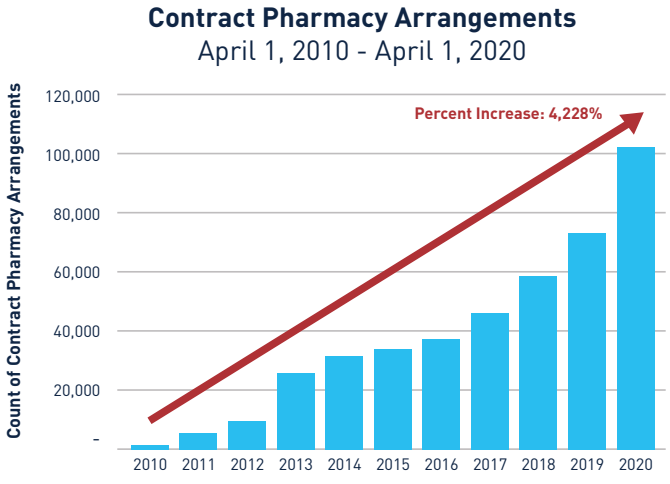
History of 340B Contract Pharmacies

Congress created the 340B program in 1992 to provide recipients of HRSA grants (known as "grantees") and safety-net hospitals access to the voluntary discounts pharmaceutical manufacturers had provided before the enactment of the Medicaid rebate statute. These voluntary discounts had declined due to the Best Price provision in the Medicaid rebate statute for these covered entities. To assist the covered entities, Congress made qualifying hospitals and safety-net clinics eligible for steep discounts on medicines under the 340B program.

340B contract pharmacies were first permitted through guidance issued by HRSA in 1996.[3] At the time, grantees (e.g., community health centers, Ryan White clinics, black lung clinics) that did not have a pharmacy license were unable to dispense 340B purchased medicines to the indigent populations they served on site. Through the 1996 guidance, HRSA enabled any 340B covered entity that did not operate its own pharmacy to contract with a single third-party pharmacy to dispense 340B purchased medicines to eligible patients on its behalf. These are referred to as contract pharmacy arrangements and were predominantly established with independently owned community pharmacies located near the 340B covered entity. In 2000, 98 percent of all contract pharmacy arrangements were with independent pharmacies, and 80 percent of these pharmacies were within ten miles of the 340B covered entity. Of the forty-nine total contract pharmacy arrangements, 98 percent were established by grantees as opposed to safety net hospitals.[4]

In 2001, in response to requests by 340B covered entities to expand the 340B contract pharmacy program, HRSA initiated a demonstration project that allowed a small number of 340B covered entities to contract with multiple third-party pharmacies. This demonstration project enabled 340B covered entities that served patients in a geographically broad area to provide 340B purchased medicines in the communities where their patients lived.[5] The profile of these multiple contract pharmacy networks looked different from the original program in that there was greater participation by national pharmacy chains (54 percent overall) and less than half of the contract pharmacies were within ten miles of the 340B covered entity.[6]

Figure 1



"The average gross margin on 340B purchased medicines dispensed through contract pharmacies is an estimated 72%... For some products, 340B contract pharmacies dispense a medicine that was purchased by the 340B covered entity for a penny, but still receive full reimbursement for the medicine from private insurance and Medicare Part D plans."

In March 2010, HRSA issued additional guidance allowing all 340B covered entities, even those with their own outpatient pharmacies, to contract with an unlimited number of third-party pharmacies. This guidance fundamentally opened the doors for all covered entities to generate additional profits on 340B purchased drugs. Subsequently, for-profit pharmacies rushed to capitalize on the outsized profit margins available on 340B purchased medicines. Between April 1, 2010, and April 1, 2020, the number of contract pharmacy arrangements increased from 2,321 to 100,451—a 4,228 percent increase (see Figure 1).

Today, more than 27,000 individual pharmacies (almost one out of every three pharmacies) participate in the 340B program as contract pharmacies, including virtually all the major national and regional chains, such as Walgreens, Walmart, CVS, Rite-Aid, Kroger, Albertsons, Costco, and many more. Hospitals enrolled in the 340B program contract on average with twenty-two distinct pharmacies, and the largest contract pharmacy networks include over 250 pharmacies, some of which are thousands of miles away from the 340B covered entity (see Case Study 1). Hospitals now account for over 44 percent of all contract pharmacy arrangements, up from 2 percent in 2000.

The enormous growth in 340B contract pharmacy arrangements seems to boil down to a single factor: outsized profit margins. The National Community Pharmacists Association (NCPA) issues an annual report on independent pharmacy financials. Between 2013 and 2018, NCPA reported that the average gross margin on all prescription medicines ranged between 22 percent and 23 percent. As we will discuss in more detail later in this report, the average gross margin on 340B purchased medicines dispensed through contract pharmacies is an estimated 72 percent. For some products, 340B contract pharmacies dispense a medicine that was purchased by the 340B covered entity for a penny but still receive full reimbursement for the medicine from private insurance and Medicare Part D plans. That reimbursement can exceed $1,000 for many specialty medicines. The profit potential inherent in the 340B program appears to have attracted the largest for-profit corporations in the world and altered the hierarchy of 340B program stakeholders.

3 Federal Register, *Vol. 61, No. 165 / Friday, August 23, 1996 / Notices* (August 23, 1996), available at: https://www.govinfo.gov/content/pkg/FR-1996-08-23/pdf/96-21485.pdf
4 Based on BRG analysis of 340B covered entity and contract pharmacy data published by HRSA.
5 Federal Register, "Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services," notice by HRSA (January 12, 2007), accessed at: https://www.federalregister.gov/documents/2007/01/12/E7-334/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services
6 Based on BRG analysis of the 340B covered entity and contract pharmacy data published by HRSA.

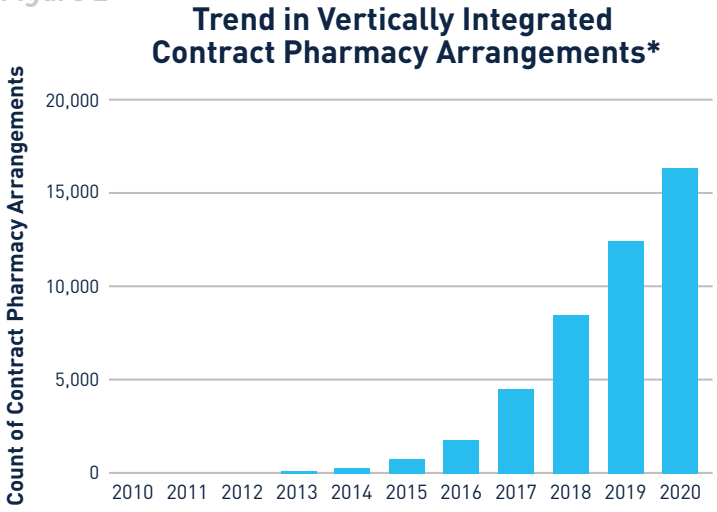
Evolution of For-Profit Pharmacy Participation

The 340B program was originally created for non-profit healthcare providers viewed as the backbone of the "safety net" of the US healthcare system.[7] The first participants in the 340B program included not-for-profit hospitals that served large indigent populations and small healthcare clinics that relied on federal grants, because many of their patients were uninsured and could not afford basic healthcare services. Between 2004 and 2010, the 340B program grew substantially driven primarily by new enrollments of disproportionate share hospitals. By 2010, 16 percent of covered entities had established contract pharmacy arrangements, and over 85 percent of those contract pharmacy arrangements were with independent community pharmacies.

That changed following the March 2010 expansion of the contract pharmacy program and the lack of oversight over how for-profit entities can benefit from the 340B program. The 2010 guidance created an opportunity for sophisticated, for-profit pharmacy chains to realize larger margins than they otherwise could. Between 2010 and 2015, large national and regional pharmacy chains established tens of thousands of contract pharmacy arrangements. By 2015, these chain pharmacies represented over 66 percent of all contract pharmacy arrangements, up from just 15 percent at the beginning of 2010. Instead of maintaining close relationships with covered entities, as had been the practice for independent pharmacies before 2010, large national and regional chains turned to sophisticated software algorithms to identify 340B prescriptions and maximize the revenue generated from these discounted fills.

Starting in 2016, a new pattern of vertically integrated specialty pharmacy enrollments emerged. Specialty pharmacies dispense expensive medications that may require special handling or patient support services. Operations for these pharmacies are typically concentrated in a small number of locations distributed throughout the US, and medicines are shipped directly to patients.

Figure 2



*Excludes certain Walgreens mail order pharmacies that disenrolled en masse in 2015/2016

Over the past two decades, PBMs, the organizations that establish pharmacy reimbursement rates, make formulary decisions, and set cost-sharing amounts, have built large national specialty pharmacies that primarily serve the beneficiaries of the PBM that owns the specialty pharmacy. In January 2016, there were 1,473 contract pharmacy arrangements between 340B covered entities and these vertically integrated specialty pharmacies. By April 2020, this count had grown to 16,293—a 1,006 percent increase in four years (see Figure 2).

The evolution in for-profit pharmacy participation in the 340B program encompasses both the types of pharmacies participating and the structure of the contracts themselves. Based on our primary research, we understand that most contract pharmacy arrangements established prior to 2010 provided for an enhanced dispensing fee paid to the contract pharmacy. This contracting structure reflected the more complex service the contract pharmacy provided (i.e., dispensing a 340B purchased medicine to a 340B patient, managing 340B eligibility, and potentially maintaining separate inventories) and the increased compensation for that service. Any profit associated with the reimbursement of the medicine (less the enhanced dispensing fee) went to the 340B covered entity as the primary stakeholder in the 340B program.

A 2018 Government Accountability Office (GAO) report based on data collected between 2014 and 2016 found that the types of contracting arrangements had evolved to include pharmacies retaining a percentage of 340B profits or overall reimbursement.[8] This shift toward 340B profit sharing by contract pharmacies suggests that for-profit pharmacies are also a primary stakeholder in the 340B program, despite this never having been conceived of nor explicitly included in the program by Congress when it passed the 340B statute. Current guidance makes no recommendations on how profit-sharing agreements between covered entities and contract pharmacies should be structured. As a result, covered entities freely negotiate the terms of agreements with contract pharmacies. Although large, sophisticated academic medical centers may have enough leverage to negotiate favorable terms with an organization wielding the combined market power of a national pharmacy, PBM, and health plan, small grantees carry little leverage when negotiating with these entities.[9]

340B Profit Margins for Retail and Specialty Medicines

Outsized profit margins on 340B purchased medicines dispensed through a retail or specialty pharmacy has attracted for-profit national pharmacies that are vertically integrated with PBMs and health plans. For nearly all contract pharmacy arrangements, the determination of whether a medicine is eligible for a 340B discount is made after the medicine is dispensed to and paid for by the patient and his or her health plan. For brand medicines, this reimbursement amount is roughly equivalent to the list price or wholesale acquisition cost (WAC) of the medicine. To determine the profit margin on a 340B purchased medicine dispensed through a 340B contract pharmacy, we must also estimate the 340B discounted price of the medicine.

7 HRSA, *Sec. 340B Public Health Service Act*, available at: https://www.hrsa.gov/sites/default/files/opa/programrequirements/phsactsection340b.pdf
8 Government Accountability Office, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018).
9 *Cares Community Health v. Department of Health and Human Services*, No. 18-5319, slip. op. at 10 (D.C. Cir. Dec. 20, 2019).

The 340B price is calculated using a statutory formula derived from two pricing metrics incorporated in the Medicaid Drug Rebate Program. At a high level, these pricing metrics for brand medicines are:

Basic Medicaid Rebate: Equal to the greater of 1) 23.1 percent of average manufacturer's price (AMP) or 2) the largest discount available in the commercial market (referred to as "Best Price").

Consumer Price Index (CPI) Penalty: A price inflation penalty that grows as increases in AMP for a medicine exceed the rate of inflation.

Using these two primary components, the 340B price is equal to AMP less the Basic Medicaid rebate less the price inflation penalty (see Figure 3). Depending on the competitive dynamics that exist in any therapeutic category, the 340B price could fall below $0.00. In these instances, the price is reset to $0.01 and is referred to as "penny pricing."

Table 1: 340B Price Calculation Examples

	Pricing Component	Formula	Diabetes Example	Oncology Example
[A]	AMP		**$500.00**	**$1,000.00**
[B]	Medicaid Rebate	Greater of [C] or [D]	250.00	231.00
[C]	Base Rebate	[A] * 23.1%	115.00	231.00
[D]	Best Price	Largest Discount	250.00	100.00
[E]	CPI Penalty	Price Increase Above CPI	225.00	200.00
[F]	340B Discounted Price	[A] - [B] - [E]	**$25.00**	**$569.00**

95 PERCENT DISCOUNT

43 PERCENT DISCOUNT

As discussed further in Appendix A, we developed a methodology for estimating the 340B price using publicly available data and applied this methodology to the eighty-six largest retail and specialty brand medicines that are commonly dispensed through a 340B contract pharmacy based on 2018 sales volume. Our methodology incorporates both concepts discussed above. Where public statements on 340B pricing are available, we have compared our results against actual 340B prices. Based on these comparisons and the structural design of our methodology, we believe that our 340B price estimates, and therefore the 340B profit margins these prices are used to calculate, are conservative.

When comparing our 340B price estimate to the WAC price for the same medicine, our analysis found the average 340B discount from WAC across the eighty-six retail and specialty brand medicines examined was 72 percent in 2018. By comparison, most non-340B pharmacies typically purchase a brand medicine at a 2 percent to 3 percent discount off of WAC.[10] For certain therapeutic categories with steep commercial discounts attributable to competition in the category, the average 340B discount exceeded 80 percent (see Figure 4). Twenty-seven of the medicines in our analysis had an average discount in 2018 of at least 90 percent, and we identified six medicines with a 340B price equal to $0.01.

Table 2: Average 340B Discounts by Therapeutic Class

Average 340B Discounts by Therapeutic Class						
Therapeutic Class*	Avg. Discount	# Medicines in Class	Medicines with a Discount of at Least:			
			72%	80%	90%	95%
Anti-infective agent	44%	11				
Antineoplastic agent	50%	8	1			
Blood modifier agent	58%	4				
Cardiovascular agent	71%	3	1	1		
Central nervous system agent	58%	13	2			
Anti-diabetes agent	90%	23	18	17	10	10
Gastrointestinal agent	90%	7	6	5	2	1
Immunological agent	47%	4				
Respiratory agent	67%	11	5	3		
Top 86 Products	**72%**	**86**	**35**	**27**	**12**	**11**

**Excludes Therapeutic Classes with one product*

10 Based on BRG analysis of National Average Drug Acquisition Cost (NADAC) data.

FAST FACTS: Contract Pharmacy Growth

	Hospitals		Grantees	
General Statistics	**2010**	**2020**	**2010**	**2020**
Total Contract Pharmacy Arrangements	193	43,217	2,128	58,252
% of Total Contract Pharmacy Arrangements	8%	43%	92%	57%
Average Contract Pharmacies per Entity	1	22	1	11
Average Distance b/w Contract Pharmacy & Entity (miles)	34	334	36	198
Penetration Rate				
Count of Entities w/ Contract Pharmacies	116	1,999	1,803	5,195
% of Entities w/ Contract Pharmacies	13%	78%	16%	27%

Because reimbursement by Medicaid, commercial, and Medicare Part D insurance plans is approximately equal to WAC for brand medicines, 340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines. This margin is more than three times greater than the average margin realized by independent pharmacies and contributes to the rapid growth of 340B contract pharmacy arrangements. We estimate that 340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B purchased medicines in 2018, which represents over 25 percent of the total $48 billion in profits realized by all providers that dispensed or administered brand medicines in 2018.[11] These profits are highly concentrated in 340B hospitals and the pharmacies they contract with, which account for almost 90 percent of all 340B purchases.[12]

There is little information on how profits are shared between 340B covered entities and their contract pharmacies. A 2018 GAO report[13] found a variety of contracting designs, but the underlying data was collected between 2014 and 2016, and 340B contract pharmacy arrangements have evolved rapidly since then. Although we don't know what share of the $13 billion in profits generated through 340B contract pharmacies are retained by for-profit pharmacies, we can estimate their relative shares of profits. To do this, we considered the total number of contract pharmacy arrangements by chain, the type of pharmacy (retail versus specialty), and the size of the 340B covered entity contracted with each pharmacy. Our analysis found that more than half of all profits realized by the 27,000 340B contract pharmacies participating in the 340B program today are concentrated in just four companies: Walgreens, CVS, Walmart, and Cigna's Accredo specialty pharmacy.

More than half of all profits realized by 340B contract pharmacies are concentrated in just four companies.

Implications of For-Profit Pharmacy Participation in the 340B Program

As the prevalence of contract pharmacy arrangements has grown and the contracting design between 340B covered entities and contract pharmacies has evolved, the implications of these arrangements are becoming clear. First, profits on 340B purchased medicines are now distributed across a vertically integrated supply chain that includes not just the covered entities but also pharmacies, contract pharmacy administrators, PBMs, health plans, and employer groups. The 340B program was originally intended to provide healthcare services to indigent populations but income from the program is now being captured by some of the largest corporations in the world.

Second, 340B covered entities are often in competition with the very pharmacies with which they contract. This occurs because the vertically integrated healthcare companies implement cost-sharing models that create incentives for 340B patients to fill their prescriptions in the contract pharmacy instead of the 340B covered entity's own pharmacy. Given the choice between a $35 copayment at the preferred contract pharmacy or a $250 coinsurance payment at the 340B covered entity's own hospital outpatient pharmacy, most patients will fill their prescriptions at the contract pharmacy. Based on our work with 340B purchase data, we estimate that almost two-thirds of all retail and specialty drugs purchased at a 340B price are dispensed by contract pharmacies. Separately, the covered entity also enters into contracts with the vertically integrated PBM, which establishes reimbursement rates for the pharmacies owned and operated by the covered entity. When PBMs reduce reimbursement rates to the covered entities' owned pharmacies, the margins at the vertically integrated contract pharmacies may exceed those at the covered entities' owned pharmacies. This creates further incentives for utilization through the vertically integrated contract pharmacy.

11 Aaron Vandervelde and Andrew Brownlee, *Revisiting the Pharmaceutical Supply Chain: 2013-2018*, BRG white paper (January 2020), available at: https://ecommunications.thinkbrg.com/44/1613/uploads/vandervelde-pharmaceutical-supply-chain-2020-final-cleaned.pdf

12 Hatwig, Christopher, *The 340B Prime Vendor Program; Supporting All 340B Stakeholders*, Apexus PPT presentation (2014).

13 Government Accountability Office, "DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement" (June 21, 2018), available at: https://www.gao.gov/products/GAO-18-480

Vertical Integration of National Pharmacies				
Health Plan	**Aetna**	**Cigna HealthSpring**		**United Healthcare**
PBM	**CVS Caremark**	**Express Scripts**		**OptumRX**
Pharmacy *(retail, mail order and/or specialty pharmacy)*	**CVS Caremark**	**Accredo**	**Walgreens**	**OptumSpecialty**
Third Party 340B Services Firm	**Wellpartner**	**Verity Solutions**	**340B Complete** **Shields Health Solutions**	

Third, the outsized profit margins on 340B purchased medicines may contribute to additional consolidation and vertical integration in the healthcare marketplace. Three of the largest pharmacy chains participating in the 340B program (Walgreens, CVS Health, and Accredo), have developed or acquired 340B contract pharmacy administrators (see Figure 5). Contract pharmacy administrators develop and operate the software algorithms that determine 340B eligibility and enable the for-profit pharmacies to influence which prescriptions are classified as 340B. Walgreens recently announced an equity investment in Shields Health Solutions,[14] which operates 340B hospital outpatient pharmacies on an outsourced basis; and Optum recently completed a series of 340B contract pharmacy acquisitions to create Optum Specialty (Optum acquired Diplomat[15] and Avella). As consolidation and vertical integration in the 340B contract pharmacy space continues, 340B covered entities will likely be forced to give up a growing share of 340B program income to these for-profit entities.

Conclusion

The role of contract pharmacies has evolved extensively since HRSA allowed 340B covered entities to contract with an unlimited number of for-profit pharmacies in 2010. What began as a close alignment between 340B covered entities serving indigent populations and independent community pharmacies has morphed into a sophisticated network of vertically integrated for-profit national pharmacies with enormous power. This evolution has fundamentally altered the 340B program and resulted in for-profit entities earning substantial profits through complex profit-sharing agreements with the 340B covered entities. Fueled by margins that are three times greater than the average non-340B medicine, the 340B contract pharmacy channel has grown dramatically over the last ten years and now accounts for over 25 percent of all margins realized by pharmacies and providers in the United States. The growing prevalence of these arrangements is taking the 340B program farther away from its original intended goal of helping safety-net entities provide care to vulnerable patients.

14 Walgreens, "Shields Health Solutions Receives Equity Investments from Welsh, Carson, Anderson & Stowe and Walgreen Co.," press release (July 30, 2019), available at: https://news.walgreens.com/press-releases/general-news/shields-health-solutions-receives-equity-investments-from-welsh-carson-anderson-stowe-and-walgreen-co.htm

15 Tozzi, John, "UnitedHealth Bought Pharmacy Company Avella to Build Optum Unit," *Bloomberg* (October 16, 2018), available at: https://www.bloomberg.com/news/articles/2018-10-16/unitedhealth-bought-pharmacy-company-avella-to-build-optum-unit

Case Study #1

Description: Academic medical center that is part of a Midwestern health system
Covered Entity Type: Disproportionate Share Hospital (DSH)
Total Contract Pharmacy (CP) Arrangements: 250+

Category	Year of First Registration	Date of Most Recent Registration	Percent of Total Active CP Network	Average Distance from Parent Site (mi)
Independent Pharmacies	2011	1/1/2020	22%	80.868
Chain Retail Pharmacies	2012	4/1/2020	64%	55.092
Specialty Pharmacies	2011	4/1/2020	14%	611.212

Case Study #2

Description: Grantee community health center located in the Northeast
Covered Entity Type: Community Health Center (CH)
Total Contract Pharmacy (CP) Arrangements: 9

Category	Year of First Registration	Date of Most Recent Registration	Percent of Total Active CP Network	Average Distance from Parent Site (mi)
Independent Pharmacies	2015	7/1/2019	100%	8.394
Chain Retail Pharmacies	N/A	N/A	0%	N/A
Specialty Pharmacies	N/A	N/A	0%	N/A

These are meant for illustrative examples. Actual contract pharmacy arrangements may vary

Appendix A: Methodology

The analysis in this paper encompasses all 340B covered entities and their respective contract pharmacies registered with Health Resources and Services Administrations (HRSA) since the inception of the program in 1992. Figures related to 340B discounts and contract pharmacy profit margins are estimates, as exact calculations would require data proprietary to the parties involved, such as detailed gross sales figures and rebate data. Therefore, these estimates rely primarily upon publicly available data or data that can be purchased through third-party vendors. In some instances, certain figures in the analysis have been estimated, conservatively, based on the authors' direct and extensive industry experience. These instances are noted below.

To understand the growing prevalence of contract pharmacies in the 340B channel as well as overall program growth, we rely upon information obtained directly from HRSA reports. Current and historical registrations for both covered entities and contract pharmacies can be obtained directly from HRSA's Office of Pharmacy Affairs (340B OPAIS) website. After acquiring data from HRSA, additional analysis and research was required for the following:

- Identification of pharmacy chains/ownership (parent corporate entities).
- Classification of pharmacy channel:
  - Most pharmacies can be classified as retail (brick and mortar) or specialty/mail pharmacies. Specialty/mail pharmacies generally focus on dispensing higher-cost medicines that may require special handling, such as cold storage. These medicines are frequently used in therapeutic areas such as immunology, oncology, or virology.
- Identification of exact geographical location (latitude and longitude) of covered entities and contract pharmacies.
- Association of demographic information based on geographic location.
- Association of Hospital Cost Report data (HCRIS).

To estimate the average 340B discount for contract pharmacy dispensed medicines, we identified a market basket of medicines representative of those medicines dispensed at contract pharmacies. First, we identified the top two hundred medicines by gross sales in the US, then limited our analysis to self-administered brand medicines with enough gross volume to be material to our calculations. Although generic medicines are included in the 340B program, margins associated with these medicines are often too small to support the fees associated with contract pharmacy utilization and were therefore excluded in our analysis. Physician-administered medicines are rarely dispensed through contract pharmacies and were also excluded from the analysis. Though our methodology does not include the full universe of 340B eligible products, our market basket is highly representative of the products that drive 340B contract pharmacy margins.

After identifying our market basket of eighty-six medicines, we estimated the two components of the 340B price for each medicine as outlined above—*2018 CPI Penalty* and *Basic Medicaid Rebate*—and calculated the 340B discount by comparing the estimated 340B price with the WAC for each medicine. Our final estimated 340B discount of 72 percent reflects the average of these discounts weighted by each medicine's gross sales.

2018 CPI Penalty: We relied on Elsevier Gold Standard pricing data to determine the WAC for each medicine at launch and in 2018. We assumed the average manufacturer's price (AMP) to be 98 percent of WAC both at launch and in 2018. Inflation data was collected from the Bureau of Labor and Statistics and used to establish the allowable increase in AMP for each product. The CPI penalty was calculated as the difference between the allowable AMP in 2018 versus the estimated 2018 AMP derived from the Gold Standard pricing data.

Basic Medicaid Rebate: As discussed in this study, this is the greater of the base Medicaid rebate (23.1 percent of AMP) or the Best Price, which represents the discount from AMP of the lowest available commercial price offered by the pharmaceutical manufacturer. The lowest available commercial price is typically the difference between the WAC and the largest rebate offered to commercial health plans. As rebate data is proprietary, we relied upon public disclosures and MACPAC estimates of Medicaid rebate amounts by therapeutic class as a proxy for the Best Price. Because the MACPAC data represents an average rebate amount for a therapeutic category (as opposed to the largest rebate), we believe the proxy rebate amount to be below the Best Price for each medicine, and therefore consider our discount estimate and the resulting profit margin calculations to be conservative.

To estimate contract pharmacies' share of 340B profit margins, we first calculate contract pharmacies' share of all 340B sales. We estimate that in 2018, 25 percent of all sales for medical-benefit medicines (physician-administered) and 6 percent of pharmaceutical-benefit medicines (self-administered) were dispensed in a 340B setting—whether at an outpatient or contract pharmacy. These estimates were informed by our experience working directly with a broad group of manufacturers participating in the 340B program and analysis of Medicare Part B and Part D claims data. Using this information in conjunction with IQVIA estimates[16] of the breakout between self-administered and physician-administered branded medicines and our estimate of the average branded discount in for 340B self-administered medicines in 2018 (72 percent), we approximate that 21 percent of all 340B sales are for self-administered medicines. Our final calculation is outlined in Table 3:

Table 3: Methodology to Estimate 340B Profit Margin

Step	Calculation	Estimated Value
A	Total Indirect Sales at 340B Price	$24.3 B
B	% of 340B Sales for Retail Medicines	21%
C = A x B	Total Retail Sales at 340B Price	$5.2 B
D	Avg. 340B Retail Discount	72%
E = C / (1-D) x 1.1	Gross 340B Retail Sales (Direct & Indirect)	$18.6B
F = E–C	**340B Profit Margin on Retail Sales**	**$13.2**

16 IQVIA, "2018 Medicine Use and Spending in the US" (May 2019), available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1573048662823

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Exhibit D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

FEB 04 2014

TO: Mary K. Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration

/S/

FROM: Stuart Wright
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431

This memorandum report describes selected covered entities' contract pharmacy arrangements and their oversight of those arrangements to prevent (1) diversion of drugs purchased through the 340B Drug Pricing Program to ineligible patients and (2) duplicate discounts through Medicaid.

SUMMARY

Covered entities participating in the 340B Drug Pricing Program (hereinafter referred to as the 340B Program) may contract with pharmacies to dispense drugs purchased through the program (hereinafter referred to as 340B-purchased drugs) on their behalf. Such pharmacies are referred to as contract pharmacies.

According to Health Resources and Services Administration (HRSA) guidance, covered entities that establish contract pharmacy arrangements must oversee these arrangements to prevent diversion of 340B-purchased drugs to ineligible patients and duplicate discounts through Medicaid. Diversion and duplicate discounts are statutorily prohibited. HRSA guidance recommends that covered entities' oversight activities include periodic comparisons of covered entity records and contract pharmacy records, as well as annual independent audits.

We found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways. The covered entities that we reviewed in our study use different methods to identify 340B-eligible prescriptions to prevent diversion in their contract pharmacy arrangements. In some cases, these different methods lead to differing determinations of 340B eligibility across covered entities. That is, two covered entities may categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract

pharmacy arrangements. As a result, there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible.

We also found that contract pharmacy arrangements create complications in preventing duplicate discounts. Most covered entities in our study prevent duplicate discounts by not dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies, though difficulties exist with identifying beneficiaries covered by Medicaid managed care organizations (hereinafter referred to as MCO Medicaid). However, some covered entities that *do* dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts.

Additionally, we found that some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies. Neither the 340B statute nor HRSA guidance addresses whether covered entities must do so; however, if covered entities do not, uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies.

Finally, we found that most covered entities in our study do not conduct all of the oversight activities recommended by HRSA. Although almost all covered entities reported monitoring their contract pharmacy arrangements, the extent of such monitoring varies. Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance.

BACKGROUND

Although the majority of covered entities do not use contract pharmacies, the use of contract pharmacies has increased rapidly over the past few years. Since 2010, the percentage of all covered entities that use contract pharmacies has risen from 10 percent to 22 percent. Moreover, the number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent.[1]

Additionally, recent HRSA audits of covered entities have found instances of diversion and duplicate discounts related to contract pharmacies. Of the 32 covered entities for which finalized HRSA audits resulted in adverse findings, 10 were cited for diversion and/or duplicate discounts through contract pharmacies.[2]

The 340B Drug Pricing Program

[1] Office of Inspector General (OIG) analysis of HRSA's covered entity database, June 2013. These growth figures reflect calculations between March 5, 2010, and May 31, 2013. Covered entities may have multiple health care delivery sites (represented by "parent" and "child" records in the database) as well as multiple contract pharmacies. To account for this complexity and avoid duplicate counting, we have defined a contract pharmacy arrangement as a unique association between a pharmacy and a covered entity "parent" record, and have attributed all contract pharmacies associated with "child" records to their "parent" records. Throughout this report, counts of covered entities represent unique "parent" records.

[2] Results of HRSA's 340B Program audits as of January 8, 2014. Accessed at http://www.hrsa.gov/opa/programintegrity/auditresults/results.html on January 13, 2014.

The Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service Act (PHS Act).[3] The 340B Program requires drug manufacturers participating in Medicaid to provide discounted covered outpatient drugs to certain eligible health care entities, known as covered entities. Congress intended for the savings from 340B-purchased drugs "to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[4] However, the 340B statute speaks only to covered entities' eligibility and compliance; it does not specify how savings from the 340B Program should be used.

Covered entities include community health centers and disproportionate share hospitals (DSHs), among other provider types.[5] As of May 31, 2013, 10,510 covered entities were participating in the 340B Program, including 1,103 community health centers and 1,039 DSHs.[6, 7]

To participate in the 340B Program, covered entities must register with HRSA, the agency responsible for administering the program. HRSA adds covered entities to its database after receiving and approving their registration forms. Covered entities must annually sign an agreement certifying that they meet 340B Program requirements and that their information in the database is correct.[8]

Once approved, covered entities may purchase covered outpatient drugs under the 340B Program at or below the 340B ceiling price.[9] 340B ceiling prices are calculated using a statutorily defined formula. Drug manufacturers that participate in Medicaid must sell covered outpatient drugs to covered entities at or below the 340B ceiling price.[10]

Prohibition of diversion. Covered entities may dispense 340B-purchased drugs only to eligible patients. According to HRSA's patient definition, an individual is an eligible patient "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 a consultation) such that responsibility for the care provided remains with the covered entity; and

[3] Veterans Health Care Act of 1992, P.L. 102-585 § 602; PHS Act § 340B; 42 U.S.C. § 256b.
[4] H.R. Rep. No. 102-384 (Part 2), at 12 (1992)(Conf. Rep.).
[5] 42 U.S.C. § 256b(a)(4) enumerates the complete list of the types of entities eligible to become covered entities.
[6] OIG analysis of HRSA's covered entity database, June 2013.
[7] References to community health centers include all covered entities in HRSA's covered entity database of the entity type Consolidated Health Center Program, which covers some additional providers. See http://opanet.hrsa.gov/OPA/CoveredEntityAcronyms.aspx.
[8] 42 U.S.C. § 256b(d)(2)(B)(i).
[9] 42 U.S.C. § 256b(a)(1).
[10] 42 U.S.C. §§ 1396r-8(a)(1) and 256b(a)(1).

(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. DSHs are exempt from this requirement."[11]

Dispensing 340B-purchased drugs to ineligible patients, a practice known as diversion, is prohibited by law.[12]

Prohibition of duplicate discounts. Subjecting drug manufacturers to duplicate discounts on 340B-purchased drugs is prohibited by law.[13] Duplicate discounts occur when a drug manufacturer pays a State Medicaid agency a rebate under the Medicaid drug rebate program on a drug sold at the already-discounted 340B price.[14] The risk of duplicate discounts applies to MCO Medicaid as well as traditional fee-for-service Medicaid (hereinafter referred to as FFS Medicaid) in States where drug manufacturers are paying rebates on drugs dispensed through MCO Medicaid.[15, 16]

Covered entities choose whether to dispense 340B-purchased drugs to Medicaid beneficiaries. Covered entities indicate their choice in HRSA's covered entity database. State Medicaid agencies use this information to identify Medicaid payments for 340B-purchased drugs and exclude those drugs from rebate requests to drug manufacturers.[17]

340B Contract Pharmacies

Covered entities may contract with one or more pharmacies to dispense 340B-purchased drugs on their behalf.[18] A pharmacy dispensing 340B-purchased drugs on behalf of a covered entity is referred to as a contract pharmacy.[19]

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[11] 61 Fed. Reg. 55156, 55157–55178 (October 24, 1996).
[12] 42 U.S.C. § 256b(a)(5)(B).
[13] 42 U.S.C. § 256b(a)(5)(A)(i).
[14] Under the Medicaid drug rebate program, drug manufacturers are required to pay rebates to State Medicaid agencies, which are calculated using a statutorily defined formula, for most covered outpatient drugs. 42 U.S.C. § 1396r-8.
[15] In general, MCO Medicaid differs from FFS Medicaid in that State Medicaid agencies prospectively pay managed care organizations a fixed monthly amount to provide care to beneficiaries, rather than paying providers directly for care provided to beneficiaries. See 42 U.S.C. § 1396b(m).
[16] Beginning in March 2010, drug manufacturers that participate in the Medicaid drug rebate program were required to pay rebates for covered outpatient drugs dispensed to individuals enrolled in MCO Medicaid if the managed care organization is responsible for coverage of such drugs. 42 U.S.C. § 1396r-8(b)(1)(A). Covered outpatient drugs dispensed through MCO Medicaid and subject to discounts under the 340B Program are not subject to rebates under the Medicaid drug rebate program. 42 U.S.C. § 1396r-8(j)(1). However, a previous OIG report found that not all States are collecting rebates on drugs dispensed through MCO Medicaid. OIG, *States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations*, OEI-03-11-00480, September 2012.
[17] OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.
[18] 75 Fed. Reg. 10272, 10277 (March 5, 2010).
[19] Covered entities may dispense 340B-purchased drugs through in-house pharmacies instead of or in addition to contract pharmacies.

Contract pharmacy inventory models. Contract pharmacy arrangements generally use one of two distinct inventory models: the pre-purchased inventory model or the replenishment inventory model.[20]

In the pre-purchased inventory model, the covered entity's 340B-purchased drugs are kept in stock at the contract pharmacy. When filling prescriptions on behalf of the covered entity, the contract pharmacy uses the covered entity's 340B-purchased drugs. When filling other prescriptions, the contract pharmacy uses its own non-340B-purchased drugs.

In the replenishment inventory model, no 340B-purchased drugs are kept in stock at the contract pharmacy. When filling prescriptions on behalf of the covered entity, the contract pharmacy uses its own non-340B-purchased drugs. When a sufficient quantity of a given drug has been dispensed on behalf of the covered entity, the covered entity purchases that quantity of the drug at the discounted 340B price and has it delivered to the contract pharmacy. This order of 340B-purchased drugs thus replaces or "replenishes" the non-340B-purchased drugs originally dispensed on behalf of the covered entity.

Contract pharmacy arrangements using the replenishment inventory model generally use computerized tracking systems because the prescribed quantity of a drug rarely matches the quantity by which the drug is ordered. For example, a drug may be prescribed in quantities of 30 pills but ordered in quantities of 100 pills. Thus, a replenishment order of 340B-purchased drugs can be placed only after the contract pharmacy has filled four prescriptions for the drug (i.e., dispensed a total of 120 pills) on behalf of the covered entity. This order replaces 100 of the 120 pills dispensed on behalf of the covered entity, leaving 20 pills awaiting replenishment. Covered entities often hire companies known as 340B administrators (hereinafter referred to as administrators) to manage these tracking systems.

Contract pharmacy billing process for insured patients. When contract pharmacies dispense 340B-purchased drugs to patients with health insurance, they bill health insurers for the 340B-purchased drugs dispensed. Pharmacies send insurance claims for dispensed drugs to electronic transaction routing companies, which forward the claims to the correct insurers. The routing companies use a combination of two codes from the insurance claims—the Bank Identification Number and Processor Control Number (hereinafter referred to as BIN/PCN)—to identify a patient's health insurer and benefits.[21]

[20] OIG analysis of interviews with covered entities and administrators, 2013.
[21] National Council for Prescription Drug Programs. *Explanation of BIN/PCN*. Accessed at http://www.ncpdp.org/pdf/ExplanationofBIN.PCN.pdf on October 25, 2013.

Covered Entity Oversight of Contract Pharmacy Arrangements

Covered entities must ensure that their contract pharmacy arrangements comply with the 340B statute and relevant HRSA guidance.[22, 23] In guidance, HRSA generally directs covered entities to:[24]

(1) ensure that contract pharmacy arrangements prevent diversion of 340B-purchased drugs to ineligible patients;
(2) ensure that contract pharmacy arrangements do not result in duplicate discounts; and
(3) conduct oversight of contract pharmacies to detect and remedy any instances of diversion, duplicate discounts, or other program violations.

HRSA has announced plans to issue formal regulations that will address program elements, including its patient definition and contract pharmacy arrangements.[25]

Preventing diversion in contract pharmacy arrangements. To prevent diversion, covered entities identify which prescriptions filled at their contract pharmacies will be categorized as 340B-eligible (hereinafter referred to as 340B-eligible prescriptions). Covered entities and their contract pharmacies may dispense 340B-purchased drugs only to individuals who meet all applicable components of HRSA's patient definition. Such individuals can, however, fill any of their prescriptions at a covered entity's contract pharmacy—not just those that originate from the covered entity. As a result, if a covered entity does not consider *all* prescriptions for an individual to be 340B-eligible, then in practice the covered entity will have to determine 340B eligibility at the prescription level. Administrators often assist covered entities in identifying 340B-eligible prescriptions.

Preventing duplicate discounts in contract pharmacy arrangements. To avoid duplicate discounts in contract pharmacy arrangements, HRSA presents covered entities with two options:

(1) not dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies; or
(2) dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies, and making an arrangement with the State Medicaid agency to prevent duplicate discounts. HRSA guidance notes that covered entities should inform HRSA of any such arrangement.[26]

[22] 75 Fed. Reg. 10272, 10274–10278 (March 5, 2010).
[23] Since the inception of the 340B Program, HRSA has generally used interpretive guidance and statements of policy, rather than formal rulemaking, to administer it. See 75 Fed. Reg. 10272, 10273 (March 5, 2010). However, HRSA recently issued a final rule addressing limited program elements. See 78 Fed. Reg. 44016, 44027–44028 (July 23, 2013).
[24] 75 Fed. Reg. 10272, 10277–10278 (March 5, 2010).
[25] HRSA. *340B Drug Pricing Program: Important Benefit, Significant Responsibility*. Accessed at http://www.hrsa.gov/opa/update.html on January 22, 2014.
[26] 75 Fed. Reg. 10272, 10278 (March 5, 2010).

Although covered entities indicate in HRSA's covered entity database whether they dispense 340B-purchased drugs to Medicaid beneficiaries, that indication does not necessarily apply to their contract pharmacy arrangements.

HRSA's recommended oversight activities. HRSA guidance recommends that covered entities conduct oversight activities for their contract pharmacy arrangements, including the following:[27]

(1) monitoring their contract pharmacy arrangements by periodically comparing the covered entity's prescribing records with the contract pharmacies' dispensing records to detect irregularities (e.g., potential diversion or duplicate discounts); and
(2) retaining independent auditors to perform annual audits.

Although HRSA guidance states that covered entities are expected to conduct oversight activities, it also states that "[t]he precise methodology utilized to ensure compliance and obtain the necessary information is up to the covered entity given its particular circumstances."[28] Covered entities must notify HRSA if they find that diversion or duplicate discounts have occurred in their contract pharmacy arrangements.[29]

Related Office of Inspector General Work

In June 2011, OIG published a review of States' reimbursement policies and oversight related to 340B-purchased drugs. OIG found that States lacked pricing information needed for oversight and that nearly half of States did not have written 340B policies.[30]

In September 2012, OIG published a review of States' collection of rebates for covered outpatient drugs dispensed through MCO Medicaid. OIG found that most States that pay for covered outpatient drugs through MCO Medicaid had obtained the utilization data needed to collect rebates, but that some had not yet collected rebates. OIG also found that most States had processes in place to verify that MCO Medicaid payments for 340B-purchased drugs were excluded from rebate requests to drug manufacturers.[31] The review did not specifically address issues related to contract pharmacy arrangements.

METHODOLOGY

Scope

We interviewed 30 covered entities—15 community health centers and 15 DSHs—to learn about how they operate and oversee their contract pharmacy arrangements. We did

[27] Ibid.
[28] Ibid.
[29] Ibid.
[30] OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.
[31] OIG, *States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations*, OEI-03-11-00480, September 2012.

not include other types of covered entities (hemophilia treatment centers, family planning clinics, etc.) in this study.

Data Collection and Analysis
To describe how covered entities operate and oversee their contract pharmacy arrangements, we interviewed 30 covered entities and 8 administrators.

We selected a purposive sample of 15 community health centers and 15 DSHs from HRSA's covered entity database. We selected our sample to represent a diverse group of covered entities, on the basis of the following considerations:

- number of covered entity sites (i.e., unique "parent" and "child" records);
- dispensing of 340B-purchased drugs to Medicaid beneficiaries;
- number of contract pharmacy arrangements; and
- location (i.e., rural versus urban, State).

The 30 covered entities in our final sample represent contract pharmacy arrangements with 199 unique contract pharmacies. See Appendix A for a detailed description of the selection process for our sample of covered entities.

We conducted structured interviews with staff from the selected covered entities regarding their contract pharmacy arrangements. Our interviews focused on the covered entities' methods to prevent diversion and duplicate discounts, as well as their oversight activities.

We also interviewed eight administrators to learn about how they assist covered entities in preventing diversion and duplicate discounts in contract pharmacy arrangements. We selected these administrators based on availability and prevalence in the industry. These administrators worked with 20 of the 30 covered entities in our final sample. The remaining 10 covered entities either worked with an administrator that we were unable to interview or did not work with an administrator.

Limitations
The results of this memorandum report are limited to the 30 covered entities selected in our purposive sample, and are not representative of or generalizable to other covered entities. We did not verify the accuracy of covered entities' or administrators' interview responses for this memorandum report, nor did we review the records of covered entities or contract pharmacies to identify instances of diversion or duplicate discounts.

Standards
This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

To prevent diversion in their contract pharmacy arrangements, covered entities in our study use different methods to identify 340B-eligible prescriptions; in some cases, this leads to differing determinations of 340B eligibility across covered entities

Covered entities in our sample reported different methods of identifying 340B-eligible prescriptions to prevent diversion in their contract pharmacy arrangements. To prevent diversion, covered entities must accurately identify 340B-eligible prescriptions filled at their contract pharmacies. Some covered entities reported that they identify 340B-eligible prescriptions when the prescriptions are written, whereas others reported that their administrators do so after the prescriptions are written.

Nine covered entities reported that they identify 340B-eligible prescriptions when the prescriptions are written. These covered entities reported that they determine whether a given prescription is 340B-eligible and indicate that determination on the prescription for the contract pharmacy. Covered entities reported using a variety of tools to distinguish 340B-eligible prescriptions for their contract pharmacies, including printed barcodes for paper prescriptions and designated values in notes fields for electronic prescriptions.

The remaining 21 covered entities reported that in at least one of their respective contract pharmacy arrangements, their administrators identify 340B-eligible prescriptions after the prescriptions are written. In such arrangements, these covered entities provide data to an administrator, which identifies 340B-eligible prescriptions by comparing the data to prescriptions filled at contract pharmacies. Covered entities reported that this method prevents diversion.

Covered entities whose administrators identify 340B-eligible prescriptions after the prescriptions are written provide their administrators with a variety of data types. For covered entities in our sample, these data types most commonly include patient lists (e.g., names, dates of birth) and/or prescriber lists (e.g., National Provider Identifiers (NPI), Drug Enforcement Administration numbers). Some covered entities reported providing clinical information (e.g., diagnosis codes, procedure codes), lists of eligible sites, and/or detailed patient encounter data. Some administrators reported that covered entities may also provide them with electronic prescribing data. Additionally, covered entities reported that they sometimes filter data before providing it to their respective administrators (e.g., by limiting the prescriber list to only those who work exclusively at the covered entity).

Administrators interviewed for this study use a variety of data-comparison methods to identify 340B-eligible prescriptions after the prescriptions are written. Some administrators reported that they customize their comparison methods to accommodate covered entities' preferences and/or data availability. For example, some covered entities and administrators reported using time limits that govern how long a patient's prescription is identified as 340B-eligible following the patient's most recent visit to the covered entity. Additionally, one covered entity and one administrator reported that 340B eligibility is not always determined solely on the basis of automatic data

comparison; in some cases, prescriptions may be "queued" for the covered entity to manually review and identify those it deems 340B-eligible.

The variety of data types and comparison methods used to identify 340B-eligible prescriptions can result in differing determinations of 340B eligibility across covered entities. In some cases, covered entities using different data types and/or comparison methods categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract pharmacy arrangements. Although our sample cannot account for all possible combinations of data types and comparison methods, covered entities and administrators did note several instances in which they would categorize similar types of prescriptions differently. The four scenarios below illustrate the different determinations of 340B eligibility that covered entities told us they would make for specific types of prescriptions.

Scenario 1: Nonexclusive physician

A physician practices part time at a covered entity, but also has a private practice. The physician first sees an individual at the covered entity. On a separate occasion, the physician sees the same individual at his private practice and writes a prescription for the individual. The individual fills the prescription at the covered entity's contract pharmacy.

One covered entity in our sample noted that it would automatically categorize the prescription in Scenario 1 as 340B-eligible. This covered entity uses a list of all prescribers to identify 340B-eligible prescriptions. Because the physician in Scenario 1 would be on the prescriber list, the prescription would be categorized as 340B-eligible, even though it was written at the physician's private practice (i.e., originated outside of the covered entity).

Another covered entity in our sample noted that it would not categorize the prescription in Scenario 1 as 340B-eligible. This covered entity also uses a prescriber list to identify 340B-eligible prescriptions, but the covered entity limits the prescriber list to only those prescribers who work exclusively at the covered entity. Because the physician in Scenario 1 would not be on the prescriber list (as he does not work exclusively at the covered entity), the prescription would not be categorized as 340B-eligible.

A third covered entity in our sample noted that it may or may not categorize the prescription in Scenario 1 as 340B-eligible, on the basis of a manual review. This covered entity provides its administrator with a list of all prescribers who work at the covered entity, but flags those prescribers who do not work exclusively at the covered entity. Its administrator automatically categorizes prescriptions from exclusive prescribers as 340B-eligible, but queues prescriptions from nonexclusive prescribers for covered entity staff to review and categorize as 340B-eligible or not 340B-eligible.

Scenario 2: Time limit after patient's visit

A physician sees an individual at a covered entity and writes a prescription for the individual. Four months after filling the original prescription, the individual refills the prescription at the covered entity's contract pharmacy. The individual is not seen at the covered entity during those 4 months.

One covered entity in our sample noted that it would not categorize the refilled prescription in Scenario 2 as 340B-eligible. This covered entity categorizes prescriptions filled at its contract pharmacies as 340B-eligible only if they are filled within 60 days of the patient's most recent visit to the covered entity.

Several other covered entities in our sample noted that they would categorize the refilled prescription in Scenario 2 as 340B-eligible. Some of these covered entities have longer time limits regarding patient visits (e.g., 12 months) that would include the prescription in Scenario 2. Alternatively, one of these covered entities has no limit as to how long after the patient's visit a prescription can be filled and still be categorized as 340B-eligible.

Scenario 3: Prescription from a referred physician

A physician sees an individual at a covered entity and refers the individual to a specialist who is not affiliated with the covered entity. The specialist writes a prescription for the individual, and the individual fills the prescription at the covered entity's contract pharmacy.

Two covered entities in our sample noted that they would not categorize the prescription in Scenario 3 as 340B-eligible. These covered entities use prescriber lists to identify 340B-eligible prescriptions. Because the specialist in Scenario 3 would not be on the prescriber list (as he does not work at the covered entity), the prescription would not be categorized as 340B-eligible.

One covered entity in our sample noted that it would categorize the prescription in Scenario 3 as 340B-eligible. This covered entity also uses a prescriber list to identify 340B-eligible prescriptions. However, the covered entity's administrator queues prescriptions written by prescribers who are not on the prescriber list for the covered entity to manually review and identify those it deems 340B-eligible. The covered entity noted that during this manual review, it categorizes prescriptions as 340B-eligible if its records indicate that the patient was referred to the prescriber. Because the covered entity's physician in Scenario 3 referred the individual to the specialist, the prescription would be categorized as 340B-eligible, even though it originated outside of the covered entity.

Scenario 4: Matching prescription to clinical information

A physician sees an individual at a covered entity for chest pain and writes the individual a prescription for a blood pressure medication (related to the chest pain). During that visit, the physician also writes the individual a prescription for a sleep medication (related to a previously diagnosed condition).

One covered entity in our sample noted that only the prescription for blood pressure medication in Scenario 4 would be categorized as 340B-eligible. This covered entity's administrator uses clinical information from patients' visits (i.e., diagnosis and procedure codes) to identify 340B-eligible prescriptions. Specifically, the administrator identifies a prescription as 340B-eligible only when it relates to one of the diagnosis or procedure codes from the patient's most recent visit. Because the prescription for blood pressure medication in Scenario 4 relates to the individual's diagnosis from his most recent visit (i.e., chest pain), it would be categorized as 340B-eligible. Because the prescription for sleep medication does not relate to that diagnosis, however, it would not be categorized as 340B-eligible.

Many covered entities in our sample do not use clinical information from patients' visits to identify 340B-eligible prescriptions, and thus would likely categorize both prescriptions in Scenario 4 as 340B-eligible. Because both prescriptions are written at the covered entity by a prescriber who works for the covered entity, there would be no basis on which to categorize the prescriptions differently without comparing them to clinical information from the patient's visit.

Twenty-two of thirty covered entities reported that to prevent duplicate discounts, their contract pharmacies do not dispense 340B-purchased drugs to Medicaid beneficiaries

Twenty-two of thirty covered entities reported preventing duplicate discounts by not dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies.[32] Twenty of these covered entities reported that their contract pharmacies do not dispense 340B-purchased drugs to either FFS Medicaid beneficiaries or MCO Medicaid beneficiaries. The remaining two reported that their contract pharmacies do not dispense 340B-purchased drugs to FFS Medicaid beneficiaries, but that they did not know whether their contract pharmacies do so for MCO Medicaid beneficiaries.

To avoid dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies, covered entities or their administrators identify prescriptions for Medicaid beneficiaries and do not categorize them as 340B-eligible. Covered entities

[32] These covered entities may still dispense 340B-purchased drugs to Medicaid beneficiaries at their in-house outpatient pharmacies and/or have physicians administer 340B-purchased drugs to Medicaid beneficiaries at their eligible sites.

and administrators reported that they identify these prescriptions by comparing the insurer's BIN/PCN to the list of Medicaid BINs/PCNs for the State. While Medicaid beneficiaries may still use contract pharmacies to fill prescriptions originating from the covered entity, those prescriptions will be filled using the contract pharmacies' own non-340B-purchased drugs.

Administrators reported difficulties in identifying prescriptions for MCO Medicaid beneficiaries. Administrators reported that it can be difficult to identify prescriptions for MCO Medicaid beneficiaries in contract pharmacy arrangements. Specifically, they reported that accurately identifying such prescriptions is difficult for two reasons: insufficient information from State Medicaid agencies and BINs/PCNs that are not exclusive to Medicaid.

First, administrators reported that BINs/PCNs for MCO Medicaid plans are not readily available. Administrators reported that as a result, they must research which BINs/PCNs represent MCO Medicaid plans, which is inefficient and may still result in incomplete information. Without a complete list of MCO Medicaid BINs/PCNs, covered entities and their administrators cannot be sure they are accurately identifying all Medicaid prescriptions to avoid duplicate discounts.

Second, administrators reported that many insurers that operate both MCO Medicaid plans and private insurance plans use the same BIN/PCN for both types of plans. One administrator reported that in an attempt to avoid the risk of duplicate discounts, it categorizes all prescriptions with BINs/PCNs used for MCO Medicaid plans as not 340B-eligible, even though some of those prescriptions may be for privately insured patients and thus do not pose a risk of duplicate discounts. As a result, covered entities may forgo potential savings from prescriptions for privately insured patients that could be categorized as 340B-eligible without risking duplicate discounts.

Although 8 of 30 covered entities reported that their contract pharmacies dispense 340B-purchased drugs to Medicaid beneficiaries, 6 did not report a method to prevent duplicate discounts. Eight of thirty covered entities reported that their contract pharmacies dispense 340B-purchased drugs to FFS Medicaid and/or MCO Medicaid beneficiaries. Only five of these covered entities reported notifying their State Medicaid agency that they do so, and none reported notifying HRSA.

Six of the eight covered entities did not report a method to avoid duplicate discounts. According to HRSA guidance, covered entities should not dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies unless they have made an arrangement with their State Medicaid agency to prevent duplicate discounts. Two of the six covered entities dispense 340B-purchased drugs to both FFS and MCO Medicaid patients through contract pharmacies, whereas four dispense 340B-purchased drugs to MCO Medicaid beneficiaries but not to FFS Medicaid beneficiaries.

Two of the eight covered entities reported methods for avoiding duplicate discounts. For example, one covered entity instructs its contract pharmacies to include the covered

entity's NPI on Medicaid claims for 340B-purchased drugs, per the State Medicaid agency's policy. The State Medicaid agency is thus able to identify those claims and exclude the 340B-purchased drugs from its rebate requests to drug manufacturers.[33]

Eight covered entities do not offer the discounted 340B price to uninsured patients in any of their contract pharmacy arrangements

Eight of thirty covered entities reported that they do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements. Neither the 340B statute nor HRSA guidance addresses whether covered entities must do so, but if covered entities do not, their uninsured patients pay the full non-340B price for prescriptions filled at contract pharmacies. Seven of these eight covered entities use administrators that determine 340B eligibility after drugs are *dispensed*, which means that their contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible. As a result, the contract pharmacies do not know to charge the discounted 340B price. Administrators may later identify uninsured patients' prescriptions as 340B-eligible, but those patients will have already paid the full non-340B price. All but one administrator reported being able to allow covered entities to offer the discounted 340B price to uninsured patients at contract pharmacies; however, some covered entities choose not to do so. Seven of the eight covered entities are DSHs.

Eighteen of thirty covered entities reported offering the discounted 340B price to uninsured patients in at least one of their contract pharmacy arrangements.[34] In a commonly reported process, covered entities work with their administrators to provide uninsured patients with a 340B discount card, which the patients present at contract pharmacies so the pharmacies know to charge the discounted 340B price. Alternately, if the covered entity identifies 340B-eligible prescriptions when the prescriptions are written, the contract pharmacy knows for all patients which prescriptions are 340B-eligible, and can therefore charge the discounted 340B price to uninsured patients. Of the 18 covered entities, 13 are community health centers.

For the remaining four covered entities in our sample, it is unclear whether their contract pharmacies offer the discounted 340B price to uninsured patients.

Almost all covered entities in our study monitor their contract pharmacy arrangements, but few have retained independent auditors as recommended in HRSA guidance

Twenty-five of thirty covered entities reported that they monitor their contract pharmacy arrangements internally to detect potential diversion or duplicate discounts. Covered entities reported monitoring their contract pharmacy arrangements in a variety of ways, including:

[33] The State Medicaid agency uses the NPI on contract pharmacies' Medicaid claims to locate the covered entity's record in HRSA's covered entity database. Because the covered entity has indicated in HRSA's covered entity database that it dispenses 340B-purchased drugs to Medicaid beneficiaries, the State Medicaid agency excludes the drugs for those claims from its rebate requests to drug manufacturers.

[34] Some of these covered entities charge uninsured patients a fee based on a sliding scale in at least one of their contract pharmacy arrangements; this sliding-scale fee may be lower than the 340B price.

- comparing drug dispensing records from their contract pharmacies to their internal records of prescriptions, patients, prescribers, and/or clinical information; and
- reviewing reports provided by administrators to look for Medicaid beneficiaries whose prescriptions were incorrectly identified as 340B-eligible.

Monitoring may be conducted on a regular schedule, or may be performed on an ad hoc basis. Of the 25 covered entities that reported monitoring their contract pharmacy arrangements internally, 17 reported doing so on a regular schedule and 8 reported doing so on an ad hoc basis.

Only 7 of 30 covered entities reported that they have retained independent auditors for their contract pharmacy arrangements, as recommended in HRSA guidance. Six of these covered entities retain auditors in addition to doing their own monitoring as described above, while one of these covered entities relies only on its auditor for oversight. HRSA guidance states that while specific compliance methods are left up to the covered entity, annual independent audits are expected.

Four covered entities reported that they neither monitor their contract pharmacy arrangements nor retain independent auditors.

Some covered entities have detected problems through their oversight activities. Ten covered entities reported that they have discovered instances that could be considered diversion or that could have resulted in duplicate discounts in their contract pharmacy arrangements.

These 10 covered entities reported that they did not notify HRSA of the instances because their administrators or contract pharmacies had corrected the problems. Eight of the ten covered entities reported that their administrators corrected the problems by changing the status of filled prescriptions from 340B-eligible to not 340B-eligible. The other two covered entities reported that their contract pharmacies were able to correct the problems. Specifically, one of the two covered entities reported that its contract pharmacy purchased non-340B drugs to replace the 340B-purchased drugs that were incorrectly dispensed. The other covered entity reported that it did not know how its contract pharmacy corrected the problem.

CONCLUSION

Contract pharmacy arrangements create complications in preventing diversion in the 340B Program, and the covered entities in our study reported addressing those complications in different ways. Covered entities in our study reported different methods of identifying 340B-eligible prescriptions, and in some cases their determinations of 340B eligibility differ from one covered entity to another for similar types of prescriptions. This suggests a lack of clarity on how HRSA's patient definition should be applied in contract pharmacy arrangements. Covered entities appear to have differing interpretations of what HRSA guidance requires; some may also have chosen to apply more stringent criteria in the absence of a clear directive. Regardless, there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible.

Contract pharmacy arrangements also create complications in preventing duplicate discounts. Most covered entities in our study reported that, to prevent duplicate discounts, they do not dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies. However, administrators reported difficulties in identifying beneficiaries covered by MCO Medicaid, and some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts.

Furthermore, some covered entities in our study have implemented additional processes to offer the discounted 340B price to uninsured patients at contract pharmacies, but others have not. Neither the 340B statute nor HRSA guidance addresses whether covered entities must offer the discounted 340B price to uninsured patients; however, if covered entities do not, uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies.

Moreover, most covered entities in our study do not conduct all of the oversight activities recommended by HRSA. Although almost all covered entities reported monitoring their contract pharmacy arrangements, the extent of such monitoring varies. Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance. Without adequate oversight, the complications created by contract pharmacy arrangements may introduce vulnerabilities to the 340B Program.

This memorandum report is being issued directly in final form because it contains no recommendations. We are continuing to review contract pharmacy arrangements in the 340B Program and may include recommendations in an upcoming report if appropriate. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-05-13-00431 in all correspondence.

APPENDIX A

Detailed Description of Process for Selecting Sample of Covered Entities

We selected a purposive sample of 30 covered entities—15 community health centers and 15 DSHs—from HRSA's covered entity database. We chose to focus on a limited sample so we could conduct in-depth interviews that captured the many details and complexities of covered entities' contract pharmacy arrangements.

We selected only covered entities with at least one contract pharmacy arrangement that had been active for a year or more (i.e., since July 1, 2012, or before). We did so because, according to initial conversations with stakeholders, it can take upwards of 6 months for contract pharmacy arrangements to become fully operational after being established. HRSA's covered entity database listed a total of 1,658 covered entities with at least 1 contract pharmacy arrangement that had been active for a year or more. The 30 covered entities in our final sample represent contract pharmacy arrangements with 199 unique contract pharmacies.

To ensure a final sample of sufficient size, we selected an initial sample of 40 covered entities. Our final sample included the first 30 covered entities that met our criteria and with which we were able to schedule interviews.

We selected our sample to represent a diverse group of covered entities, on the basis of the following considerations:

- Number of covered entity sites (i.e., unique "parent" and "child" records)

  We classified covered entities by 3 categories: those with only 1 site, those with 2–9 sites, and those with 10 or more sites. We selected at least one covered entity from each category.

- Dispensing of 340B-purchased drugs to Medicaid beneficiaries

  We classified covered entities by 3 categories: those for which all sites dispense 340B-purchased drugs to Medicaid beneficiaries, those for which some sites do so, and those for which no sites do so. We used the covered entity's indication in HRSA's covered entity database to make this classification. We selected only covered entities from the "all" or "some" categories, to increase the likelihood of including at least some covered entities that dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies.

- Number of contract pharmacy arrangements (only those active for a year or more)

  We classified covered entities by 3 categories: those with only 1 contract

pharmacy arrangement, those with 2–9 contract pharmacy arrangements, and those with 10 or more contract pharmacy arrangements. We selected at least one covered entity from each category.

- Location

  We classified covered entities by three categories: rural; both rural and nonrural (i.e., some sites were marked rural and some sites were marked nonrural); and nonrural or no indication. We used the rural indicator in HRSA's covered entity database to make this classification.[35] We selected at least one covered entity from each category. We also attempted to select covered entities from a variety of different States.

Table 1 shows the breakdown of the 1,658 covered entities with at least 1 contract pharmacy arrangement active for a year or more, as well as the 30 covered entities in our final sample, by the categories described above.

Table 1: All Covered Entities and Final Sample, By Category

Category	Number of All Covered Entities	Number of Covered Entities in Final Sample
Number of Covered Entity Sites		
1	816	6
2–9	661	16
10+	181	8
Dispensing of 340B-Purchased Drugs to Medicaid Beneficiaries		
All sites	530	23
Some sites	133	7
No sites	995	0
Number of Contract Pharmacy Arrangements		
1	851	8
2–9	629	17
10+	178	5
Location		
Rural (DSH only)	73	5
Both Rural and Nonrural (DSH only)	4	2
Nonrural or No Indication	1,581	23
Total	**1,658**	**30**

Source: OIG analysis of HRSA's covered entity database, 2013.

[35] The rural indicator in HRSA's covered entity database applies only to DSHs. As such, only DSHs are represented in the "rural" and "both rural and nonrural" classifications.

Exhibit E

United States Government Accountability Office

GAO

Report to Congressional Committees

September 2011

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

GAO-11-836

September 2011

GAO
Accountability * Integrity * Reliability

Highlights

Highlights of GAO-11-836, a report to congressional committees

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

Why GAO Did This Study

The Health Resources and Services Administration (HRSA), within in the Department of Health and Human Services (HHS), oversees the 340B Drug Pricing Program, through which participating drug manufacturers give certain entities within the health care safety net—known as covered entities—access to discounted prices on outpatient drugs. Covered entities include specified federal grantees and hospitals. The number of covered entity sites has nearly doubled in the past 10 years to over 16,500.

The Patient Protection and Affordable Care Act (PPACA) mandated that GAO address questions related to the 340B program. GAO examined: (1) the extent to which covered entities generate 340B revenue, factors that affect revenue generation, and how they use the program; (2) how manufacturers' distribution of drugs at 340B prices affects covered entities' or non-340B providers' access to drugs; and (3) HRSA's oversight of the 340B program. GAO reviewed key laws and guidance, analyzed relevant data, and conducted interviews with 61 340B program stakeholders selected to represent a range of perspectives, including HRSA, 29 covered entities, 10 manufacturers and representatives, and 21 others. Selection of stakeholders was judgmental and thus, responses are not generalizable.

What GAO Recommends

To ensure appropriate use of the 340B program, GAO recommends that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements. HHS agreed with our recommendations.

View GAO-11-836. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

Thirteen of the 29 covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs, which includes the costs of purchasing and dispensing drugs. Of those remaining, 10 did not generate enough revenue to exceed drug-related costs, and 6 did not report enough information for us to determine the extent to which revenue was generated. Several factors affected 340B revenue generation, including drug reimbursement rates. Regardless of the amount of revenue generated, all covered entities reported using the program in ways consistent with its purpose. For example, all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Entities generating 340B program revenue that exceeded drug-related costs were also able to serve more patients and to provide additional services.

According to the 61 340B program stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. Specifically, 36 stakeholders, including those representing manufacturers, covered entities, and non-340B providers, did not report any effect on covered entities' or non-340B providers' access. The remaining 25, also representing a wide range of perspectives on the 340B program, reported that it affected access primarily in two situations: (1) for intravenous immune globulin (IVIG), a lifesaving drug in inherently limited supply; and (2) when there was a significant drop in the 340B price for a drug resulting in increased 340B demand. In both situations, manufacturers may restrict distribution of drugs at 340B prices because of actual or anticipated shortages. Stakeholders reported that restricted distribution of IVIG resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices. They also reported that restricted distribution when the 340B price of a drug dropped significantly helped maintain equitable access for all providers.

HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements—such as, entities' transfer of drugs purchased at 340B prices only to eligible patients, and manufacturers' sale of drugs to covered entities at or below the 340B price. HRSA primarily relies on participant self-policing to ensure program compliance. However, its guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent. Other than relying on self-policing, HRSA engages in few activities to oversee the 340B program. For example, the agency does not periodically confirm eligibility for all covered entity types, and has never conducted an audit to determine whether program violations have occurred. Moreover, the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients. This further heightens concerns about HRSA's current approach to oversight. With the number of hospitals in the 340B program increasing significantly in recent years—from 591 in 2005 to 1,673 in 2011—and nearly a third of all hospitals in the U.S. currently participating, some stakeholders, such as drug manufacturers, have questioned whether all of these hospitals are in need of a discount drug program.

Contents

Abbreviations

ADAP	AIDS Drug Assistance Program
CMS	Centers for Medicare & Medicaid Services
DSH	disproportionate share hospital
FQHC	federally qualified health center
GPO	group purchasing organization
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IVIG	intravenous immune globulin
PHSA	Public Health Service Act
PPACA	Patient Protection and Affordable Care Act
PSSC	Pharmacy Services Support Center
PVP	Prime Vendor Program

United States Government Accountability Office
Washington, DC 20548

September 23, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Our nation's health care safety net provides services to low-income, uninsured, underinsured, and other individuals who experience barriers accessing care, regardless of their ability to pay. Certain types of providers within the safety net have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program.[1] The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA),[2] requires drug manufacturers to give 340B discounts to entities covered under the law—known as covered entities—in order to have their drugs covered by Medicaid.[3]

Covered entities include clinics and hospitals that provide general health care services, as well as those that serve patients with specific conditions or diseases, and are typically eligible for the program because they receive some type of federal support, such as a federal grant. According

[1]Outpatient drugs covered under the 340B program may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, that can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration. 42 U.S.C. §§ 256b(b)(2), 1396r-8(k)(2). When payment for an outpatient drug is bundled with payment for other services, the drug is not covered by the 340B program.

[2]42 U.S.C. § 256b.

[3]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. Medicaid programs vary from state to state.

to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.[4] Covered entities' current spending on 340B drug purchases is estimated to be about $6 billion annually.

Participation in the 340B program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent off the cost of drugs, according to HRSA. In addition, covered entities can generate 340B revenue.[5] For example, covered entities can purchase drugs at the 340B price for all patients eligible under the program regardless of their income or insurance status, and generate revenue, such as through a patients' insurance reimbursement, that may exceed the 340B price paid for the drugs.[6] As of July 2011, there were more than 16,500 covered entity sites

[4]HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the PHSA. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act); *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the PHSA).

[5]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs.

[6]In 1996, HRSA issued a definition of a 340B patient that defines the situations under which covered entities can use drugs purchased at 340B prices for their patients. While income and insurance status do not dictate whether a patient is eligible under the program, certain patients, such as those who do not receive health care services consistent with the scope of a grant that made an entity eligible for the program or those whose only service from the covered entity is the dispensing of drugs, are prohibited from receiving drugs purchased at the 340B price. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

enrolled in the program—about double the number reported in 2001.[7] Because they must participate in the 340B program to receive Medicaid reimbursement for their drugs, incentives for participation by drug manufacturers also are strong. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA requires program participants to meet certain conditions set forth both in law and agency guidance. For example, under the PHSA, covered entities are prohibited from transferring 340B drugs to individuals who are not eligible patients of the entities.[8] Similarly, to help ensure covered entities receive the discounts they are entitled to, HRSA has issued nondiscrimination guidance prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to other, non-340B healthcare providers.[9] This includes not conditioning the sale of drugs to covered entities on restrictive conditions, such as requiring them to commit to minimum purchase amounts, which would discourage entities from participating in the program. However, stakeholders, including both covered entities and drug manufacturers, have raised questions about the extent to which 340B program requirements are followed and the extent to which HRSA ensures compliance. Further, because the 340B program has no requirements on how 340B revenue can be used,[10] stakeholders, such as drug manufacturers, have raised questions about covered entities' generation of revenue and whether they are using it in ways consistent with the purpose of the program. Additionally, due to continued growth in the

[7]Data are the most recent available from HRSA's covered entity database and represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there are about 3,200 unique organizations currently participating in the program—the agency was unable to provide historical data on unique organizations for all entity types. Additionally, because a covered entity may enroll under any and all eligible grant types it receives, it is possible that certain unique organizations and eligible sites are reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[8]42 U.S.C. § 256b(a)(5)(B).

[9]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

[10]According to HRSA, while there are no 340B-specifc requirements, all covered entities eligible for the program based on their grantee status may be required to use 340B revenue in accordance with their grant requirements.

number of covered entities participating in the program, some stakeholders have raised questions about whether increased use of 340B discounts shifts a larger share of drug costs to others in the health care system.

The Patient Protection and Affordable Care Act (PPACA) amended the 340B program by expanding entity eligibility for the program to include additional types of hospitals.[11] PPACA also contained provisions to improve 340B program integrity, and included a provision explicitly prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, consistent with HRSA's nondiscrimination guidance.[12] The passage of PPACA has raised some questions for 340B stakeholders about the program. For example, although proponents of the explicit prohibition on manufacturers contend that it is necessary to prevent discrimination against covered entities, critics are concerned about how it could affect non-340B providers' access to drugs.[13] Additionally, PPACA extends health insurance coverage to more Americans, and some stakeholders, such as drug manufacturers, have questioned whether covered entities will need the discounts provided through the 340B program given this increased coverage.

PPACA directed us to address several questions related to the 340B program. In response to the mandate, we examined: (1) the extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program; (2) how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers; and (3) HRSA's oversight of the 340B program.

[11]Entities that became eligible for the 340B program through PPACA include certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

[12]Pub. L. No, 111-148, § 7102(b).

[13]For this report, we consider providers as having access to a drug if they are able to obtain the amount necessary to meet the needs of their patients—for covered entities this includes being able to obtain the drug at the 340B price.

To examine the extent to which covered entities generate revenue through their participation in the 340B program, factors that affect their revenue generation, and how entities use the program, we conducted interviews with a judgmental sample of 29 covered entity organizations primarily selected to represent five covered entity types located in five states. We selected entity types based on factors, including high levels of participation in the 340B program and variation in organizational structure and the types of services provided. We selected states based on factors, including geographic variation and the percentage of uninsured in the state. Specifically, we interviewed 7 federally qualified health centers (FQHC),[14] 5 family planning clinics, 5 AIDS Drug Assistance Programs (ADAP), 5 hemophilia treatment centers, and 5 general acute care hospitals with a Medicare disproportionate share hospital (DSH) adjustment percentage of greater than 11.75 percent[15]—in this report we refer to these hospitals as DSH hospitals.[16] These entities were located in Illinois, Massachusetts, Tennessee, Texas, and Utah. We specifically selected Massachusetts to gain a better understanding of the potential effect of PPACA's health insurance reforms on the 340B program.[17] In addition to interviewing covered entities located in the five states, we conducted interviews with 2 additional DSH hospitals located in other states, because of questions raised in stakeholder interviews about how these hospitals were using the program. When possible, we collected

[14]FQHCs are urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations and have received a "Federally Qualified Health Center" designation from the Centers for Medicare & Medicaid Services (CMS).

[15]General acute care hospitals are eligible for the 340B program when they have a Medicare DSH adjustment percentage of greater than 11.75 percent and meet certain other requirements. Medicare is the federally financed health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. The Medicare DSH adjustment percentage is an additional Medicare payment to acute care hospitals paid under the inpatient prospective payment system—a Medicare reimbursement method based on a predetermined, fixed amount. A hospital's DSH adjustment percentage is generally based on its DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

[16]While additional types of hospitals are eligible for the 340B program, we only interviewed DSH hospitals because the remaining hospital types had only recently started participating in the program.

[17]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

relevant documentation from covered entities. Although we selected covered entities to interview that represented a variety of entity types, not all covered entity types are represented. Further, our selection of covered entities was judgmental, and our sample is not generalizable. (See appendix I for more details on how we selected covered entities and appendix II for more information about the entity types eligible to participate in the 340B program.)

To examine how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers, we conducted interviews with 61 340B program stakeholders, including our judgmental sample of 29 covered entities, as well as 32 other program stakeholders representing a wide range of perspectives on the program.[18] Included were interviews with 6 drug manufacturers, selected based on factors such as having a large market share and producing drugs with reported challenges related to their distribution at 340B prices, and 6 organizations representing drug manufacturers and others involved in distributing drugs from manufacturers to providers. We also interviewed stakeholders representing providers, including 9 organizations representing covered entities, 2 organizations representing non-340B providers, and 5 organizations representing both covered entities and non-340B providers. Finally, we interviewed HRSA and the Centers for Medicare & Medicaid Services (CMS), as well as HRSA's 2 340B program contractors. (See appendix I for more details on interviewees and how we selected them.) Similar to our selection of covered entities, our selection of other program stakeholders was judgmental and, as such, responses are not generalizable. In addition, we reviewed relevant documentation from interviewees, and analyzed industry data as well as data from HRSA's covered entity database to determine the number of hospitals in the U.S. currently participating in the 340B program. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

To examine HRSA's oversight of the 340B program, we conducted interviews with the 61 program stakeholders discussed above and reviewed relevant documentation. We reviewed information from HRSA and other HHS agencies, including those that administer the grants that

[18]We conducted multiple interviews with certain organizations for a total of 65 interviews.

make entities eligible for the 340B program.[19] We also reviewed key laws, guidance, and relevant literature related to the program and to safety net providers. We analyzed data from HRSA's covered entity database to determine changes in 340B program participation among covered entity types since 2001. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

We conducted our performance audit from September 2010 through September 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B program was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives certain safety net providers discounts on outpatient drugs comparable to those made available to state Medicaid agencies.[20] HRSA, through its Office of Pharmacy Affairs, is responsible for administering and overseeing the 340B program,[21] which according to federal standards, includes designing and implementing necessary policies and procedures to enforce agency objectives and assess program risk. These policies and procedures include internal controls that provide reasonable assurance that an

[19]HHS agencies that administer the grants that make entities eligible for the 340B program include HRSA, Indian Health Services, Office of Population Affairs, and the Centers for Disease Control and Prevention. CMS calculates Medicare DSH adjustment percentages for hospitals.

[20]The Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

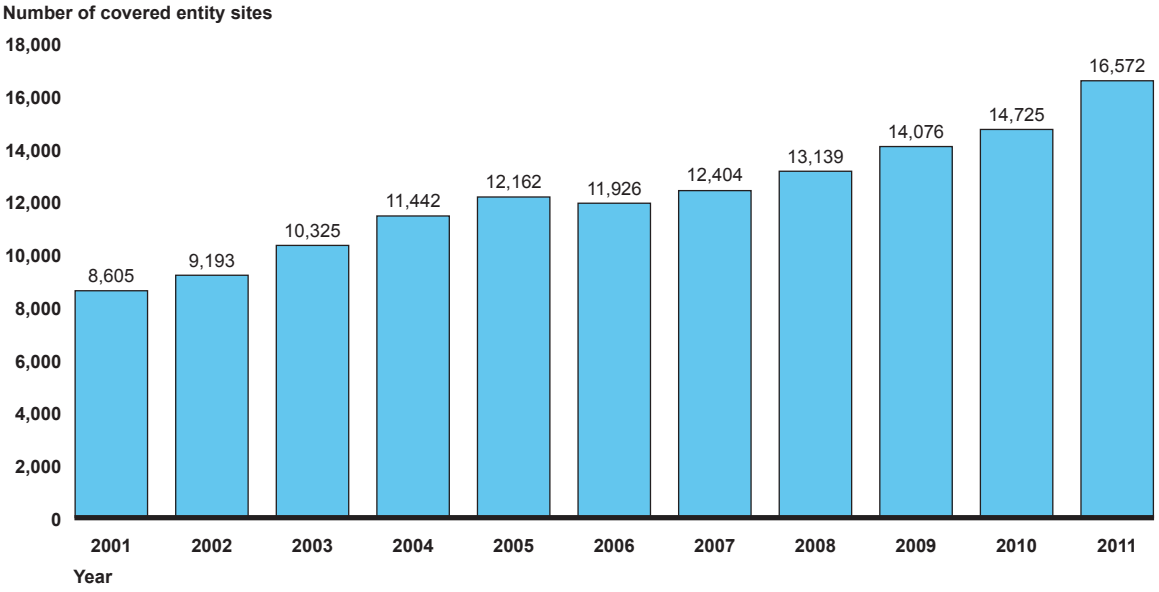
[21]The Pharmacy Services Support Center (PSSC) and the Prime Vendor Program (PVP) assist HRSA with the administration of the 340B program and are managed by contractors. The PSSC provides guidance and free technical assistance to covered entities and helps ensure that patients of covered entities receive comprehensive pharmacy services. The PVP establishes a distribution network for pharmaceuticals to covered entities and negotiates prices for a portfolio of drugs below the 340B price. Participation in the PVP is free and voluntary for covered entities.

agency has effective and efficient operations and that program participants are in compliance with applicable laws and regulations.[22]

Program Participants

Eligibility for the 340B program is defined in the PHSA. Entities generally become eligible by receiving one of 10 federal grants or by being one of six hospital types. (See appendix II for a complete list of covered entity types and their eligibility requirements.) To participate in the 340B program, eligible entities must register with HRSA and be approved. Entity participation in the 340B program has grown over time to include over 16,500 covered entity sites (see fig. 1).

Figure 1: Growth in Covered Entity Sites, 2001 to 2011



Source: GAO analysis of HRSA data.

[22]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

Federal grantees are eligible for the 340B program by virtue of receiving certain federal grants administered by different agencies within HHS. Eligible grantees include clinics that offer primary and preventive care services, such as FQHCs,[23] family planning clinics, and clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, such as hemophilia treatment centers. Participating clinics may offer eligible services at one or multiple sites. They also include state-operated ADAPs, which serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals.

Hospitals eligible for the 340B program include certain DSH hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. While DSH hospitals have been eligible for the program since its inception, children's hospitals became eligible in 2006, and the remaining hospital types became eligible through PPACA.[24]

Hospital eligibility for the 340B program has more elements than that of federal grantees, because unlike federal grantees, hospitals do not qualify for the program based on receipt of a federal grant. Rather, they must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify; however, critical access hospitals are exempt from this requirement.[25] Additionally, all hospitals must be (1) owned or operated

[23]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[24]See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082. While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006) (amending 42 U.S.C. § 1396r-8(a)(5)(B)).

[25]To be eligible for the 340B program, rural referral centers and sole community hospitals must have a DSH adjustment percentage that is equal to or greater than 8 percent, and DSH, children's, and free-standing cancer hospitals must have a DSH adjustment percentage that is greater than 11.75 percent. Although children's and free-standing cancer hospitals do not receive payments under the Medicare inpatient prospective payment system, they must have a payer mix that would result in a DSH adjustment percentage of greater than 11.75 percent.

by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government,[26] or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report.[27]

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B program and must participate if they want their drugs covered by Medicaid. To participate, manufacturers are required to sign a pharmaceutical pricing agreement with HHS in which both parties agree to certain terms and conditions and submit this agreement to HRSA.

Program Structure and Operation

Covered entities typically purchase and dispense 340B drugs through pharmacies and can structure their programs in different ways. Entities can have (1) an in-house pharmacy model, in which the pharmacy is housed within the covered entity, (2) a contract pharmacy model, in which the entity contracts with an outside pharmacy to dispense drugs on their behalf, or (3) both. Historically, only covered entities that did not have an in-house pharmacy were allowed to contract with a single outside pharmacy to provide services. In March 2010, however, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies.[28] Some covered entities use HRSA's Pharmacy Services Support Center (PSSC) or private companies that provide technical assistance, information

[26]According to HRSA, a hospital is said to be "formally granted governmental powers" when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

[27]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 180, 47884 (Sept. 19, 1994).

[28]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

technology, and other services to help develop, implement, and manage their 340B pharmacy program.

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities;[29] however, the provision establishing the 340B pricing formula indicates that manufacturers may sell a drug at a price that is lower than the ceiling price.[30] As such, covered entities may negotiate prices below the ceiling price. Manufacturers are responsible for calculating the 340B price on a quarterly basis. Occasionally the formula results in a negative price for a 340B drug.[31] In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA's penny pricing policy.

Key Program Requirements

Covered entities must follow certain program requirements as a condition of participating in the 340B program. For example, covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA's current definition of a patient. This definition was issued in 1996 and outlines three criteria which generally state that diversion occurs when 340B discounted drugs are given to individuals who are not receiving health care services from covered entities or are only receiving non-covered services, such as inpatient hospital services, from covered entities. (See table 1 for more information on HRSA's definition of a 340B patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

[29]In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug's average manufacturer price. See 42 U.S.C. § 256b (a)(1). Average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies. It includes direct manufacturer sales to retail community pharmacies, as well as sales by wholesalers. 42 U.S.C. §§ 256b(b), 1396r-8(k).

[30]42 U.S.C.§ 256b(a)(10).

[31]When a drug's average manufacturer price increases more quickly than the rate of inflation, the government requires the manufacturer to pay an additional rebate amount. This may cause the drug's unit rebate amount to be greater than the drug's average manufacturer price, which would result in a negative 340B price.

Table 1: HRSA's Definition of a Patient Eligible for Discounted Drugs under the 340B Program

	Criteria for patient eligibility[a]
1.	The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.
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.[b]
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 FQHC look-alike status has been provided.[c]

Source: GAO analysis of HRSA guidance.

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207, 55156 (Oct. 24, 1996).

[a]These criteria do not apply to ADAPs; rather, an individual will be considered a patient of an ADAP if enrolled in the ADAP program.

[b]An individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

[c]DSH hospitals are exempt from this requirement.

Covered entities also are prohibited from subjecting manufacturers to duplicate discounts whereby drugs prescribed to Medicaid patients are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. To avoid duplicate discounts, covered entities can either purchase drugs for Medicaid patients outside the 340B program, in which case the state Medicaid agency may claim the rebate, or they can use drugs purchased at 340B prices, in which case the agency may not claim the rebate. Covered entities that decide to use 340B drugs for Medicaid patients must notify HRSA so that it can coordinate with state Medicaid agencies for billing purposes. Further, certain covered entities—DSH hospitals, children's hospitals, and freestanding cancer hospitals—are prohibited from purchasing outpatient drugs through any group purchasing organization (GPO).[32] However, they may purchase drugs through the specified HRSA contractor, the Prime Vendor Program (PVP). Rural referral centers, sole community hospitals, and critical

[32]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

access hospitals participating in the 340B program are allowed to purchase outpatient drugs through any GPO.

Drug manufacturers also must follow certain 340B program requirements. Specifically, they must sell outpatient drugs to covered entities at or below the statutorily determined price. In addition, HRSA's nondiscrimination guidance prohibits manufacturers from distributing drugs in ways that discriminate against covered entities compared to other providers. This includes ensuring that drugs are made available to covered entities through the same avenue that they are made available to non-340B providers, and not conditioning the sale of drugs to covered entities on restrictive conditions, which would have the effect of discouraging participation in the 340B program.

340B Revenue Generated by Covered Entities Varied, but All Entities Reported That the Program Was Used to Support or Expand Access to Services

About half of the covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs—the costs of purchasing and dispensing a drug—and revenue generation depended on several factors. Regardless of the amount of 340B revenue generated or the savings realized through 340B discounts, covered entities generally reported using the 340B program to support or expand access to services.

About Half of Covered Entities Reported Generating 340B Revenue That Exceeded Drug-Related Costs, and Revenue Generated Depended on Several Factors

Thirteen of the 29 covered entities we interviewed reported that they generated revenue through the 340B program that exceeded drug-related costs.[33] Of the 16 remaining, 10 did not generate enough 340B revenue to cover all drug-related costs, and 6 covered entities were unable or did not report enough information for us to determine the extent to which they generated 340B revenue due, in part, to their inability to track 340B-specific financial information.

In general, 340B revenue—whether exceeding drug related costs or not—was generated through reimbursement received for drugs dispensed by 340B in-house or contract pharmacies, though several factors affected the extent to which the covered entities we interviewed generated revenue through the program:[34]

- **Third-party reimbursement rates**: Eighteen of the 29 covered entities we interviewed generated 340B revenue by receiving reimbursement from third-party payers and tracked revenue by payer source. Of the 18, most reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers.[35] However, a few of these covered entities reported that their ability to generate 340B revenue from private insurers, including Medicare Part D plans, was decreasing because some insurers were reducing contracted reimbursement rates for drugs based on the entity's status as a 340B provider. Of the 18 covered entities, most of those that used 340B drugs for Medicaid patients reported that state-determined Medicaid reimbursement rates for these drugs were generally lower, compared to private insurers and Medicare. For example, most reported that Medicaid reimbursement for a 340B drug was set at the price paid for the drug—the 340B price

[33]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs. When data provided by covered entities was used to determine revenue generation, the most recent year of reported data was used.

[34]Even though 6 covered entities were unable to report the amount of revenue they generated through the program, they were able to report what factors affected overall revenue generation.

[35]Medicare reimburses outpatient prescription drugs either through Medicare Part B or Part D. Part B covers drugs administered by physicians, such as chemotherapy drugs, and payment for those drugs is set by a fee schedule established quarterly by CMS. Part D sponsors are typically private insurers that contract with CMS to cover outpatient prescription drugs and negotiate reimbursement rates directly with health care providers.

or any lower price—plus a dispensing fee, the latter of which generally did not cover the costs of dispensing the drug.[36] This is typically referred to as reimbursement at actual acquisition cost, which reduces a covered entity's ability to generate revenue because the state, rather than the entity, benefits from any savings from purchasing drugs at the 340B price.[37] However, a few covered entities generated more 340B revenue through Medicaid than others because they had contractual agreements with their states to share 340B-related savings.[38] Covered entities in two of the five states included in our selection had such agreements. Finally, a majority of the 18 covered entities reported that revenue generated from uninsured patients was lower than that from all other payers.

- **ADAP status**: Factors that affected 340B revenue generation for the five ADAPs we interviewed were different than for other entity types, because unlike other covered entity types, ADAPs do not receive third-party reimbursement for drugs. Rather, ADAPs serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals who, for example, are uninsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs. ADAPs can choose to cover costs of drugs by either paying for the drugs directly or by assisting patients with the costs associated with health insurance, including payments for premiums and co-payments or deductibles. When ADAPs purchase drugs directly, they realize 340B savings on drugs—either at the point of purchase or after the fact through manufacturer rebates—but do not generate revenue through the program. When ADAPs assist with patients' health insurance by paying for co-payments or

[36]A dispensing fee is typically a set dollar amount per prescription that covers the overhead costs of dispensing a drug, such as pharmacy staff time.

[37]State Medicaid agencies may reimburse entities at actual acquisition cost, because when entities decide to use drugs purchased at 340B prices for Medicaid patients, the state can no longer claim Medicaid rebates for those drugs.

[38]These contractual agreements are commonly referred to as shared savings agreements. Shared savings agreements provide covered entities reimbursement above actual acquisition cost, for example, by paying a higher dispensing fee to covered entities than the fee paid to other providers. According to the HHS Office of Inspector General, states may be interested in shared savings agreements with covered entities because 340B prices can be considerably lower than states' standard Medicaid reimbursement rates and entering into such agreements could encourage entities to use 340B drugs for Medicaid patients while still saving money for states.

deductibles on a drug, they sometimes generate revenue by collecting the rebates representing the full 340B discount on a drug for which they may have only paid a portion of the price. Three of the five ADAPs we interviewed reported generating revenue this way.

- **Ability to leverage resources to access the lowest drug prices**: Some of the 29 covered entities we interviewed reported leveraging resources, such as through their larger parent organizations or the PVP, to access drugs at prices below the 340B ceiling price, potentially increasing the difference between the price paid for the drug and the reimbursement received. In addition, some covered entities said they had access to sophisticated information technology—for example by contracting with private companies—or had more staff to help ensure that they were obtaining the lowest priced drugs.

As more people gain insurance coverage under PPACA, covered entities may serve more patients with private insurance and Medicaid,[39] which may affect the extent to which they generate 340B revenue. One covered entity located in Massachusetts reported that after the state implemented universal health care, while they received more revenue from reimbursement for low-income patients that gained private insurance, these patients often could not afford associated co-payments or deductibles, and the entity covered these costs.[40] In addition, according to one ADAP we interviewed, as more individuals gain private insurance, the ADAP may increasingly choose to pay for health insurance for patients rather than paying for patients' drugs directly. This may enable it to generate revenue through the 340B program if it can claim more rebates for drugs for the newly insured patients. According to some covered entities, the impact of serving more Medicaid patients may depend on the Medicaid reimbursement rate that entities receive. For example, patients that gain Medicaid coverage may begin to seek services from covered entities, and for those entities that lose money on Medicaid patients, this may decrease their ability to generate 340B revenue. Conversely, for covered entities that have contractual agreements to share 340B-related

[39]PPACA contains provisions to expand private health insurance and Medicaid coverage to more Americans. See, e.g., Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271.

[40]HRSA officials told us that this statement is consistent with their belief that low-income patients will continue to require assistance with health care costs after gaining insurance.

savings with their states, the increased Medicaid population may increase their ability to generate 340B revenue.

Covered Entities Reported Using the 340B Program to Support or Expand Access to Services

Regardless of the amount of revenue generated through the program, all of the 29 covered entities we interviewed reported that the 340B program, including the up-front savings they realized on the cost of drugs, allowed them to support their missions by maintaining services and lowering medication costs for patients, which is consistent with the purpose of the program. For example, some covered entities reported that they used the 340B revenue generated by certain patients to offset losses incurred from other patients, which helped support the financial stability of the organization and allowed them to maintain services. Further, one covered entity reported that without 340B revenue or the savings on drugs through its participation in the program, it would be unable to offer all the services it provides—both pharmaceutical and clinical—and another reported that it would have to close its outpatient pharmacy without the program. In addition to maintaining services, some covered entities passed 340B savings on to patients by providing lower-cost drugs to uninsured patients. For example, many covered entities determined the amount that a patient is required to pay based on the lower cost of 340B-priced drugs.

In addition, the 13 covered entities that generated 340B revenue that exceeded drug-related costs were able to use this revenue to serve more patients and to provide services that they might not have otherwise provided, including additional service locations, patient education programs, and case management, which is also consistent with the purpose of program. One covered entity, for example, reported that it used the revenue generated through the 340B program to provide additional service delivery sites in other parts of the state, which eliminated the need for some patients to travel more than 60 miles to receive services. A few covered entities reported using 340B revenue to support patient and family education programs, such as those where pharmacists provide education on drug interactions. Additionally, one covered entity reported using 340B program revenue to fund a case management program that did not generate any revenue on its own;[41] some services provided through this program included arranging

[41]Case management services facilitate access to appropriate health care, and are not typically reimbursed by payers.

transportation for patients to receive clinical services, coordinating necessary specialty care, and providing translation services.

Even though the uses of revenue generated through the 340B program were for similar purposes, some covered entities relied on the program more than others. For example, one FQHC reported that 340B revenue accounted for approximately 5 percent of its total budget, and was used to provide additional services within the organization. However, one hemophilia treatment center reported that 340B revenue accounted for about 97 percent of its total budget and was used to support all of its program operations.[42]

Manufacturers' Distribution of Drugs at 340B Prices Generally Did Not Affect Providers' Access to Drugs Except in Two Situations

According to stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. For example, 36 of the 61 program stakeholders we interviewed did not report any effect on covered entities' or non-340B providers' access to drugs related to manufacturers' distribution of drugs at 340B prices. These stakeholders represented a wide range of perspectives on the 340B program, including those representing manufacturers, covered entities, and non-340B providers.

The remaining 25 program stakeholders—also representing a wide range of perspectives on the 340B program—reported that manufacturers' distribution of drugs at 340B prices affected providers' access to drugs primarily in two situations.[43] The two situations were: (1) for intravenous immune globulin (IVIG), a lifesaving immune deficiency drug, the supply

[42]The organizational structure of hemophilia treatment centers we interviewed varied, and those that operated stand-alone programs were more dependent on 340B revenue than those that were integrated into hospitals.

[43]While stakeholders consistently reported two situations in which manufacturers' distribution of drugs at 340B prices affected providers' access to these drugs, some, such as covered entities, reported other situations that had effects on access, but it was not clear that the other situations were related to manufacturers' distribution of drugs at 340B prices.

of which is inherently limited;[44] and (2) when there was a significant drop in the 340B price of a drug, which may result in increased demand for the drug by covered entities. Both situations relate to the restricted distribution of drugs, which may occur during shortages or when shortages are anticipated.

Stakeholders reported that manufacturers' restricted distribution of IVIG at 340B prices resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices in order to meet their demand for the drug.[45] Manufacturers restrict the distribution of IVIG on an ongoing basis, because it is susceptible to shortages. Stakeholders, including five of the seven DSH hospitals we interviewed, reported that because of the restricted distribution of IVIG at 340B prices, 340B hospitals often must purchase some IVIG at higher, non-340B prices to meet their patients' needs. For example, DSH hospitals reported that when they were unable to access IVIG at 340B prices, additional IVIG was available for purchase at higher, non-340B prices directly from manufacturers, from specialty pharmacies,[46] or from GPOs.[47] Moreover, one DSH hospital reported that it had to purchase about one-third of the IVIG it needed at non-340B

[44]IVIG is primarily used to treat patients with immune deficiency diseases, a group of disorders in which the immune system fails to produce enough antibodies, thereby predisposing individuals to increased risk of infection. Factors inherent to the development and distribution of IVIG limit its supply making it susceptible to shortages, including that IVIG is made from human plasma, which is an inherently scarce resource, and that IVIG takes between seven and 12 months to manufacture. Additionally, only a few manufacturers develop and distribute these drugs in the United States.

[45]Hospitals are the primary purchaser of IVIG in the United States.

[46]Specialty pharmacies handle and distribute drugs that, among other things, have a high acquisition cost and require special handling practices.

[47]In general, 340B hospitals are prohibited from purchasing outpatient drugs through GPOs. While no DSH hospital we interviewed reported purchasing IVIG through GPOs, GPOs we interviewed told us that 340B hospitals have purchased IVIG through this avenue when they are unable to access it at the 340B price. During a December 2005 congressional hearing on the 340B program, an organization representing 340B hospitals argued that in situations when hospitals are unable to purchase IVIG at 340B prices, they are faced with either violating federal law by purchasing IVIG through GPOs, buying IVIG at cost-prohibitive retail prices, or denying their patients access to these drugs. See "Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency," Hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, December 15, 2005. While 340B hospitals can receive the benefits of group purchasing through the PVP, the PVP does not have any contracts for IVIG.

prices—paying about $20,000 to $25,000 more per month than what it would have paid if it could have purchased it at 340B prices.

Although manufacturers' distribution of IVIG at 340B prices may not meet 340B hospitals' demand, some stakeholders, such as drug manufacturers, reported that changes in the amount of IVIG allocated for sale at 340B prices could negatively affect non-340B providers' access to these drugs. For example, one IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of the drug purchased by providers in 2004—allocating 95 percent of its projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B price.[48] This manufacturer stated that its distribution was fair, and that changing distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs. However, HRSA officials told us that the allocation of IVIG in this way is not sufficient or fair. Nearly a third of the nation's hospitals currently participate in the 340B program, and one large GPO we interviewed reported that 340B hospitals tended to be the bigger hospitals in the company's membership base.[49] Thus, if other manufacturers similarly restrict the distribution of IVIG at 340B prices, it is unlikely that covered entities' demands will be met at the 340B price.[50]

Stakeholders reported that manufacturers' distribution of drugs at 340B prices also affected providers' access to drugs when the 340B prices dropped significantly. In certain cases, when the 340B price of a drug dropped, some covered entities stockpiled the drug, which resulted in shortages in the supply for other providers, including other covered entities. For example, two covered entities we interviewed reported challenges accessing drugs when their 340B prices dropped, because other entities purchased large amounts of these drugs. In other cases

[48]This manufacturer reported that it based its allocation of IVIG on 2004 purchasing patterns, because this was the last period before demand exceeded supply for the product and an allocation system became necessary. While data on the number of hospitals participating in the 340B program in 2004 are not available, the number of 340B hospitals has grown from 591 in 2005 to 1,673 in 2011.

[49]While certain 340B hospitals are prohibited from purchasing outpatient drugs through GPOs, all 340B hospitals can purchase inpatient drugs through GPOs.

[50]The Department of Justice is examining the IVIG market in the United States, in part, due to concerns about the distribution of these drugs at 340B prices.

when the 340B prices dropped, manufacturers restricted the distribution of those drugs at 340B prices to ensure that all providers had equitable access. For example, one manufacturer reported that after the price of an oral contraceptive dropped to a penny as a result of HRSA's penny pricing policy, it received an order from a covered entity that exceeded the manufacturer's current national supply by 50 percent. In response, this manufacturer consulted with HRSA to ensure compliance with the agency's nondiscrimination guidance and restricted the distribution of drugs at 340B prices by allocating its supply based on the projected demand in the market and providers' past purchasing patterns.

HRSA's Oversight of the 340B Program Is Inadequate

HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance. Changes in the settings where the program is used may heighten concerns about the inadequacy of HRSA's oversight, and HRSA's plans for improving oversight are uncertain.

HRSA's Oversight Is Inadequate to Ensure Participants' Compliance with 340B Program Requirements

HRSA's oversight of the 340B program is inadequate because it primarily relies on covered entities' and manufacturers' self-policing—that is, participants ensuring their own compliance with program requirements. Upon enrollment, HRSA requires both covered entities and manufacturers to certify that they will comply with applicable 340B program requirements and any accompanying agency guidance. As part of this certification, agency officials told us that they expect participants to develop the procedures necessary to ensure compliance, maintain auditable records that demonstrate compliance, and inform HRSA if violations occur. For example, covered entities must develop adequate safeguards to prevent drugs purchased at 340B prices from being diverted to non-eligible patients, such as inventory tracking systems that separately purchase and dispense 340B drugs, and manufacturers must ensure that they properly calculate the 340B price of their drugs. In both cases, program participants must keep auditable records that can show that they have complied with program requirements and produce that documentation if requested by HRSA.

HRSA officials told us that covered entities and manufacturers can also monitor each other's compliance with program requirements, but in practice, participants may face limitations to doing so. For example, two covered entities we interviewed reported that it is difficult to determine whether they have been charged correctly for drugs because manufacturers' calculations of 340B prices are not transparent—namely,

there is no centralized list of 340B prices.[51] An organization representing covered entities also told us that its members had reported this difficulty. Similarly, three drug manufacturers we interviewed reported that, although they sometimes have suspected covered entities of diverting 340B drugs, it is difficult to prove diversion took place. An organization representing some manufacturers explained that, although manufacturers have the authority to audit covered entities, they have only conducted them in egregious circumstances, because agency requirements for these audits—such as a requirement to hire an independent third party to conduct the audits—are costly and administratively burdensome.

HRSA's guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others' compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with its intent.[52] For example, HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly. Stakeholders we interviewed, including those representing covered entities and drug manufacturers, raised concerns that the guidance will be interpreted too broadly leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance. However, one of these stakeholders representing covered entities also noted that, in order to ensure compliance, some entities may adhere to a narrow interpretation of the guidance and thus, limit the benefit of the program for their organization. The agency itself has recognized the need to further specify the definition of a 340B patient to ensure that it is interpreted correctly.

[51]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

[52]In May 2011, HRSA published its first proposed regulation on the 340B program, Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 76 Fed. Reg. 29, 183 (proposed May 20, 2011). Until this point the agency had provided program guidance through notices published in the Federal Register, which were typically finalized after a notice and comment period, as well as more informal guidance on its web site.

For example, HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through "other arrangements," as long as the responsibility for care provided remains with the entity. However, HRSA does not define "other arrangements," and officials told us that what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care.

In addition, HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program.[53] Rather, the agency bases eligibility for these hospitals on the application of broad statutory requirements that they are either formally delegated governmental powers by a unit of a state or local government or have a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. HRSA has stated that the determination of whether hospitals meet the first requirement is evaluated by the agency on a case-by-case basis. For the second requirement, HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals.[54] Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.

[53]We use the term hospitals that are not publicly owned or operated to refer to public and private, nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B program.

[54]HRSA officials told us that contracts are selectively reviewed if further clarification is necessary.

Moreover, HRSA's nondiscrimination guidance is not specific in the practices that manufacturers should follow to ensure that drugs are equitably distributed to covered entities and non-340B providers when distribution is restricted. Some stakeholders we interviewed, such as covered entities, have raised concerns about the way IVIG manufacturers have interpreted and complied with the guidance in these cases, because covered entities have sometimes had to purchase IVIG at higher, non-340B prices. Additionally, given current guidance, one stakeholder reported that manufacturers can offer a certain amount of drugs at 340B prices, and while the distribution may not be equitable, still contend that they are complying with the guidance. Although PPACA included a provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, officials told us they do not have plans to provide any additional specificity to the nondiscrimination guidance.

Finally, in the case of HRSA's penny pricing policy, agency officials told us that it is well understood by 340B stakeholders and manufacturers we interviewed were generally aware of the policy. However, the agency has never formalized guidance in writing and there have been documented cases of manufacturers charging covered entities more than a penny for drugs when the policy should have been in effect.[55]

Beyond relying on participants' self-policing, HRSA engages in few activities to oversee the 340B program and ensure its integrity, which agency officials said was primarily due to funding constraints. For example, HRSA officials told us that the agency verifies eligibility for the 340B program at enrollment, but does not periodically recertify eligibility

[55]In a 2006 report, the HHS Office of Inspector General found that manufacturers did not always follow HRSA's penny pricing policy. Both in this report and in a 2005 report, the Office of Inspector General recommended that HRSA formalize its penny pricing policy in writing. See HHS Office of Inspector General, *Review of 340B Prices*, OEI-05-02 -00073 (Washington, D.C.: 2006); and HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

for all covered entity types.[56] As a result, there is the potential for ineligible entities to remain enrolled in the program. In addition, HRSA officials told us that they do not require a review of the procedures participants put in place to ensure compliance, and, although the agency has the authority to conduct audits of program participants to determine whether violations have occurred, it has never done so.[57] For example, officials said that they do not verify whether covered entities have systems in place to prevent diversion. Also, while HRSA encourages manufacturers to work with the agency to develop processes for restricting the distribution of drugs that are equitable to covered entities and non-340B providers, the agency only reviews manufacturers' plans to restrict access to drugs at 340B prices if a manufacturer contacts HRSA or concerns with a plan are brought to the agency's attention. Similarly, although HRSA calculates 340B prices separately from manufacturers, officials told us that, at this time, the agency does not use these calculations to verify the price that manufacturers charge covered entities, unless an entity reports a specific pricing concern.[58]

HRSA's oversight activities are further limited because the agency lacks effective mechanisms to resolve suspected violations and enforce program requirements when situations of non-compliance occur. If covered entities and manufacturers are not able to resolve conflicts on their own, HRSA has had an informal dispute resolution process in place since 1996 through which program participants can request that HRSA

[56]HRSA currently recertifies eligibility for sexually transmitted diseases, tuberculosis, and Ryan White grantees, consistent with requirements under the PHSA. In addition, HRSA verifies the grantee status of FQHCs as well as hospitals' DSH percentages on a quarterly basis. As resources allowed, HRSA has also periodically recertified 340B eligibility for other entity types. For example, HRSA recertified eligibility for family planning clinics in 2010. PPACA added a provision requiring HRSA to conduct annual recertification of eligibility for all covered entity types. HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[57]HRSA officials told us that while they do not conduct audits, if a potential violation of program requirements is brought to their attention, they will refer the matter to the HHS Office of Inspector General. Officials said that they have made two such referrals in the past year related to the diversion of 340B drugs.

[58]HRSA previously operated a voluntary pilot program with manufacturers to improve the integrity of 340B pricing calculations. Twelve manufacturers participated in the program, which was discontinued in March 2008 due to concerns regarding the confidentiality of drug pricing data and a lack of funding to run the program.

review evidence of a suspected violation and the agency then decides whether to initiate the process. However, despite reports by program participants about suspected violations they were unable to resolve on their own, HRSA officials told us that they have only initiated the dispute resolution process twice since its inception.[59] Additionally, HRSA has not issued regulations implementing monetary penalties for non-compliance established by PPACA, and HRSA has rarely utilized the sanctions that existed prior to PPACA. For example, participants found to be in violation of 340B program requirements face termination from the program. Yet according to HRSA officials, since the program's inception, only two covered entities have been terminated from the program due to findings of program violations and no manufacturer has ever been terminated for this reason.[60] Covered entities also are expected to pay back manufacturers for discounts received while out of compliance, and manufacturers are expected to pay back covered entities for overcharges. However, HRSA has not enforced these expectations and officials were unable to tell us the extent to which repayments have occurred.

Because of HRSA's reliance on self-policing to oversee the 340B program as well as its nonspecific guidance, the agency cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk. As a result, covered entities may be inappropriately

[59]For example, a covered entity we interviewed said that it suspected certain drug manufacturers of implementing strategies to avoid offering drugs at correct 340B prices, but because of the lack of transparency in how 340B prices are calculated, could not determine this on its own. According to the entity, when it contacted HRSA about these strategies, agency officials said that they did not have the resources to help. However, HRSA officials told us that they were unaware of any instances where the agency has not helped a covered entity under these circumstances. Officials from one manufacturer reported that it provided HRSA with evidence that a covered entity had engaged in multiple instances of diversion, and after attempting to resolve the instances with the entity on its own, requested a hearing through the dispute resolution process in January of 2010. HRSA officials told us that the agency dismissed the manufacturer's request to initiate the process, because the covered entity disputed the manufacturer's claim that it had attempted to resolve the issue on its own, and that the agency is currently considering the manufacturer's appeal of this dismissal.

[60]In a 2005 report on the 340B program, the HHS Office of Inspector General noted that terminating a manufacturer from the 340B program also means that the manufacturer would be terminated from the Medicaid program, making it a difficult sanction to put into practice, given the effects on access to medications for Medicaid beneficiaries. See HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

claiming 340B discounts from drug manufacturers or qualifying for the program when they should not be, potentially increasing the likelihood that manufacturers will offset providing lower prices to covered entities with higher prices for others in the health care system. Additionally, manufacturers may be charging covered entities more than the 340B price for drugs, which would limit the benefit of the program for these entities.

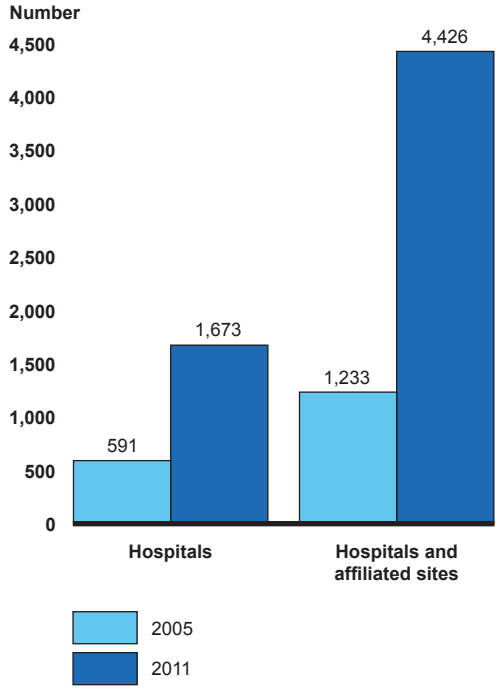
Changes in the Settings Where the 340B Program Is Used May Heighten Concerns about HRSA's Inadequate Oversight

Over time, the settings where the 340B program is used have shifted to more contract pharmacies and hospitals than in the past. According to HRSA officials, the number of covered entities using contract pharmacies has grown rapidly since its new multiple contract pharmacy guidance was issued in March 2010—as of July 2011, there were over 7,000 contract pharmacy arrangements in the program.[61] Hospitals' participation in the 340B program has also grown markedly in recent years. In 2011, the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005 (see fig. 2).[62] Further, although participation in the 340B program has increased among other covered entity types over time, hospitals' participation in the 340B program has grown faster than that of federal grantees. In 2005, hospitals represented 10 percent of program participants, and as of July 2011, they represented 27 percent.

[61]HRSA was unable to provide the precise rate of growth of contract pharmacies within the 340B program due to data limitations. Specifically, HRSA currently only tracks contract pharmacy arrangements and is working to develop the ability to capture individual contract pharmacies. Data on the number of contract pharmacy arrangements are the most recent available from HRSA's covered entity database.

[62]One reason for hospital growth could be that more hospitals may have become eligible as a result of state-level Medicaid expansions in recent years. The number of Medicaid patients served by a hospital affects its DSH adjustment percentage, which helps determine hospital eligibility for the 340B program.

Figure 2: 340B Program Participation among Hospitals and Their Affiliated Sites, 2005 and 2011



Source: GAO analysis of HRSA data.

Note: 2005 was the earliest year data were reliable for hospitals without their affiliated sites.

Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program. Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients.[63]

[63]Some covered entities have in-house pharmacies that also serve as retail pharmacies for the broader community. However, among the covered entities we interviewed, we found that this was not often the case.

Also, for a number of reasons, operating the 340B program in the hospital environment creates more opportunities for drug diversion compared to other covered entity types. First, hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not get 340B drugs. Second, hospitals tend to have more complex contracting arrangements and organizational structures than other entity types—340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and given HRSA's nonspecific guidance on the definition of a 340B patient, broad interpretations of the guidance may be more likely in the hospital setting and diversion harder to detect. Third, hospitals dispense a comparatively larger volume of drugs than other entity types—while representing 27 percent of participating covered entities, according to HRSA, DSH hospitals alone represent about 75 percent of all 340B drug purchases.

The increasing number of hospitals participating in the 340B program has raised other concerns for some stakeholders we interviewed, such as drug manufacturers, including whether all of these hospitals are in need of a discount drug program. Nearly a third of all hospitals in the U.S. currently participate in the 340B program, and HRSA estimates that more may be eligible.[64] The number of hospitals eligible to participate may increase due to PPACA's Medicaid expansion, because the number of Medicaid patients served by a hospital affects its DSH adjustment percentage—one factor that determines hospital eligibility. Further, one organization we interviewed questioned whether the DSH adjustment percentage is the best measure to determine hospitals' eligibility for the 340B program, because of research indicating that it may not be an adequate proxy for the amount of uncompensated care a hospital provides.[65] The DSH hospitals we interviewed reported a wide range of payer mixes—with the percentage of Medicaid and uninsured patients ranging from about 15 percent of total patient volume for one hospital to about 85 percent for another. However, payer mix may not be the only factor to consider when identifying hospitals that provide care to the

[64]According to HRSA, over 400 additional DSH hospitals may be eligible for the 340B program based on their DSH adjustment percentage. This estimate does not include the additional hospital types made eligible for the program through PPACA.

[65]See MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: 2007), pp.78-79.

medically underserved and are part of the health care safety net. There is no established definition of a safety net hospital, and some researchers have argued that it should include factors other than payer mix, for example the disproportionate provision of critical services, that are either too expensive or unprofitable for other hospitals to provide, such as emergency room or trauma care.[66]

HRSA's Plans to Improve Oversight of the 340B Program Are Uncertain and May Not Address All Areas of Concern

While PPACA's 340B program integrity provisions address many of the deficiencies in HRSA's current approach to oversight, the agency has taken few steps to implement these provisions. PPACA requires HRSA to increase oversight of both covered entities and manufacturers, and outlines specific steps for HRSA to take in accomplishing this goal. (See table 2 for the 340B program integrity provisions included in PPACA.) However, according to officials, the agency does not have adequate funding to implement the integrity provisions. Officials also noted that once funding is secured, it could take several years to develop the systems and regulatory structure necessary to implement them.

[66]See for example, Barbara Wynn, et. al., "Analysis of the Joint Distribution of Disproportionate Share Hospital Payments," *PM-1387-ASPE* (Washington, D.C.: 2002); and Megan McHugh, Raymond Kang, and Romana Hasnain-Wynia, "Understanding the Safety Net: Inpatient Quality of Care Varies Based on How One Defines Safety-Net Hospitals," *Med Care Research and Review*, published online April 27, 2009.

Table 2: Key 340B Program Integrity Provisions Included in PPACA

Program participant	Requirements for HRSA	Required start date	Implementation status as of August 2011
Covered entities	Conduct annual recertification of eligibility for all covered entity types.	Not specified[a]	Developing implementation plan[b]
	Develop more detailed guidance on the procedures covered entities can follow to avoid the Medicaid duplicate discount.	Not specified[a]	Not started
	Establish a standard identification system for all covered entities by which each covered entity site can be identified for the purposes of ordering, purchasing, and delivery of 340B drugs.	Not specified[a]	Not started
	Impose certain sanctions on covered entities that knowingly and intentionally divert 340B drugs, by one or more of the following: • requiring a covered entity to pay manufacturers interest on the discounts they received for those drugs; • if the violation was also systematic and egregious, terminating the covered entity from the program and prohibiting re-enrollment for a period of time; and • referral to federal authorities.	Not specified[a]	Not started
Manufacturers	Improve mechanisms to ensure manufacturers charge the correct 340B prices on drugs, including: • making a centralized list of HRSA-verified 340B prices available to covered entities, • conducting selective audits of manufacturers, and • establishing procedures by which manufacturers repay covered entities for overcharges.	Not specified[a]	Not started
	Impose civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities more than the 340B price.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking
Both	Develop a formal dispute resolution process, including: • establishing procedures for covered entities to obtain information from manufacturers,[c] and • requiring manufactures to audit covered entities prior to submitting a request to initiate the dispute resolution process.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking

Source: GAO analysis of Pub. L. No. 111-148, § 7102, 124 Stat. 119, 823 and interviews with HRSA officials.

[a]PPACA provides that these activities are to be conducted from amounts appropriated under a new authorization of appropriations. As of August 2011, no such appropriations have occurred.

[b]HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[c]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

Independent of the provisions in PPACA, HRSA also has recently developed guidance to further specify the definition of a 340B patient. While the Office of Management and Budget completed its review of this definition in April 2011, as of August 2011, HRSA had not yet released it for stakeholder comment. In 2007, HRSA also proposed updating this guidance, but it was never finalized.[67]

Even if HRSA implements PPACA's provisions and updates its definition of a patient, these steps may not be sufficient to address all areas of concern. For example, PPACA specifically requires HRSA to conduct selective audits of manufacturers, but it did not establish the same requirement for audits of covered entities. As such, the effectiveness of HRSA's oversight of covered entities will, in part, be dependent on what additional steps the agency takes to ensure program integrity. Similarly, if in implementing PPACA's provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, HRSA does not add specificity to the existing nondiscrimination guidance, it may be inadequate to ensure that all providers are able to equitably access drugs, particularly when manufacturers restrict the distribution of drugs at 340B prices. Also, as part of its 2007 proposed guidance on the definition of a patient, HRSA requested stakeholder comment on the elements that should be required in private, nonprofit hospitals' contracts with state or local governments as well as the different situations in which hospitals that are not publicly owned or operated should be formally granted government powers. However, HRSA officials told us that they have not issued additional guidance on these issues, and that they are not addressed in the clarifying guidance on the definition of a patient currently awaiting agency approval.

Conclusions

The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services, and we found that the covered entities we interviewed reported using it for these purposes. However, HRSA's current approach to oversight does not ensure 340B program integrity, and raises concerns that may be exacerbated by changes within the program. According to HRSA, the agency largely relies on

[67]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of a "Patient," 72 Fed. Reg. 1543 (Jan. 12, 2007).

participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers. As a result, HRSA may not know when participants are engaging in practices that are not in compliance. Furthermore, we found that HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent. Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance. With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance are put in place. For covered entities, this may be particularly true in settings where there is heightened concern about the opportunities for the diversion of 340B drugs.

PPACA outlined a number of provisions that, if implemented, will help improve many of the 340B program integrity issues we identified. For example, PPACA requires HRSA to recertify eligibility for all covered entity types on an annual basis, which would help ensure entities that lose eligibility for the program do not remain enrolled. Additionally, PPACA requires HRSA to develop a formal dispute resolution process, including procedures for covered entities to obtain information from manufacturers, and maintain a centralized list of 340B prices—provisions that would help ensure covered entities and manufacturers are better able to identify and resolve suspected violations. PPACA also requires HRSA to institute monetary penalties for covered entities and manufacturers, which gives program participants more incentive to comply with program requirements. Finally, PPACA requires HRSA to conduct more direct oversight of manufacturers, including conducting selective audits to ensure that they are charging covered entities the correct 340B price.

However, we identified other program integrity issues that HRSA should also address. For example, the law does not require HRSA to audit covered entities or further specify the agency's definition of a 340B patient. While HRSA has developed new proposed guidance on this definition, it is uncertain when, or if, the guidance will be finalized. Because the discounts on 340B drugs can be substantial, it is important for HRSA to ensure that covered entities only purchase them for eligible patients both by issuing more specific guidance and by conducting audits of covered entities to prevent diversion. Additionally, while PPACA included a provision prohibiting manufacturers from discriminating against

covered entities in the sale of 340B drugs, HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance. Absent additional oversight by the agency, including more specific guidance, access challenges covered entities have faced when manufacturers' have restricted distribution of IVIG at 340B prices may continue and similar challenges could arise for other drugs in the future.

Also, current HRSA guidance may allow some entities to be eligible for the program that should not be. Hospitals qualify for the 340B program in part based on their DSH adjustment percentage. Even though the PHSA establishes additional eligibility requirements for hospitals that are not publicly owned or operated, these requirements are broad, and HRSA has not issued more specific guidance to implement them. We found that nearly a third of all hospitals in the U.S. are participating in the 340B program, more are currently eligible and not participating, and more may become eligible as Medicaid is expanded through PPACA. As the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system. As such, it is important that HRSA take additional action to ensure that eligibility for the 340B program is appropriately targeted. While HRSA officials reported that the agency does not have the resources to implement the PPACA provisions or otherwise increase oversight of the 340B program, limited resources could be prioritized to address areas of greatest risk to the program.

Recommendations for Executive Action

PPACA contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, we recommend that the Secretary of HHS instruct the administrator of HRSA to take the following four actions to strengthen oversight:

- conduct selective audits of 340B covered entities to deter potential diversion;
- finalize new, more specific guidance on the definition of a 340B patient;
- further specify its 340B nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; and

- issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.

Agency Comments and Our Evaluation

In commenting on a draft of this report, HHS stated that it agreed with our recommendations. HHS also had additional comments on several content areas of the report, and we made changes as appropriate to address these comments. (HHS' comments are reprinted in appendix III.) Finally, HHS provided technical comments, which we incorporated as appropriate.

HHS stated that HRSA would continue to work on 340B program integrity efforts and prioritize these efforts based on available funding. HHS also outlined steps that HRSA plans to take in response to each of our recommendations. While we appreciate HHS' commitment to improving oversight of the 340B program, we are concerned that the steps are not sufficient to ensure adequate oversight.

With regard to our first recommendation that HRSA conduct selective audits of covered entities to deter potential diversion, HHS stated that HRSA will continue working with manufacturers to identify and address potential diversion and implement a plan to better educate covered entities about diversion. However, HHS did not state that HRSA will conduct its own audits of covered entities and we reiterate the importance of the agency doing so as part of its ongoing oversight responsibilities.

With regard to our second recommendation that HRSA finalize new, more specific guidance on the definition of a 340B patient, HHS stated that HRSA will review the draft of proposed guidance to update the definition and revise this guidance in light of changes in PPACA. While we agree that it may be important for HRSA to consider the impact of PPACA on the definition, given that PPACA became law more than a year ago, and the potential for broad interpretations of current guidance, we encourage HRSA to complete its review in a timely fashion.

With regard to our third recommendation, that HRSA further specify its non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices, HHS stated that HRSA will: implement a plan to specify existing policy regarding 340B non-discrimination and drug distribution; provide clearer guidance to manufacturers for working with HRSA and develop specific allocation

plans where needed; and continue to work with the Department of Justice when fair, voluntary allocation plans are not developed. However, we are concerned that these steps do not require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices. Without taking this step, HRSA may not know when manufacturers are inequitably distributing drugs to covered entities and non-340B providers.

With regard to our fourth recommendation that HRSA issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program, HHS stated that HRSA will implement a plan to better educate covered entities on existing criteria for hospital participation in the program and initiate a phased approach to recertifying eligibility for all participating covered entities. Here, we are concerned that these steps do not include further specification of eligibility criteria for hospitals that are not publicly owned or operated, because we determined that additional specification of statutory requirements was needed to ensure that the 340B program is appropriately targeted.

We are sending copies of this report to the Secretary of HHS and appropriate congressional committees. In addition, the report is available at no charge on the GAO web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or at draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Debra A. Draper
Director, Health Care

Appendix I: Selection of Interviews with Program Stakeholders

Type of stakeholder	Number of stakeholders interviewed	Interview details

Covered entities	29	27 were selected to take into account certain criteria:
		• Entity Type:
		  • We selected five types of covered entities and specifically interviewed: 7 federally qualified health centers (FQHC), 5 disproportionate share hospital (DSH) hospitals, 5 hemophilia treatment centers, 5 family planning clinics, and 5 AIDS Drug Assistance Programs (ADAP). (See appendix II for a list of all entities eligible to participate in the program.)
		  • We picked these types based on:
		  • variation in operational structure,
		  • variation in services and drugs provided,
		  • high levels of 340B participation,
		  • experience with the program, and
		  • potential difficulty accessing drugs at 340B prices.
		• Location:
		  • We selected entities in five states: Illinois, Massachusetts, Tennessee, Texas, and Utah.
		  • States were selected based on variation in a number of factors, including: geography, percent of uninsured individuals, and Medicaid reimbursement policies.[a]
		  • We included Massachusetts to gain a better understanding of the potential effect of the Patient Protection and Affordable Care Act (PPACA) health insurance reforms on the 340B program.[b]
		• We used information provided by trade organizations representing covered entities to help select individual covered entities to interview.
		2 additional DSH hospitals were selected based on concerns raised in stakeholder interviews about how these entities were using the program.

Drug manufacturers	6	Selected based on market share and those that produce drugs with reported challenges related to their distribution at 340B prices.
Organizations representing drug manufacturers and others involved in drug distribution	6	Includes 4 manufacturer trade organizations, 1 distributor, and 1 pharmacy benefits manager.[c]

Type of stakeholder	Number of stakeholders interviewed	Interview details
Organizations representing providers	16	Includes organizations representing providers, including covered entities and non-340B providers: • 9 organizations that represent covered entities, including 6 trade organizations and 3 private companies that provide services and information technology to help covered entities establish and manage their 340B programs. • 2 organizations representing non-340B providers, including 1 trade organization and 1 non-340B provider. • 5 organizations that represent both covered entities and non-340B providers, including 3 trade organizations and 2 group purchasing organizations (GPO).[d]
Federal agencies and contractors	4	HRSA, the contractors that help administer the 340B program, and the Centers for Medicare & Medicaid Services.
Total	**61**	

Source: GAO.

[a]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals.

[b]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

[c]Distributors manage the sale of drugs to purchasers on behalf of manufacturers. Pharmacy benefit managers administer the prescription drug benefits of health insurance plans on behalf of plan sponsors.

[d]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

Appendix II: Select Information on Entities Eligible to Participate in the 340B Program

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Federal Grantees					
Federally-qualified health center (FQHC)[b,c]	Receives a section 330 grant under the Public Health Service Act (PHSA) (42 U.S.C. § 254b); meets the requirements to receive such a grant; or is an outpatient health program or facility operated by certain tribal or urban Indian organizations	Urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations.	1992[d]	4,826	Health Resources and Services Administration (HRSA)
Urban Indian organizations[e]	Receives funds under title V of the Indian Health Care Improvement Act (25 U.S.C. §§1651 et seq.)	Provide a variety of health programs to eligible individuals.	1992[d]	26	Indian Health Service
Family planning clinics (Title X)	Receives a grant or contract under Section 1001 PHSA (42 U.S.C. § 300)	Provide comprehensive family planning services.	1992[d]	3,868	Office of Population Affairs
Sexually transmitted diseases grantee	Receives funds under Section 318 of the PHSA (42 U.S.C. § 247c) and is certified by the Secretary of HHS	Provide screening and treatment for sexually transmitted diseases.	1992[d]	1,472	Centers for Disease Control and Prevention
Tuberculosis grantee	Receives funds under Section 317E of the PHSA (42 U.S.C. § 247b-6) and is certified by the Secretary of HHS	Provide treatment for tuberculosis.	1992[d]	1,221	Centers for Disease Control and Prevention
Native Hawaiian Health Centers	Receives funds under the Native Hawaiian Health Care Act of 1988 (42 U.S.C. §§ 11701 et seq.)	Provide comprehensive health promotion and disease prevention services to Native Hawaiians.	1992[d]	11	HRSA
State-operated Ryan White AIDS Drug Assistance Program (ADAP)	Receives financial assistance under title XXVI of the PHSA (42 U.S.C. §§ 300ff-11 et seq.)	Serve as a “payer of last resort” to cover the cost of providing HIV-related medications to low-income individuals who are uninsured or underinsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs.	1992[d]	90[f]	HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Other Ryan White grantees	Receives a grant under Part C of title XXVI of the PHSA or non-governmental grantees that receive any financial assistance under title XXVI of the PHSA if certified by the Secretary of HHS	Provide primary care and support services to individuals with HIV or AIDS.	1992[d]	520	HRSA
Hemophilia treatment centers	Receives a grant under section 501(a)(2) of the Social Security Act (42 U.S.C § 701(a)(2))	Provide medical care to individuals with hemophilia.	1992[d]	99	HRSA
Black lung clinics	Receives funds under Section 427(a) of the Black Lung Benefits Act (30 U.S.C. § 937(a))	Provide medical treatment to individuals disabled from pneumoconiosis (black lung) as a result of their employment at U.S. coal mines.	1992[d]	13	HRSA
Hospitals					
Disproportionate share hospitals (DSH)	DSH as defined under Section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B)) with a DSH adjustment percentage greater than 11.75[g]	General acute care hospitals paid under the Medicare inpatient prospective payment system.	1992[d]	3,061	Centers for Medicare & Medicaid Services (CMS)
Children's hospitals	Children's hospital as described under Section 1886 (d)(1)(B)(iii) of the Social Security Act with a DSH adjustment percentage greater than 11.75[g]	Primarily provide services to individuals under 18 years of age.	2006[h]	147	CMS
Critical access hospitals	Critical access hospital as determined under Section 1820(c)(2) of the Social Security Act (42 U.S.C. § 1395i-4(c)(2)) (no DSH requirement)[g]	Located in rural areas, provide 24-hour emergency care services, and have no more than 25 inpatient beds.	2010[i]	941	CMS and HRSA
Sole Community Hospitals	Sole community hospital as defined under Section 1886(d)(5)(D)(iii) of the Social Security Act (42 U.S.C. § 1395ww(d)(5)(D)(iii))with a DSH adjustment percentage equal to or greater than 8[g]	Isolated from other hospitals by distance, weather, or travel conditions.	2010[i]	200	CMS and HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Rural Referral Centers	Rural referral center as defined under Section 1886(d)(5)(C)(i) of the Social Security Act (42 U.S.C. §1395ww(d)(5)(C)(i)) with a DSH adjustment percentage equal to or greater than 8[g]	Large rural hospitals that provide services for patients from a wide geographic area.	2010[i]	72	CMS and HRSA
Free-standing cancer hospitals	Free-standing cancer hospital as described under Section 1886 (d)(1)(B)(v) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B(v))with a DSH adjustment percentage greater than 11.75[g]	Not a unit of another hospital, has a primary purpose of treating or conducting research on cancer.	2010[i]	5	CMS
Total				**16,572**	

Source: GAO analysis of federal laws and regulations.

[a]Data are the most recent available from HRSA's covered entity database and represent both covered entities and their associated sites. Because a covered entity may enroll under any and all eligible grant types it receives, it is possible that a site is reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[b]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[c]This category includes: FQHC look-alikes; Consolidated Health Centers; Migrant Health Centers; Health Care for the Homeless; Healthy Schools/Healthy Communities; Health Centers for Residents of Public Housing; and Tribal Organizations created under the Indian Self Determination Act (Pub. L.. No. 93-638) and administered by the Indian Health Service.

[d]Eligible to participate in the 340B program from its inception. See Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967.

[e]Section 1905(l)(2)(B) of the Social Security Act includes outpatient health programs or facilities operated by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services in the definition of FQHCs.

[f]According to HRSA, some states have both direct purchase and rebate programs, which are counted separately in the 340B covered entity database, which is the reason for the difference in the number of ADAPs in the database versus the number of states that have ADAP programs overall.

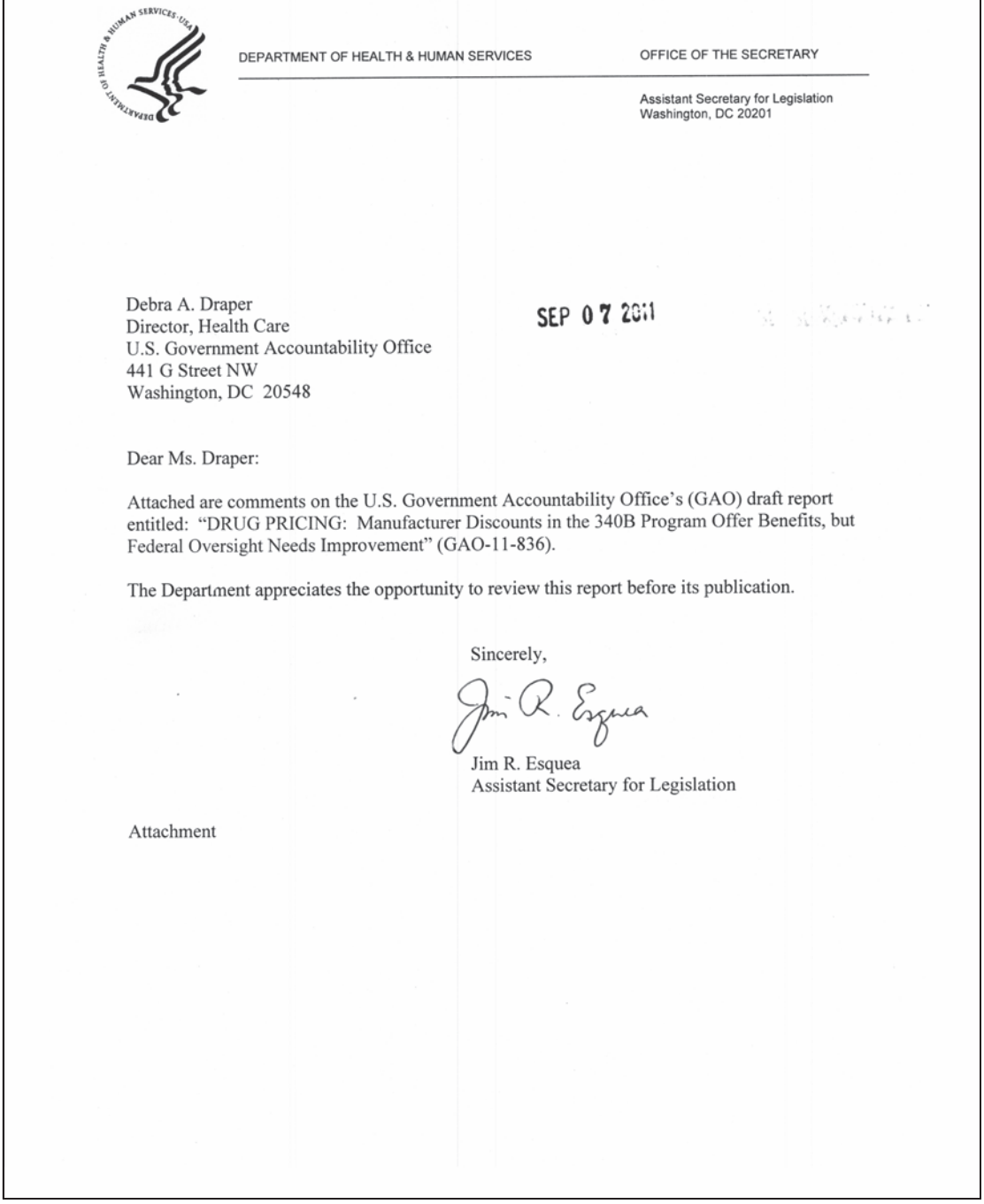
[g]Facility must also be (1) owned or operated by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Medicaid is the joint federal-state program that finances health care for certain low-income people, and Medicare is the federal health care program for the elderly and disabled. Children's hospitals and free-standing cancer hospitals do not receive payments under Medicare's inpatient prospective payment system; however, they must have a payer mix that would result in a DSH adjustment percentage greater than 11.75 percent. Facilities except critical access hospitals, Rural Referral Centers, and Sole Community Hospitals, must not obtain covered outpatient drugs through group purchasing.

[h]While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006).

[i]Became eligible to participate in the 340B program under PPACA. Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302,124 Stat.1029, 1082.

Appendix III: Comments from the Department of Health and Human Services

Note: Page numbers in the draft report may differ from those in this report.



DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

SEP 07 2011

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (GAO-11-836).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

The Department appreciates the opportunity to review and comment on this draft report. We offer the following general comments on several content areas of the report:

The extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program:

On Page 16, the report states that in Massachusetts where the state implemented universal health care, low-income patients gained private insurance, but "these patients often could not afford associated copayment or deductibles and the entity covered these costs". HRSA requests that the report reflect that this finding is consistent with the Health Resources and Services Administration's (HRSA) assessment that low-income patients will continue to require such assistance and the covered entities will provide valuable services to the safety net community.

On Page 18, the report states that "Even though the uses of revenue generated through the 340B Program were for similar purposes, some covered entities relied on 340B revenue more than others." The report goes on to state differences in revenue for FQHCs versus hemophilia centers. HRSA requests that the following explanation be incorporated into the report: Because each 340B entity type is unique in the types of services it provides and the patients it treats, the drug purchases of each entity type vary greatly (*i.e.*, generics versus brand or certain specialty drugs); therefore, their savings will also vary greatly.

Regarding how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers:

On Page 20, the report states that "One IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of drug purchased by providers in 2004--allocating 95 percent of the projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B Price" and "this manufacturer states that its distribution was fair and changing the distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs." HRSA requests that the report be edited to include:

> "HRSA does not believe that using the 2004 allocation of 95 percent to non-340B providers and 5 percent to 340B providers for a critical life saving drug is fair or sufficient. In 2005, there were 77 Hemophilia Treatment Centers and 591 Disproportionate Share Hospitals (DSH) purchasing IVIG through the 340B Program. This number has increased significantly to 99 Hemophilia Treatment Centers and

1

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

> 1,673 hospitals that now include children's hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, and rural referral centers. The allocation of IVIG drugs to 340B providers needs to be correlated to the increase in the 340B hospitals, as many of the same hospitals that purchased IVIG with no problems as non-340B providers in 2004 are now having tremendous difficulty in purchasing IVIG in 2011 as 340B providers. With 340B hospitals representing almost 33 percent of the hospitals of in the U.S. in 2011, 5 percent allocation for a life saving drug is not adequate."

On Page 21, the report states that some covered entities have stockpiled drugs when the price of a drug dropped. HRSA recommends that the report note that HRSA has worked with manufacturers in the past during an expected drop in price to develop an allocation process that is equitable across 340B and non-340B entities to prevent stockpiling. In addition, HRSA also encourages manufacturers to work with the agency to develop allocation processes to prevent issues with stockpiling.

HRSA's oversight of the 340B Program

On Page 24, the report states that HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program. HRSA requests that the report reflect that while HRSA has not published formal guidance in this area, HRSA has both criteria and a process in place to ensure hospitals satisfy 340B requirements. These criteria are utilized during the enrollment process and include:

- The criteria for hospital eligibility to participate in the 340B Program is outlined in section 340B(a)(4)(L)(i) which states the 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 or eligible for assistance under the State plan under this title." This information is on the HRSA Office of Pharmacy Affairs (OPA) website.
- Prior to enrolling a hospital into the Program, OPA verifies that the hospital meets the three statutory requirements for participation in the 340B program: 1) non-profit status is verified by IRS documentation; 2) DSH eligibility, if applicable, is verified by the Medicare-cost report and 3) private hospitals must have a contract with state or local governments to provide health care services to low income

2

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX of the Social Security Act. As part of the registration process, the hospital must submit a form that attests to the aforementioned statement that is signed by both an authorized public official and a hospital executive. Contracts are selectively reviewed if further clarification is necessary.

- OPA provides hospitals a list of recommendations during the enrollment process that can be used in developing a contract. HRSA strongly recommends and encourages the covered entity to seek legal counsel when preparing these contracts.

On page 24, the report states that some stakeholders expressed concern about the application of the requirements against non-discrimination. The conclusion of the report states that absent additional guidance, "access challenges covered entities have faced when manufacturers' have restricted distribution of certain drugs at 340B prices may continue." The language in the conclusion suggests that several challenges are known and identified; however, in its report the only access challenges identified involved IVIG. HRSA has been working with the Department of Justice (DOJ) to evaluate and improve access to IVIG for 340B entities. HRSA recommends that GAO provide additional detail regarding the access challenges found in order for HRSA to address these concerns and take appropriate action.

On Page 25, the report states that HRSA verifies eligibility for 340B at enrollment, but does not periodically recertify eligibility for all covered entity types. HRSA requests that the report reflect that HRSA has been meeting the statutory requirement; HRSA recertified and continues to recertify STD, TB, and HIV/AIDS programs annually as expressly required under section 340B (a)(7) of the Public Health Services Act (42 U.S.C. 256b). These were the only entities that required annual certification by the Secretary prior to the PPACA. In addition, HRSA monitors DSH percentages and FQHC grant status on a quarterly basis. Each quarter OPA verifies the proprietary status of participating hospitals by matching its list of participating hospitals with CMS's list of hospitals to ensure that ineligible private hospitals are not participating. As a result of the PPACA, HRSA is required to annually recertify all 340B covered entities. OPA's FY2011 budget of $4.4M will allow for the planning of and initiation of a phased approach to recertification to begin in fall of 2011.

On Page 31, footnote (a) states that no appropriation has occurred for annual recertification. HRSA recommends that this statement be replaced with the following, "HRSA program FY2011 budget of $4.4M will allow for the planning and initiation of a phased approach to recertification to begin in fall 2011."

3

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

On Page 32, the report states that the PPACA specifically requires HRSA to conduct selective audits of manufacturers but it did not establish the same requirement for audits of covered entities. HRSA requests that the report clarify that the agency has had the authority to audit covered entities under section 340B(a)(5)(C) of the Public Health Service Act since the inception of the program.

GAO Recommendations

HRSA agrees with the recommendations and will continue to build on program integrity efforts and work to prioritize efforts based on funding. Implementation of a cost recovery fee as outlined in the FY 2012 President's budget would allow for the initiation of the implementation of all recommendations and program integrity provisions outlined in PPACA. The 340B Drug Pricing program integrity risk assessment is scheduled to begin in the fall of 2011.

GAO Recommendation #1: *Conduct selective audits of 340B covered entities to deter potential diversion.*

HRSA Actions:

- HRSA and the manufacturers have the authority to audit 340B covered entities. HRSA will continue to work with the manufacturers to identify potential diversion and work with manufacturers to develop audit plans where evidence suggests potential diversion may be occurring.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources, such as targeted webinars on diversion, peer to peer learning, FAQs, policy letters to covered entities, and more assistance to covered entities in assessing risk.

GAO Recommendation #2: *Finalize new, more specific guidance on the definition of a 340B patient.*

HRSA Actions:

- HRSA will review the draft of the proposed patient definition guidelines in view of PPACA changes and develop revised guidelines for publication.

4

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

Recommendation #3: *Further specify its 340B non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices.*

HRSA Actions:

- HRSA will develop and implement a comprehensive educational and communication plan which will specify the existing policy regarding 340B non-discrimination and drug distribution to include, webinars, and policy letters to manufacturers regarding non-discrimination guidance.
- HRSA will continue to work with manufacturers to provide clearer guidance for manufacturers on working with HRSA and develop specific allocation plans where needed.
- HRSA will continue to work with DOJ when fair, voluntary allocation plans are not developed.

Recommendation #4: Issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program.

HRSA Actions:

- HRSA will further publicize its existing criteria for hospital participation in the 340B program by placing the criteria and process on the program website and issuing policy letters to affected covered entities outlining these criteria.
- HRSA will initiate a phased approach to recertification for all participating entities, including hospitals, beginning in fall of 2011. This recertification process will enable HRSA to verify that hospitals continue to meet the statutory requirements for program participation.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources such as targeted webinars on the hospital criteria, peer to peer learning, FAQs, and letters to covered entities.

5

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to the contact named above, Gerardine Brennan, Assistant Director; Jennie Apter; Kristin Ekelund; Kelli Jones; Dawn Nelson; Rachel Svoboda; and Jennifer Whitworth made key contributions to this report.

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Exhibit F

https://www.wsj.com/articles/the-federal-program-that-keeps-insulin-prices-high-11599779400

OPINION | COMMENTARY

The Federal Program That Keeps Insulin Prices High

Middlemen pocket discounts while forcing patients, employers and Medicare to pay more.

By Adam J. Fein
Sept. 10, 2020 7:10 pm ET

PHOTO: GETTY IMAGES/ISTOCKPHOTO

Listen to this article
6 minutes

Perhaps the biggest flashpoint in the political debate about prescription drug prices is the cost of insulin. This summer an executive order from President Trump required low prices for some patients, and Eli Lilly last week announced new measures to make insulin more affordable for diabetics. Yet many aren't aware that a federal program is goosing the price of insulin and other treatments, and keeping the prices high for patients who need these drugs.

Over the past few months the little-known 340B Drug Pricing Program has become the source of intense jockeying over who should benefit from the deep drug discounts—sometimes as much as 100%—that manufacturers provide to hospitals and their

pharmacy partners. Drug manufacturers Sanofi, Merck and Novartis are demanding transparency to ensure that their discounts aren't diverted.

Congress created the 340B Drug Pricing Program in 1992 with the vague goal of helping providers "stretch scarce federal resources" by requiring manufacturers to offer steep drug discounts to certain "safety net" hospitals. But the program includes no clear mandate on how the rebates should be spent. Good intentions have been swamped by middlemen that pocket discounts while forcing patients, employers and the Medicare program to pay more for prescription drugs.

For 18 years, 340B remained a minor, generally uncontroversial part of the U.S. health-care system. But shortly after the Affordable Care Act passed in 2010, the Obama administration announced an expansion: Hospitals could purchase and dispense discounted drugs through an unlimited number of external (or contract) commercial pharmacies.

For years I've been studying the economics of the complex and opaque intersection of the 340B program and the pharmacy industry. My analysis has found that since 2010 the 340B program has grown by almost 500% and is approaching the size of the nation's Medicaid outpatient drug market. The number of external pharmacies in the 340B program has also skyrocketed, from fewer than 1,300 in 2010 to 28,000 in 2020. That means almost half the U.S. pharmacy industry now profits from the 340B program, which was designed as a narrow support to certain hospitals.

Profit margins of up to 100% allow hospitals to pay inflated fees to their pharmacy partners, which can earn margins well above what the patient's insurance company usually pays. Public companies such as Walgreens, CVS, Walmart, Cigna, UnitedHealth Group, and Kroger have rushed into the 340B business. A booming industry of consultants and technology companies helps hospitals and commercial pharmacies profit from this aspect of the 340B program.

Patients don't benefit from these discounts. Instead, they are expected to pay their health plans' full out-of-pocket costs. A patient with a high-deductible health plan must pay the full list price for his medicine. The same sad math applies to seniors in the Medicare Part D program. Seniors taking many expensive specialty therapies must pay 5% of their

prescription's price without discounts—even when the manufacturer has practically given the product away.

Unlike Medicaid, the pharmacy component of 340B doesn't have—and has never had—a regulatory infrastructure. That's because the Obama administration's 2010 notice bypassed the usual rule-making and comment procedures. Consequently, there's no requirement that hospitals appropriately use the billions in 340B pharmacy discounts, no fair-market-value standards for pharmacies' fees, and zero transparency around the profits earned by the billion-dollar public companies that dominate 340B pharmacy networks.

Even worse, multiple government watchdogs have found that hospitals often don't provide discounted drug prices to uninsured low-income patients who filled prescriptions at a hospital's 340B contract pharmacy. The Government Accountability Office discovered that in a sample of 28 hospitals, 16 (57%) didn't provide discounted drug prices to needy patients at 340B pharmacies.

Manufacturers can find themselves paying a Medicaid rebate and a 340B discounts for the same prescription. Such double dipping occurs because there is a lack of transparency into claims data that would allow states and manufacturers to apply payment policies correctly. Health and Human Service's Inspector General in a report last month identified this lack of transparency as one of its top unimplemented recommendations to the agency.

Manufacturers understandably oppose paying 200% in discounts while others in the system make money. Hospitals and pharmacies have fought requests for data that manufacturers need to verify or track 340B discounts.

Congress needs to clean up this mess. The health-care system has changed a lot in the 28 years since the discount program was introduced. The 340B program needs to be modernized so that it benefits seniors and other patients—while supporting the genuine safety-net services of health-care providers. In the absence of sensible regulations, manufacturers will struggle to make sure that patients benefit from discounts on prescription drugs.

Mr. Fein is CEO of Drug Channels Institute.

Appeared in the September 11, 2020, print edition.

Exhibit G

DRUG CHANNELS INSTITUTE
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October 30, 2020

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510
340B@help.senate.gov

The Honorable Greg Walden
Republican Leader
U.S. House of Representatives Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, D.C. 20515
340B@mail.house.gov

Dear Chairman Alexander and Ranking Member Walden:

I appreciate the opportunity to present my views about the federal 340B Drug Pricing Program.

Congress created the 340B Drug Pricing Program in 1992 with the vague goal of helping providers "stretch scarce federal resources" by requiring manufacturers to offer steep drug discounts to certain covered entities—hospitals and other designated healthcare providers.

Covered entities increasingly rely on external (or contract) commercial pharmacies to extend 340B pricing to a broad set of patients. As I document below, nearly half of the country's retail, mail, and specialty pharmacies now profit from the 340B program. However, there is no requirement that the billions of dollars in 340B pharmacy discounts are used appropriately, no fair-market-value standards for pharmacies' fees, and zero transparency around the profits earned by the billion-dollar public companies that dominate 340B pharmacy networks.

Consequently, the program's good intentions have been overwhelmed by middlemen that pocket discounts while forcing patients, employers, and the Medicare program to pay more for prescription drugs. The unmanaged and unregulated growth of contract pharmacies is also causing significant channel distortions within the U.S. pharmaceutical distribution and reimbursement system.

As I will explain, these distortions:

- Overcharge uninsured patients for their prescriptions
- Require patients with commercial and Medicare Part D insurance to pay for the 340B funds earned by covered entities and contract pharmacies
- Permit large, public pharmacy and insurance companies to profit inappropriately from 340B discounts at the expense of needy and uninsured patients
- Curb manufacturers' willingness to offer rebates to Medicare Part D and commercial payers, raising net drug costs for these payers

I conclude with a set of policy recommendations for the contract pharmacy program.

QUALIFICATIONS

First, a few words about my industry experience and knowledge of these issues. I am an expert in the complex economic interactions within the U.S. pharmacy distribution and reimbursement system. I earned my Ph.D. in Managerial Science and Applied Economics from the Wharton School of Business at the University of Pennsylvania. I am president of Pembroke Consulting, Inc., a management consulting and research firm based in Philadelphia. For more than 20 years, I have consulted on channel, trade, payer, pharmacy, and other commercial issues in the pharmaceutical industry. I am also CEO of Drug Channels Institute (DCI), a Pembroke Consulting subsidiary that provides management education for and about the pharmaceutical industry.

I write the widely read *Drug Channels* website. There, I analyze the latest news and research affecting pharmaceutical economics and the drug distribution system. *Drug Channels* attracts a large, diverse audience throughout the pharmaceutical and healthcare industries. I also research and write detailed annual industry reports on the economics of pharmacies, wholesalers, and pharmacy benefit managers (PBMs).

For years I've been studying the economics of the complex and opaque intersection of the 340B program and the pharmacy industry. Over the past eight years, I have published more than 70 articles about the 340B program in *Drug Channels* and other publications.

I. MARKET OBSERVATIONS

Below are the results of my research into the 340B programs and contract pharmacies.

1) The 340B Drug Pricing Program is a large and growing part of the U.S. pharmaceutical market.

In recent years, the Health Resources and Services Administration (HRSA) has provided *Drug Channels* with data measuring the 340B program. Apexus, the HRSA-designated Prime Vendor, reports these data to HRSA.

According to the data provided by HRSA, discounted purchases made under the program totaled at least $29.9 billion in 2019[1]—an increase of 23% from the $24.3 billion in 2018. What's more, I have found that since 2014, purchases under the program have grown at an average rate of 27% per year. Over the same period, manufacturers' net drug sales have grown at an average annual rate of less than 5%.[2]

Hospitals account for 86% of total 340B purchases, according to data provided to me from Apexus.[3]

Many partisan supporters try to minimize 340B's share of the total U.S. market. In reality, the many years of above-market growth have made the 340B program into a significant and growing part of the industry. I estimate that the 340B program has grown to account for more than 8% of the total U.S. drug market and as much as 16% of manufacturer's total rebates and discounts for brand-name drugs.

2) The number of external pharmacies in the 340B program has skyrocketed.

A covered entity can purchase and dispense 340B drugs through internal and external (contract) pharmacies. In 2010, HRSA permitted eligible entities (including those that have an in-house pharmacy) to access 340B pricing through multiple contract pharmacies.[4]

Since this change in guidance, 340B covered entities have dramatically expanded their use of contract pharmacies:

- In 2010, there were fewer than 1,300 contract pharmacies.[5]
- As of July 2020, I found nearly 28,000 unique pharmacy locations acting as 340B contract pharmacies.[6] That's a more than 21-fold increase in just 10 years.
- These pharmacies have more than 112,000 contractual relationships with more than 8,000 340B covered entities. About three-quarters of these covered entities are disproportionate share and children's hospitals.

This growth means that almost half of the U.S. pharmacy industry now profit from the 340B program, which was designed as a narrow support to certain hospitals and providers.

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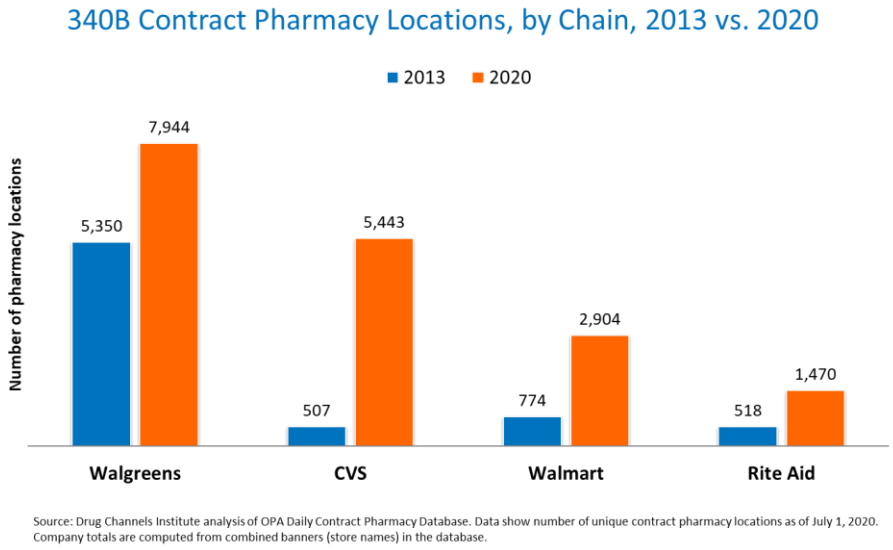
[1] Fein, Adam J., New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales, *Drug Channels*, June 9, 2020. Note that the data from Apexus include only indirect sales made via wholesalers. The $29.9 billion figure is therefore less than the actual total of 340B purchases at discounted prices. That's because the Apexus data exclude an unknown amount of manufacturer sales made directly to healthcare institutions and some sales by specialty distributors.
[2] *Medicine Spending and Affordability in the United States*, IQVIA Institute for Human Data Science, 2020, 5
[3] Email communication from Apexus, February 16, 2016.
[4] Health Resources and Services Administration, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, *Federal Register*, March 5, 2010.
[5] U.S. Government Accountability Office, Status of Agency Efforts to Improve 340B Program Oversight, May 15, 2018.
[6] Fein, Adam J., Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?, *Drug Channels*, July 14, 2020.

The 340B program is now approaching the size of the nation's Medicaid outpatient drug market, which was projected to be $34.9 billion in 2019.[7] Unlike Medicaid, the pharmacy component of 340B doesn't have—and has never had—a regulatory infrastructure. That's because the 2010 notice bypassed the usual rulemaking and comment procedures.

3) Large, for-profit pharmacy companies are the primary operators of contract pharmacies.

Four large pharmacy chains—Walgreens, CVS, Walmart, and Rite Aid—account for nearly two-thirds of the program's contract pharmacy locations. These companies have dominated contract pharmacies for years. The chart below shows the growth in 340B participation for these companies since my first analysis, in 2013.[8] In line with overall program growth, the largest chains have dramatically increased the number of their locations acting as 340B contract pharmacies.



Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database. Data show number of unique contract pharmacy locations as of July 1, 2020. Company totals are computed from combined banners (store names) in the database.

- Walgreens remains the dominant 340B contract pharmacy participant. As of mid-2020, we found that nearly 8,000 Walgreens locations act as 340B contract pharmacies. The chain therefore accounts for more than one-quarter of all contract pharmacy locations.

- CVS has dramatically increased its participation in the 340B program. About half of all CVS locations are now 340B contract pharmacies. The company's growth has been facilitated by CVS Health's acquisition of Wellpartner, a provider of 340B contract pharmacy services.

- Other major retail chains—Walmart, Rite Aid, Kroger, and Albertsons—account for more than 6,000 additional 340B contract pharmacy locations. Thousands of independent pharmacies and small chains participate, too.

[7] Office of the Actuary in the Centers for Medicare & Medicaid Service, National Health Expenditures (projected), March 2020.
[8] Fein, Adam J., Walgreens Dominates 340B Contract Pharmacy Mega-Networks, *Drug Channels*, July 16, 2013.

4) For-profit, insurer-owned specialty pharmacies now play a significant role in the 340B program.

Specialty pharmaceuticals (also known as specialty drugs) are brand-name or generic drugs for patients undergoing intensive therapies for such chronic, complex illnesses as cancer, rheumatoid arthritis, multiple sclerosis, and HIV. Specialty drugs accounted for slightly more than 2% of all U.S. outpatient prescriptions, but more than one-third of the pharmacy industry's total revenues.

The country's largest specialty pharmacies are fully or partially owned by large, vertically integrated organizations that offer health insurance, manage pharmacy benefits, operate pharmacies, and deliver medical care to patients.[9]

The four largest specialty pharmacies are operated by CVS Health's Caremark business, Cigna's Express Scripts business, UnitedHealth Group's OptumRx business, and Walgreens Boots Alliance/Prime Therapeutics.[10] Drug Channels Institute estimates that these four companies account for more than 70% of prescription revenues from pharmacy-dispensed specialty drugs.[11]

Our research has documented these insurers' deep involvement in the 340B program:

- As of mid-2020, specialty locations associated with the top four specialty pharmacies are operating a combined 224 locations that act as contract pharmacies for 340B covered entities.[12] CVS Health and UnitedHealth also operate an additional 78 infusion sites that function as 340B contract pharmacies.

- These 302 locations have more than 17,000 contractual relationships with covered entities. Most of the relationships are with disproportionate share hospitals and children's hospitals. Thus, specialty pharmacies and infusion sites account for 15% of total contract pharmacy relationships with 340B hospitals and other covered entities. Yet they represent only 1% of 340B contract pharmacy locations.

- Each specialty pharmacy location has dozens or even hundreds of contract pharmacy relationships. This is unsurprising, because specialty pharmacies typically fill prescriptions from a central location and then deliver the products directly to a patient's home. For example, the typical CVS Specialty location has agreements with 225 covered entities; a typical Accredo pharmacy has agreements with 159 covered entities; and a typical AllianceRx Walgreens Prime location has agreements with 618 covered entities.

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[9] Fein, Adam J., Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?, *Drug Channels*, December 12, 2019.

[10] Prime Therapeutics is a PBM owned by 18 Blue Cross and Blue Shield health plans. Note that Prime now outsources many of its PBM functions to Cigna's Express Scripts business. See: Fein, Adam J., Prime Therapeutics Deepens Its Reliance on Express Scripts: Our Four Takeaways From Their New Pharmacy Relationship, *Drug Channels*, October 15, 2020.

[11] Fein, Adam J., The Top 15 Specialty Pharmacies of 2019: PBMs Stay On Top, *Drug Channels*, April 28, 2020.

[12] Fein, Adam J., PBM-Owned Specialty Pharmacies Expand Their Role In—and Profits From—the 340B Program, *Drug Channels*, July 21, 2020.

5) Hundreds of covered entities have established contract pharmacy mega-networks.

Many covered entities have relatively small 340B contract pharmacy networks. However, some hospitals have built extraordinarily large networks.

Based on my analysis of HRSA data,[13] about 500 healthcare providers (6% of covered entities with contract pharmacies) account for more than 40% all contract pharmacy relationships. These providers have built networks averaging 99 pharmacies. Six large health systems have networks with more than 300 contract pharmacies.

The table below summarizes our findings about contract pharmacy networks. In addition to the mega-networks, a further 2,000 providers have networks with 11 to 50 pharmacies, accounting for 40% of contract pharmacy arrangements. By contrast, 70% of all 340B covered entities that utilize contract pharmacies have small networks with 10 or fewer pharmacy locations.

340B Covered Entities, By Number of Contract Pharmacies, July 2020

340B Contract Pharmacies in Network	340B Covered Entities	Share of 340B Entities with a 340B Contract Pharmacy	Total Number of 340B Contract Pharmacy Relationships	Share of 340B Contract Pharmacy Relationships	Average Network Size
One pharmacy	1,856	23%	1,856	2%	1
2 to 10 pharmacies	3,764	47%	17,393	15%	5
11 to 50 pharmacies	1,964	24%	45,501	40%	23
50 to 100 pharmacies	482	6%	47,948	43%	99
Total	8,066	100%	112,698	100%	14

Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database (7/1/20).

These networks are seemingly designed to enrich certain covered entities and pharmacies, not to help needy and uninsured patients. There are no regulations or guidance on network size or how 340B entities should monitor such large networks. These covered entities are not required to justify such large networks on the basis of access needs for uninsured, underinsured, and needy populations. We also do not know how or if hospitals monitor out-of-state mail and specialty pharmacies.

II. CHANNEL DISTORTIONS FROM 340B CONTRACT PHARMACIES

I believe that the growing use of contract pharmacies leads to at least five significant problems in the U.S. drug distribution and reimbursement system. I have outlined some of these issues in a peer-reviewed article[14] and in a recent *Wall Street Journal* opinion piece.[15]

[13] Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database (7/1/20)
[14] Fein, Adam J., Challenges for Managed Care from 340B Contract Pharmacies, *Journal of Managed Care and Specialty Pharmacy*, March 2016.
[15] Fein, Adam J., The Federal Program That Keeps Insulin Prices High, *The Wall Street Journal*, September 10, 2020.

1) Needy patients do not always benefit from prescriptions filled at contract pharmacies.

There is compelling evidence that uninsured and indigent patients do not always benefit from 340B drug discounts earned from third-party or patient paid prescriptions dispensed by contract pharmacies.

The small amount of public information about the operation of 340B contract pharmacy arrangements paints a dismal picture for uninsured patients using hospitals' 340B contract pharmacies.

- The Office of Inspector General (OIG) found that in a sample of 15 hospitals, 10 (67%) required uninsured patients to pay the full, non-340B price, even though hospitals were purchasing the drugs at the deeply discounted 340B price.[16]

- The Government Accountability Office (GAO) found that in a sample of 28 hospitals, 16 (57%) did not provide discounted drug prices to low-income, uninsured patients who filled prescriptions at the hospital's 340B contract pharmacy.[17]

These problems stem partly from the ways in which covered entities manage contract pharmacy relationships. Covered entities and their software vendors classify outpatient prescriptions as "340B eligible." They do this via non-public processes that are not subject to formal regulations.

Due to the lack of regulations, different entities have different standards for identifying 340B-eligible prescriptions. The OIG has described four common scenarios that would result in differing determinations of 340B eligibility across covered entities.[18] The OIG notes that "two covered entities may categorize similar types of prescriptions differently, i.e., 340B-eligible versus not 340B-eligible, in their contract pharmacy arrangements."

In a separate report, the Government Accountability Office (GAO) noted, "[S]ome covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care."[19]

2) Most prescriptions at hospitals' 340B contract pharmacies are dispensed to insured patients.

By using external pharmacies, a 340B covered entity profits from prescriptions filled by a pharmacy that is not owned or operated by the covered entity. They do this after the prescription has been adjudicated

[16] Office of Inspector General, Contract Pharmacy Arrangements in the 340B Program, February 2014.
[17] U.S. Government Accountability Office, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, June 2018.
[18] Office of Inspector General, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431IG. February 4, 2014.
[19] U.S. Government Accountability Office, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, September 2011.

and paid by such third-party payers as Medicare Part D and commercial health plans. (Medicaid prescriptions are excluded by statute.)

Since 340B prescriptions at contract pharmacies cannot be identified at the time of adjudication, Medicare Part D and commercial payers reimburse 340B and non-340B outpatient prescriptions at the same rate. Consequently, covered entities generate 340B funds from the difference between:

- The drug's market rate pharmacy reimbursement (paid by a Medicare or private plan) plus the patient's out-of-pocket contribution, and

- The drug's discounted 340B price from the manufacturer

A 340B entity only profits when prescriptions are paid at nondiscounted rates. Consequently, the vast majority of prescriptions filled at contract pharmacies are dispensed to patients who have prescription drug insurance—not to uninsured or financially needy patients. That's why Medicare and other third-party payers end up being responsible for the balance of the profit earned by a 340B covered entity and the contract pharmacy.

3) Patients covered by commercial insurance and Medicare Part D pay for the 340B funds earned by covered entities and contract pharmacies.

A patient with commercial or Medicare Part D insurance can't detect that their prescription is eligible for 340B pricing. The pharmacist at a contract pharmacy can't tell, either. That's because the determination is made weeks or months later. Consequently, the 340B covered entity requires insured patients to pay more for their prescriptions at contract pharmacies so the covered entity can generate 340B funds.

Patients therefore don't benefit from 340B discounts. Instead, they are expected to pay their health plans' full out-of-pocket costs. Patients taking specialty and brand-name drugs often have out-of-pocket costs tied to coinsurance or within the deductible phase. They therefore pay full price—or a percentage of full price—for drugs that are sold to 340B hospitals at deep discounts. An insured patient could pay thousands of dollars out of pocket—even as the 340B hospital and its contract pharmacy generate substantial profits.

Medicare Part D patients also fund 340B savings. Like commercial plans, Medicare Part D plans often use percentage cost sharing instead of fixed dollar copayments for drugs on higher tiers. Furthermore, Medicare beneficiaries, unlike those in most private insurance plans, can face unlimited out-of-pocket prescription drug costs if they reach the catastrophic coverage limit. Consequently, a significant number of Medicare beneficiaries had very high levels of out-of-pocket spending. More than 1 million Part D enrollees had total drug spending above the catastrophic coverage threshold. They spent an average of $3,214 out of pocket.[20]

[20] Kaiser Family Foundation, How Many Medicare Part D Enrollees Had High Out-of-Pocket Drug Costs in 2017?, June 2019.

As a matter of principle, a senior on a fixed income should not pay hundreds or thousands of dollars out-of-pocket for a drug that a large health system bought at a deep discount.

The OIG documented a troubling analog in the Medicare Part B program.[21] The OIG noted that for many cancer drugs, the Part B beneficiary's coinsurance was greater than the amount a covered entity spent to acquire the drug. In addition to the patient's out-of-pocket coinsurance, hospitals also received additional payments from the Medicare program. This further demonstrates how large hospital systems use seniors to generate 340B funds.

4) External contract pharmacies are profiting inappropriately from 340B discounts.

High 340B profits allow hospitals to pay inflated fees to their pharmacy partners, which earn margins well above what the patient's insurance company usually pays.

Rather than earning traditional dispensing spreads and fees, 340B contract pharmacies earn per-prescription fees paid by the 340B entity.[22] These fees can include fixed dollar payments as well as revenue-sharing and profit-sharing arrangements. These arrangements permit for-profit pharmacies to share in the 340B discounts that covered entities earn.

Given 340B prescription profit opportunities, a covered entity can offer—and large pharmacy chains and insurers can demand—overly generous payments. I estimate that contract specialty pharmacies earn profits that are three to four times larger than a specialty pharmacy's typical gross profit from a commercial insurer or Medicare Part D plan.[23] As I discuss above, these profits flow to some of the largest public companies in the U.S.

Contract pharmacy fees aren't required to be based on the existing fair market value standards utilized in other federal programs. In fact, when it comes to contract pharmacy fees, there's no guidance at all.

5) The lack of transparency into 340B prescription claims raises costs to Medicare Part D and commercial payers.

Manufacturers cannot identify 340B prescriptions dispensed by contract pharmacies. This disrupts rebate negotiations and raises net drug costs.

The 340B statute prohibits manufacturers from having to provide a discounted 340B price and a Medicaid drug rebate for the same drug, i.e., "duplicate discounts." The prohibition on duplicate discounts applies to traditional Medicaid arrangements as well as Medicaid programs operated by managed care organizations, also known as Managed Medicaid.

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[21] Office of Inspector General, Part B Payments For 340b-Purchased Drugs, November 2015, 9.
[22] U.S. Government Accountability Office, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, June 2018, Appendix I.
[23] Fein, Adam J., How Hospitals and PBMs Profit—and Patients Lose—From 340B Contract Pharmacies, *Drug Channels*, July 23, 2020.

However, manufacturers often find themselves paying a Medicaid rebate and a 340B discounts for the same prescription. Such double dipping occurs because there is a lack of transparency into claims data that would allow states and manufacturers to apply payment policies correctly. The OIG recently identified this lack of transparency as one of its top unimplemented recommendations.[24]

Unlike the provisions in Medicaid, there are no statutory protections for prescriptions paid by commercial third-party payers and Medicare Part D plans. Even if manufacturers negotiate contract language prohibiting duplicate discounts, manufacturers often end up paying rebates on the same prescriptions to commercial payers for products that covered entities purchase at 340B prices. That's because manufacturers cannot identify which prescriptions have been dispensed with 340B discounts.

The National Council for Prescription Drug Programs (NCPDP), which sets electronic communication standards for pharmacy care, allows the identification of an individual prescription's status under the 340B Drug Pricing Program.[25] However, hospitals and contract pharmacies have refused to utilize this voluntary standard.

Manufacturers understandably oppose paying 200% in discounts while others in the system make money. Hospitals and pharmacies are fighting requests for data that manufacturers need to verify or track 340B discounts.

Manufacturers would be justified in reducing managed care formulary rebates to offset paying duplicate discounts based on presumed 340B-dispensed claims. Lower rebates to commercial and Medicare Part D plans would raise the net costs of drugs to government and private payers.

III. POLICY RECOMMENDATIONS FOR 340B CONTRACT PHARMACIES

Our healthcare system has changed a lot in the 28 years since the 340B program was introduced. The program needs to be modernized so that it benefits seniors and other patients—while supporting the genuine safety-net services of healthcare providers.

I respectfully offer the following guidelines for improving the operation and accountability of contract pharmacies within the 340B program:

- **Mandate that contract pharmacies for 340B covered entities charge no more than the discounted 340B price to uninsured, underinsured, and vulnerable patients.** There is simply no excuse for overcharging needy patients, per the situations documented by the OIG and GAO.

[24] Office of Inspector General, Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs, August 2020, 29.
[25] National Council for Prescription Drug Programs, 34ØB Information Exchange, Reference Guide Version 1.Ø. July 2011.

- **Require that contract pharmacy fees be based on fair market value standards.** This would prevent for-profit pharmacies from capturing 340B discounts. It would also protect smaller covered entities that lack negotiating clout with the larger 340B contract pharmacy providers.

- **Revise hospital eligibility for the 340B program to create a clearer patient definition.** As I note above, most prescriptions at 340B contract pharmacies are dispensed to patients with commercial and Medicare Part D insurance. The program should be updated to target benefits towards needy patients and true safety-net providers.

- **Limit the number and geographic scope of contract pharmacy arrangements.** Covered entities are not required to justify large networks on the basis of access needs for vulnerable populations. Smaller, more controlled networks will ensure that only eligible patients use the contract pharmacy.

- **Require greater transparency into profits generated by 340B contract pharmacies.** Such a requirement would ensure that discounts provided under the 340B program are being utilized appropriately. There is compelling evidence that hospitals are double-counting 340B savings against their fundamental legal and statutory community benefit obligations as non-profit organizations.[26] Hospitals' community benefit obligations are distinct from any funds received from the 340B program.

- **Require contract pharmacies to identify 340B prescriptions at the time of adjudication (payer prescription approval).** This change would make manufacturers more willing to offer larger rebates to third-party payers.

Please contact me if I can answer any questions or provide additional information.

Sincerely,

Adam J. Fein, Ph.D.
afein@drugchannels.net

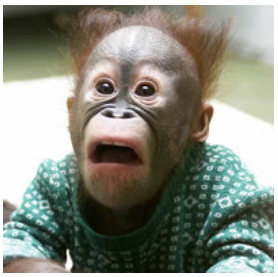
[26] U.S. Government Accountability Office, Opportunities Exist to Improve Oversight of Hospitals' Tax-Exempt Status, September 2020.

Exhibit H

DRUG CHANNELS
Expert Insights on Pharmaceutical Economics and the Drug Distribution System

TUESDAY, MAY 14, 2019

EXCLUSIVE: 340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines



The 340B Drug Pricing Program continues to expand at double-digit rates. According to our government contacts, discounted 340B purchases hit a record $24.3 billion in 2018. That figure is an astonishing 26% higher than its 2017 counterpart.

What's more, we have found that since 2014, purchases under the program have grown at an average rate of 28% per year. By comparison, manufacturers' net drug revenues have grown at an average rate of below 5% over the same period. Consequently, the 340B program has grown to account for at least 7% to 8% of the total U.S. drug market.

Nearly all of the billions in 340B discounts have accrued to hospitals. Yet hospitals' charity care has dropped amid the 340B program's growth. The charts have the details.

So where did the money go? We have no idea, because hospitals and their lobbyists fight any call for them to disclose or account for how they use their 340B profits—while consistently misrepresenting the program's size and growth. Be skeptical when you read random stories about the generosity of a 340B covered entity. As always, the plural of anecdote is not data.

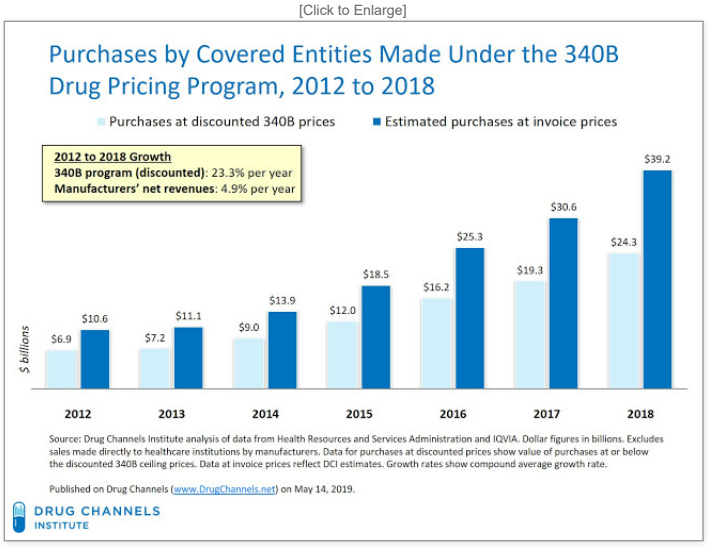
Read on for the latest details and ponder who really benefits from the 340B program's size—and how much longer this shocking growth can continue.

UNSTOPPABLE

For the past few years, the Health Resources and Services Administration (HRSA) has provided *Drug Channels* with data measuring the 340B program. For general background on the program, see Section 11.5 of our *2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. I also highlight a few other resources below.

The following chart shows the ongoing surge in covered entities' purchases made under the 340B Drug Pricing Program.

[Click to Enlarge]



We include the estimated invoice value of these purchases. The undiscounted invoice figure is our highly conservative guess based on HRSA estimates of total savings in 2015 by covered entities. We believe that this savings rate underestimates actual discount rates, so the figures above differ slightly from our previous estimates. The actual undiscounted figures are unknown, but are likely larger.

Here's a summary of our latest findings:

- Discounted purchases made under the program via Apexus, the HRSA-designated Prime Vendor, totaled $24.3 billion in 2018—an increase of 25.9% from $19.3 billion in 2017.
- The compound average growth rate (CAGR) of 340B purchases was 28.1% from 2014 through 2018. Wow.

Drug Channels is written by Adam J. Fein, Ph.D. Dr. Fein is CEO of Drug Channels Institute, a subsidiary of Pembroke Consulting, Inc. Read More...

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- Manufacturers' net revenues (per the latest IQVIA report) grew at a CAGR of only 4.4% from 2014 to 2018.

340B ACCOUNTED FOR 7% to 8% OF THE MARKET IN 2018

Many partisan supporters try to minimize 340B's share of the total U.S. market. In reality, the 340B program is a significant and growing part of the industry. Here are two computation approaches that yield comparable results:

1) 340B as a share of discounted purchases

The discounted HRSA figures above include purchases at or below the deeply discounted 340B ceiling prices. An appropriate comparison must therefore also be discounted purchases.

According to IQVIA's *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*, manufacturers' net revenues were $344 billion in 2018.

Using net revenues, 340B's share in 2018 was **7.1%**, or $24.3 billion ÷ $344 billion.

2) 340B as a share of undiscounted purchases

An alternative method compares estimated undiscounted 340B purchases at invoice prices with IQVIA's *invoice-price spending* market size. This figure was $482 billion in 2018. It represents the amounts paid to wholesalers and distributors by their pharmacy or hospital customers, including prompt-payment and volume discounts but excluding such off-invoice discounts as 340B discounts an PBM rebates.

Using invoice-price spending, 340B's share in 2018 was **8.1%**, or $39.2 billion ÷ $482 billion.

These are very rough estimates that understate 340B's actual share of the market. That's because the data from Apexus includes only indirect sales made via wholesalers. The $24.3 billion figure is therefore less than the actual total of 340B purchases at discounted prices, because it excludes an unknown amount of manufacturer sales made directly to healthcare institutions.

For an alternative estimate, I recommend Measuring the Relative Size of the 340B Program: 2017 Update. Using different assumptions about 340B discounts, Berkeley Research Group concluded that 340B was 10.1% of the U.S. market in 2017.

Note that 340B Health, which lobbies for hospitals that participate in the 340B program, continues to falsely claim that 340B was "less than 2% of total drug company revenues" in 2015. It wasn't true then and is certainly not true today.

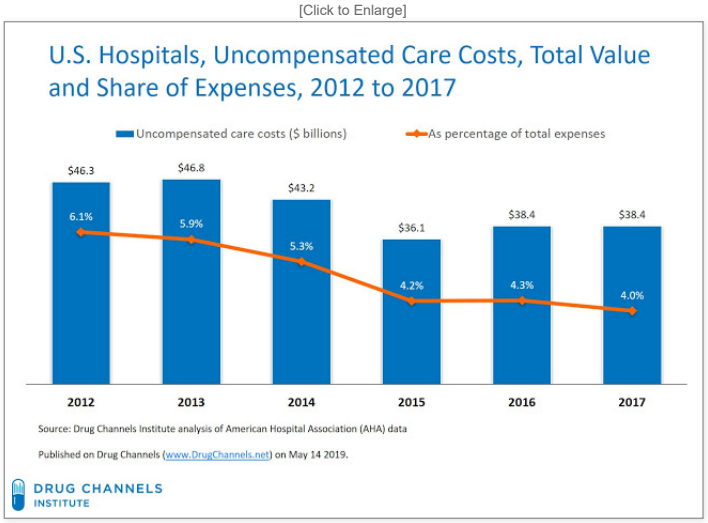
HOSPITAL CHARITY CARE HAS NOT KEPT PACE WITH 340B

The 340B program is highly controversial, in part because its founding legislation did not specify or restrict how covered entities should utilize the funds that the program generates. Here are some complementary data that raise additional questions.

Most 340B purchases are made by hospitals. The 340B program's defenders usually argue that hospitals provide charity care that justifies the amazing growth shown above.

An embarrassing point of comparison: The total value of hospitals' uncompensated care has declined, from $46.8 billion in 2013 to $38.4 billion in 2017 (the most recent year available). These data come from the American Hospital Association. Uncompensated care as a percentage of hospitals' total expenses has also declined, from 5.9% in 2013 to 4.0% in 2017.

[Click to Enlarge]



BTW, uncompensated care has hit a historic low as a percentage of expenses. This figure remained unchanged from 2016 to 2017, despite a 7% increase in community hospital operating expenses.

My simple observation is consistent with data from the U.S. Government Accountability Office (GAO). In a June 2018 report, the GAO found that more than 20% of 340B hospitals provide minimal amounts of charity care. Links and my discussion appear in our July 2018 news roundup.

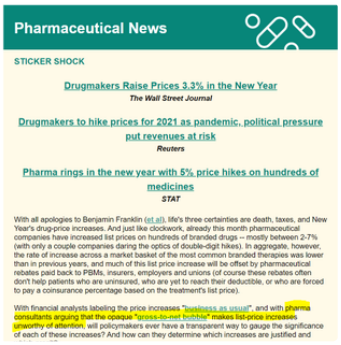
Tweets by @DrugChannels

Adam J. Fein
@DrugChannels

Thanks for the shout out, @icer_review! #GrossToNetBubble

Alas, you have mischaracterized my POV. I agree that b/c of benefit designs, list prices *do* matter to patients (See drugch.nl/2VYBuTb)

Just watch the rhetoric. Don't be a Drug Pricing Flat Earther! #DPFE 😉



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Hospitals have many non-340B, government-granted incentives to subsidize charity care. The majority of hospitals in the United States operate as nonprofit organizations and, as such, are exempt from most federal, state, and local taxes. In exchange, they are expected to provide various "community benefits" to maintain this non-profit status. (See Nonprofit Hospitals' Community Benefit Requirements from the Robert Wood Johnson Foundation.) Much of the uncompensated care reported in the chart above is tied to these requirements—and not to the 340B program.

LEARN MORE

Long time readers know that I think the 340B program is long overdue for reform, especially in light of the many abuses and problems that have been uncovered. Substantial evidence suggests that 340B savings are not always shared with patients and their insurance providers, including Medicare.

To learn more about the 340B program, consider these useful articles:

- 340B DRUG DISCOUNT PROGRAM: The Issues Spurring Discussion, Stakeholder Stances and Possible Resolutions, The Community Access National Network (highlighted in our March 2019 news roundup)
- GAO Confirms It: 340B Hospitals and Contract Pharmacies Profit from Low-Income, Uninsured Patients (our writeup of a highly troubling GAO report)
- Challenges for Managed Care from 340B Contract Pharmacies, *Journal of Managed Care & Specialty Pharmacy*
- Click here to read all *Drug Channels* articles about the 340B Drug Pricing Program.

Print Posted by Adam J. Fein, Ph.D. on Tuesday, May 14, 2019 14 Comments
Labels: 340B, Health Care Policy, Hospitals

William Roth • 2 years ago

Adam, thanks for the post. Your question of "where does the money go" is an excellent one. This was one of my topics at points at my address at Asembia. The main industry problem with this trend are the sins and the sloppiness that comes with all this extra margin for the health system. 1/3 of the nations hospitals are using this program now and if something like Medicare being able to negotiate their own prices goes through, the duplicate discount rule applies and 340b will go away, even if just for those products. If the health system simply took the margin, that would be one thing, but the hospitals have created a dependency on it

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Specialty Pharmacy M&A: Our Look at 2018's Deals (...
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► 2017 (155)
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► 2015 (157)
► 2014 (148)
► 2013 (147)
► 2012 (145)
► 2011 (137)
► 2010 (139)
► 2009 (108)
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have created a dependency on it.

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Michael Thompson • 2 years ago

Your chart portraying that U.S. Hospitals uncompensated care percentage dropping from 6% to 4% seems highly improbable... We are living in an era where high-deductible health plans, the sheer number of uninsureds, violent crime in urban populations, an influx of uninsured people at our southern border needing care and a general tendency to use a hospital's ED for Primary Care do not synch up with your chart--not in the least..

Share ›

Adam J. Fein Mod ➚ Michael Thompson • 2 years ago

Your intuition is not consistent with the facts.

The data above come directly from AHA.

As I note, uncompensated care has hit a historic low as a percentage of expenses. The AHA has tried to hide this fact by removing the computation from its annual report. See my tweet from January 2018.

Share ›

Nachman Avruch ➚ Adam J. Fein • 2 years ago

It hit a historical low because the proportion of individuals covered by insurance or Medicaid is at a historical high thanks to the ACA. But Medicaid and Medicare reimburse below cost, yet this gap isn't captured in charity care. Public and private non-profit hospitals are struggling, scaling back services or closing across the country. It's a wonder that these facts are never reflected in your commentary. From reading you alone, one would get the impression all 340b hospitals are rolling in mountains of margin, where is the evidence for that?

Share ›

Josh Free ➚ Nachman Avruch • 2 years ago

Good points and good question. Also, as charity care went down due to Medicaid expansion, DSH percentages went up and more hospitals qualified. This makes sense as hospitals were hit with an influx of patients with the worst payer (to your point).

Share ›

Anonymous • 2 years ago

I'm a subscriber to Drug Channel newsletter and very interested in following your research. I do have a question on the latest article, since I have worked in hospital business offices. As more patients became eligible for ACA insurances, the "charity care" from hospitals switched to "bad debt" on patient deductibles under an insured plan. Is that reflected in your analysis?

Share ›

Adam J. Fein Mod ➚ Anonymous • 2 years ago

Thanks for your question.

The AHA data defines uncompensated care as the "sum of a hospital's bad debt and the financial assistance it provides." Therefore, the analysis accounts for the switch that you describe.

Full definition below.

Share ›

Jake Chaffee ➚ Adam J. Fein • 2 years ago

Related to post above questioning data, this trend is supported by state-specific data. In states that have expanded Medicaid programs, like Michigan, uncompensated care is roughly 45 percent of average amount provided in 2013. This equates to hundreds of millions of dollars reduction in uncompensated care. The percent of uncompensated care costs as total costs is now below 2%!!

^ | v • Share ›

Nachman Avruch ➚ Adam J. Fein • 2 years ago

Does AHA capture below cost reimbursement from government payers? That is the most significant element of the DSH qualification for the program. The costs of charity care have simply shifted into under compensated care.

^ | v • Share ›

Josh Free • 2 years ago

Adam, I agree with most of your content, but I think you've missed the mark on this one.

First, let's step back and understand why 340b exists. The stated goal of the program is to allow qualifying covered entities to stretch scarce resources. The reason most qualify in the first place (DSH, others) is because they're inadequately reimbursed for their services by virtue of their payer mix. So they use the money to further their existing mission, which they would struggle to do otherwise.

I'm all for transparency and greater accountability, however to imply that 340b dollars need to be used for medication assistance programs, free drugs for patients, or other specific services is false.

So if we've established why they need this funding, next in my mind is why the drug manufacturers foot the bill. Well, look at it this way: These hospitals and other covered entities that have more than their fair share (ie: Disproportionate Share Hospitals) are taking the financial hit when they care for patients that are poor payers or non-payers. But guess who always gets

see more

^ | v • Share ›

David Scott ➚ Josh Free • 2 years ago

On the point where 340B pumps the breaks on drug costs--in my opinion, it would likely have the effect on increasing net costs for patients. In particular, DSH hospitals have (statistically significant) higher rates of consolidation in hematology-oncology and more hospital based administration of parenteral drugs. (NEJM, Feb 2018). Data shows that 340B hospitals provide more drugs, and more expensive drugs to 340B eligible patients. (GAO-15-442, pg. 29).

^ | v • Share ›

Josh Free ➚ David Scott • 2 years ago • edited

Not an untrue statement, however additional context may be relevant. Patients on high cost therapies frequently qualify for Medicaid and are likely to boost your DSH percentage if they're admitted. So what does that mean? For many hospitals, if you're offering services to the sickest and most expensive patients with the most expensive drugs, you qualify for 340B anyway. Not always, but often. Perhaps they are providing more expensive drugs and more drugs, but I speculate 340B status is correlated, not causative.

The implication is that patients would be denied care if the hospital didn't qualify. I would say that would be a serious ethical problem, I'm skeptical that's really happening.

Also keep in mind that 340B patients are retrospectively

qualified in many cases. So the caregivers frequently don't know if the encounter will be 340B eligible, especially if it's an outpatient prescription going to a contract pharmacy. It's very difficult for the prescriber to know if that encounter benefits the hospital at all at the time of the prescription.

^ | v • Share ›

David Scott ➚ Josh Free • 2 years ago

I agree, caution should be applied when inferring causation from correlation. And it is true that eligible patients are often tallied after the fact. However in my opinion, the bar to qualify as an eligible patient is so low, that a privately insured fully-covered patient can receive drugs that were purchased on 340B contracts.

Last year, Berkeley Research Group published a report (*Increases in part B drug utilization at enrolling 340B hospitals*) detailing spending trends for DSH hospitals before and after qualifying for 340B. Now PhRMA sponsored the report, so I understand extra scrutiny should be given to the findings. Nevertheless, the study did find that in the year following receiving DSH status, hospital per capital drug spend increased over 30%.

I get there are a lot of complicated factors at play which drive drug selection. However, this cautions me to think, if there is an economic reward for hospitals to choose more expensive drugs, or prescribe more drugs, then there is a chance that some will. That is human nature--and I don't necessarily fault the hospitals. They are responding to real incentives that the government is offering them. I think the real burden is on our elected officials who set the rules.

^ | v • Share ›

Josh Free ➚ David Scott • 2 years ago

Regarding the part about a privately insured patient receiving 340B purchased drugs—that's actually a fact. It happens all the time and it's exactly the way the program was designed. It's the encounter that's eligible, not the patient.

The patient encounter just needs to be at an eligible location, with responsibility for care lying with the covered entity, and it has to be a covered outpatient drug. There is no patient specific qualification. If Bill Gates, Warren Buffett and Jeff Bezos all got an infusion at a covered entities' infusion center, the drugs would likely be purchased under 340B.

It's an absurdly designed program, but it's what we have. Just to make it sound even crazier, keep in mind that most entities qualify based on inpatient stays, but 340B discount only applies to outpatient drugs. Does that make sense? Not really in my opinion. But is it ultimately unfair? I don't think so. It's a strange way to achieve the end goal, that's for sure.

I speculate one of the reasons 340B is still growing 10 years after ACA is because the program is so insanely complex that covered entities are still figuring out how to optimize.

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Exhibit I

United States Government Accountability Office

Report to Congressional Requesters

June 2018

DRUG DISCOUNT PROGRAM

Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

GAO-18-480

GAO Highlights

Highlights of GAO-18-480, a report to congressional requesters

June 2018

DRUG DISCOUNT PROGRAM

Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

Why GAO Did This Study

Covered entities can provide 340B drugs to eligible patients and generate revenue by receiving reimbursement from patients' insurance. The number of pharmacies covered entities have contracted with has increased from about 1,300 in 2010 to nearly 20,000 in 2017. GAO was asked to provide information on the use of contract pharmacies. Among other things, this report: 1) describes financial arrangements selected covered entities have with contract pharmacies; 2) describes the extent that selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and 3) examines HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies. GAO selected and reviewed a nongeneralizable sample of 30 contracts between covered entities and pharmacies, 20 HRSA audit files, and 55 covered entities to obtain variation in the types of entities and other factors. GAO also interviewed officials from HRSA and 10 covered entities.

What GAO Recommends

GAO is making seven recommendations, including that HRSA's audits assess for duplicate discounts in Medicaid managed care, and HRSA require information on how entities determined the scope of noncompliance and evidence of corrective action prior to closing audits. HHS agreed with four of the recommendations, but disagreed with three recommendations, which GAO continues to believe are warranted to improve HRSA's oversight as explained in the report.

View GAO-18-480. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

The 340B Drug Pricing Program (340B Program), which is administered by the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), requires drug manufacturers to sell outpatient drugs at a discount to covered entities so that their drugs can be covered by Medicaid. Covered entities include certain hospitals and federal grantees (such as federally qualified health centers). About one-third of the more than 12,000 covered entities contract with outside pharmacies—contract pharmacies—to dispense drugs on their behalf. GAO's review of 30 contracts found that all but one contract included provisions for the covered entity to pay the contract pharmacy a flat fee for each eligible prescription. The flat fees generally ranged from $6 to $15 per prescription, but varied by several factors, including the type of drug or patient's insurance status. Some covered entities also agreed to pay pharmacies a percentage of revenue generated by each prescription.

Thirty of the 55 covered entities GAO reviewed reported providing low-income, uninsured patients discounts on 340B drugs at some or all of their contract pharmacies. Of the 30 covered entities that provided discounts, 23 indicated that they pass on the full 340B discount to patients, resulting in patients paying the 340B price or less for drugs. Additionally, 14 of the 30 covered entities said they determined patients' eligibility for discounts based on whether their income was below a specified level, 11 reported providing discounts to all patients, and 5 determined eligibility for discounts on a case-by-case basis.

GAO found weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies, such as:

- HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. Specifically, manufacturers cannot be required to provide both the 340B discount and a rebate through the Medicaid Drug Rebate Program. However, HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care. As a result, it cannot ensure compliance with this requirement for the majority of Medicaid prescriptions, which occur under managed care.
- HRSA requires covered entities that have noncompliance issues identified during an audit to assess the full extent of noncompliance. However, because HRSA does not require all the covered entities to explain the methodology they used for determining the extent of the noncompliance, it does not know the scope of the assessments and whether they are effective at identifying the full extent of noncompliance.
- HRSA does not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing the audit. Instead, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity came into compliance with 340B Program requirements.

Given these weaknesses, HRSA does not have a reasonable assurance that covered entities have adequately identified and addressed noncompliance with 340B Program requirements.

Contents

Figures

Abbreviations

CMS	Centers for Medicare & Medicaid Services
FQHC	federally qualified health center
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
TPA	third-party administrator

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

June 21, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
House of Representatives

The Honorable Michael C. Burgess
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The 340B Drug Pricing Program (340B Program), named for the statutory provision authorizing it in the Public Health Service Act, requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities—certain hospitals and recipients of federal grants—to have their drugs covered by Medicaid.[1] According to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B Program, the purpose of the 340B Program is to enable covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.[2] In 2017, there were more than 12,000 covered entities and more than 38,000 total sites participating in the 340B Program.

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the cost of the drugs, according to HRSA. In addition, covered entities can generate revenue as they can purchase 340B drugs for eligible patients whose insurance

[1]42 U.S.C. § 256b. Medicaid is a joint federal-state program that finances health care, including prescription drugs, for certain low-income and medically needy populations.

[2]HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the Public Health Service Act. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act). *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act).

reimbursement exceeds the 340B price paid for the drugs. The statute authorizing the 340B Program does not dictate how covered entities should use this revenue or require discounts on the drugs to be passed along to patients. Incentives for participation by drug manufacturers are strong because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs.

A covered entity typically purchases and dispenses 340B drugs through pharmacies—either through an in-house pharmacy; through the use of a contract pharmacy arrangement, in which the entity contracts with an outside pharmacy and pays it to dispense drugs on its behalf; or both. The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance, and in March 2010, HRSA issued final guidance allowing covered entities to have an unlimited number of contract pharmacies.[3] Since that time, the number of contract pharmacies has increased significantly, from about 1,300 at the beginning of 2010 to around 20,000 in 2017.

Covered entities are required to meet certain conditions set forth both in law and interpretive agency guidance.[4] For example, they are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the covered entities.[5] They are also prohibited from subjecting manufacturers to "duplicate discounts" in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.[6] Covered entities that use contract pharmacies are responsible for overseeing those pharmacies to ensure compliance with 340B Program prohibitions on drug diversion and duplicate discounts. Some covered entities hire and pay a private company, referred to as a third-party administrator (TPA), to help determine patient eligibility and manage 340B inventory as a means to ensure compliance with 340B Program requirements at contract pharmacies.

[3]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).

[4]Since the establishment of the 340B Program, HRSA has used interpretive guidance and statements of policy to provide guidance to covered entities regarding compliance with program requirements, including statutory prohibitions on duplicate discounts and diversion. See, for example, 75 Fed. Reg. 10273 (Mar. 5, 2010).

[5]42 U.S.C. § 256b(a)(5)(B).

[6]42 U.S.C. § 256b(a)(5)(A).

In a September 2011 report, we identified inadequacies in HRSA's oversight of the 340B Program and recommended ways for HRSA to improve oversight and ensure appropriate use of the program.[7] In response, HRSA has taken action to improve its oversight of covered entities, including implementing a systematic approach to conducting audits of covered entities.[8] Given the growth in the 340B Program, there has been continued interest in program oversight, and how the increase in contract pharmacies affects the integrity of the program. You asked us to review the use of contract pharmacies in the 340B Program. In this report we

1. describe the extent to which covered entities contract with pharmacies to distribute 340B drugs, and characteristics of these pharmacies;
2. describe financial arrangements selected covered entities have with contract pharmacies and TPAs related to the administration and dispensing of 340B drugs;
3. describe the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and
4. examine HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies.

To examine the extent to which covered entities contract with pharmacies to distribute 340B drugs and the characteristics of these pharmacies, we analyzed HRSA's 340B Program database to identify the covered entities registered to participate in the 340B Program and the contract pharmacies registered to dispense 340B drugs for each entity, as of July 1, 2017—the most current data available when we began our analysis.[9] The pharmacy characteristics we reviewed included the type of pharmacy and the distance between the pharmacy and the covered entities with which it had a contract. To determine the types of pharmacies that participated as contract pharmacies, we matched the pharmacies included in the 340B database with data from the National Council for

[7]See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Washington, D.C.: Sept. 23, 2011).

[8]See GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight*, GAO-17-749T (Washington, D.C.: July 18, 2017).

[9]According to the data we received from HRSA, at the time of our analysis, there were more than 12,000 covered entities registered to participate in the 340B Program.

Prescription Drug Programs' DataQ—a database used by health care payers and claims processors across the country to identify pharmacies, which contains information reported by pharmacies on their pharmacy type and ownership, among other items.[10] We used the addresses included in the 340B database to determine the location of each covered entity, its affiliated sites, and its contract pharmacies and used this information to determine the distance between the entity and its contract pharmacies.[11] We calculated the distance (in miles) from the pharmacy to the nearest site of the covered entity. To assess the reliability of the 340B and DataQ databases, we obtained information from officials who are knowledgeable about them regarding steps taken to ensure the accuracy of the information contained in each, and performed checks to identify missing or incorrect data. Based on these steps, we determined that the data were sufficiently reliable for the purposes of our reporting objective.

To describe financial arrangements selected covered entities have with contract pharmacies and TPAs, we reviewed a sample of contracts between entities and pharmacies and collected information from selected entities and TPAs. We selected a nongeneralizable sample of 30 pharmacy contracts from among those that HRSA had collected—contracts the agency obtained during audits of covered entities from fiscal years 2014 through 2016.[12] We selected contracts to obtain variation in the type of covered entity (15 hospitals and 15 federal grantees) and geographic location. For these selected contracts, we identified the types and amounts of fees that covered entities agreed to pay contract pharmacies for dispensing and managing 340B prescriptions, as well as

[10]We matched the contract pharmacies in the 340B database to DataQ using the pharmacy's Drug Enforcement Agency number, which is a unique identifier used for tracking prescribers of controlled substances. About 1 percent of the 340B contract pharmacies (162 pharmacies) did not have a Drug Enforcement Agency number in the 340B database, and an additional 2 percent of the 340B contract pharmacies (405 pharmacies) for which a number was available in the 340B database did not have a corresponding record in DataQ, and thus their pharmacy types are unknown.

[11]We excluded 26 contract pharmacies that categorized themselves as mail order pharmacies from our distance calculations. In addition, we also excluded 103 covered entities (less than 3 percent of entities with contract pharmacies) and 644 contract pharmacies (about 3 percent of contract pharmacies) from our distance analysis because we were unable to determine their physical locations based on their addresses.

[12]HRSA collects copies of contracts between covered entities and their contract pharmacies as part of its audit process. Fiscal years 2014 through 2016 were the most recent period for which HRSA completed audits, and thus, the most recent time period of contracts HRSA had on file at the time we began our analysis.

determined factors that may have impacted the fee amounts. To describe financial arrangements covered entities have with TPAs, beginning in September 2017, we sent a data collection instrument—which we refer to as a questionnaire in this report—to a nongeneralizable sample of 60 covered entities that had contract pharmacies to obtain information about the arrangements they had with TPAs.[13] We received responses from 55 of the covered entities—28 hospitals and 27 federal grantees. In addition, we interviewed 10 of the 55 covered entities that responded to our questionnaire to obtain more detailed information about the fees they pay their TPAs. We selected covered entities to receive the questionnaire and for interviews to achieve variation in terms of their type, geographic location, and number of contract pharmacies. Finally, we interviewed two TPAs to gain insights about the types of financial arrangements they have with covered entities.

To describe the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients, we used the same questionnaire as previously noted to collect information about any discounts provided. This included information on the proportion of pharmacies at which discounts on 340B drugs were available, how covered entities determined which patients were eligible for those discounts, the prices these patients generally paid to obtain the drugs, and how covered entities inform patients and contract pharmacies about the availability of discounts. Additionally, we asked officials from the 10 covered entities we interviewed for additional information about discounts provided on 340B drugs dispensed to low-income, uninsured patients at contract pharmacies.

To examine HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies, we reviewed relevant policies, procedures, and guidance, including HRSA's 2010 guidance on contract pharmacy services and documentation of the agency's audit procedures. We also analyzed summaries of HRSA's audits of covered entities for fiscal years 2012 through 2017, posted on its website as of February 8,

[13]Four covered entities that received our questionnaire informed us that although they had contract pharmacies registered in HRSA's 340B database, they did not use them and thus, would not be able to answer our questionnaire. As a result, we sent the questionnaire to four additional covered entities.

2018.[14] We conducted an in-depth review of a nongeneralizable sample of 20 audits that were conducted from fiscal years 2014 through 2016 for covered entities that had contract pharmacies at the time of the audit.[15] We selected this sample from among audits that were closed by HRSA to obtain variation in terms of covered entity type and audit findings.[16] We also interviewed HRSA officials about their oversight activities, including their audit process, and spoke with the contractor that has conducted audits on HRSA's behalf since fiscal year 2017.[17] Additionally, we asked officials from the 10 covered entities interviewed about their practices for overseeing contract pharmacies. Finally, we evaluated HRSA's contract pharmacy guidance, covered entity oversight, and audit process against federal internal control standards related to control activities, information and communication, and monitoring.[18]

We conducted this performance audit from January 2017 to June 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B Program was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives 340B covered entities discounts on outpatient drugs comparable to those made available to

[14]As of that date, audit results were available for all audits conducted through fiscal year 2016 and 169 of the 200 audits conducted in fiscal year 2017.

[15]At the time we began our review, fiscal year 2017 audits were ongoing, so we reviewed selected audits from the prior three years.

[16]If the audit contains findings, HRSA closes the audit once the covered entity attests that all required corrective actions to address the findings have been addressed and any necessary repayments have been made to affected manufacturers.

[17]Beginning in fiscal year 2017, HRSA contracted with The Bizzell Group to perform the audits on its behalf. The Bizzell Group provides a completed audit protocol to HRSA, which the agency then uses to determine the audit findings and issue a final audit report. HRSA spent $3.8 million in fiscal year 2017 for 340B Program audit services.

[18]See GAO, *Standards for Internal Control in the Federal Government,* GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

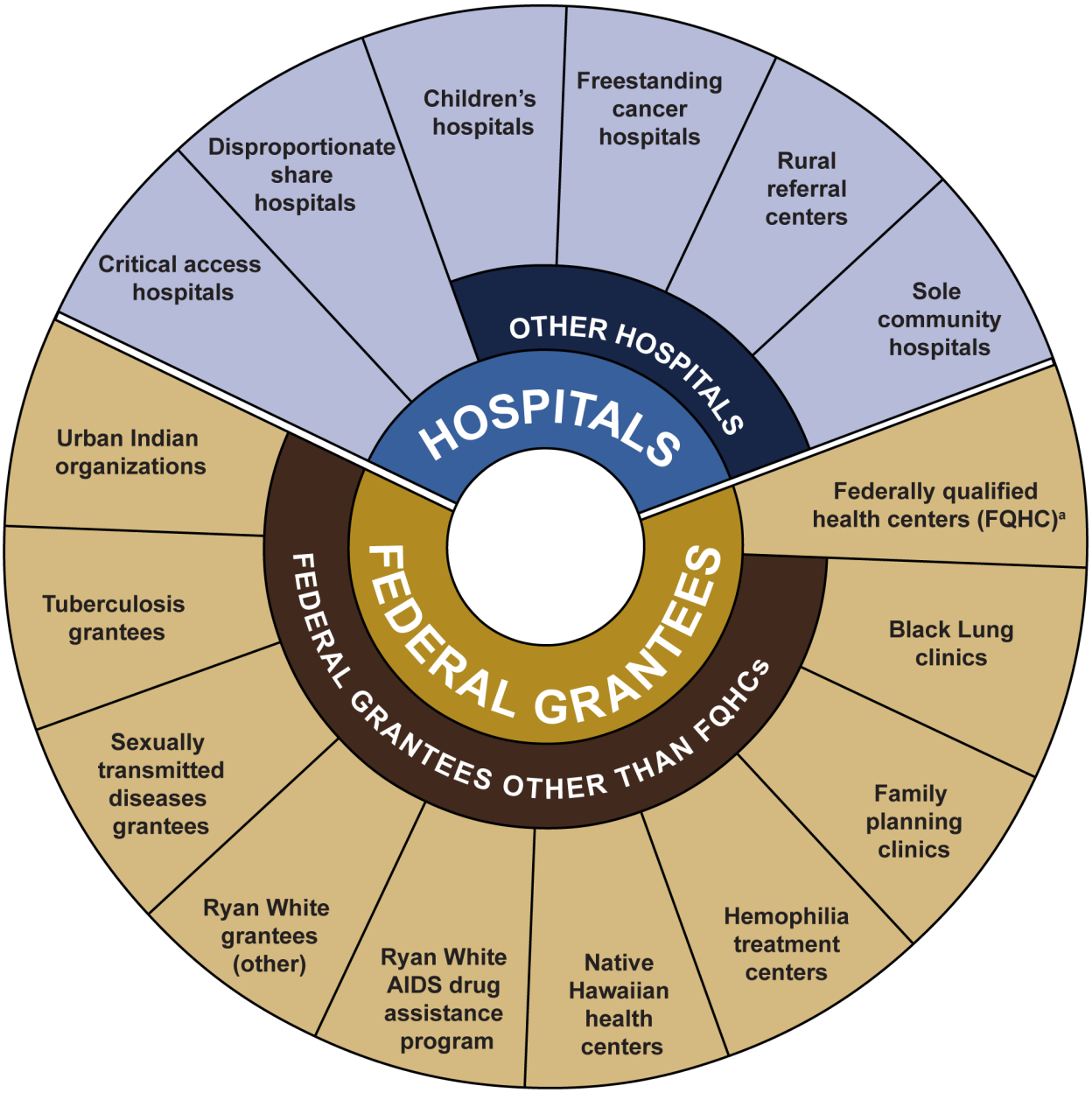
state Medicaid agencies.[19] HRSA is responsible for administering and overseeing the 340B Program.

340B Program Eligibility

Eligibility for the 340B Program, which is defined in the Public Health Service Act, has expanded over time. Covered entities generally become eligible for the 340B Program by qualifying as certain federal grantees or as one of six specified types of hospitals. Eligible federal grantees include federally qualified health centers (FQHCs), which provide comprehensive community-based primary and preventive care services to medically underserved populations, as well as certain other federal grantees, such as family planning clinics and Ryan White HIV/AIDS program grantees. Eligible hospitals include critical access hospitals—small, rural hospitals with no more than 25 inpatient beds; disproportionate share hospitals—general acute care hospitals that serve a disproportionate number of low-income patients; and four other types of hospitals (see fig. 1).

[19]The Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding Social Security Act § 1927; codified as amended at 42 U.S.C. § 1396r-8).

Figure 1: Types of Entities Eligible to Participate in the 340B Program



Source: GAO analysis of section 340B of the Public Health Service Act. | GAO-18-480

[a]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program, but do not receive federal grants, are referred to as FQHC look-alikes and are eligible to participate in the 340B Program.

Some covered entities, typically hospitals and FQHCs, have multiple sites: the main site, which HRSA refers to as the parent site, and one or more other associated sites referred to as child sites. Child sites can include satellite clinics, off-site outpatient facilities, hospital departments, and other facilities. According to HRSA officials, to participate in the 340B Program and be considered part of the covered entity, the associated sites must meet program requirements and be registered with HRSA as a child site.

Program Structure, Operation, and Key Requirements

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a participating drug manufacturer may charge covered entities.[20] Covered entities must follow certain requirements as a condition of participating in the 340B Program. For example, covered entities are prohibited from

- subjecting manufacturers to "duplicate discounts" in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.[21]
- diverting any drug purchased at the 340B price to an individual who is not a patient of the covered entity. Under HRSA guidance defining this term, diversion generally occurs when 340B drugs are given to individuals who are not receiving health care services from covered entities or are receiving services that are not consistent with the type of services for which the covered entity qualified for 340B status. (See table 1 for more information on HRSA's definition of an eligible patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the 340B Program definition of a patient regardless of their financial or insurance status.

[20]Manufacturers may sell a drug at a price that is lower than the ceiling price. As such, covered entities may negotiate prices below the ceiling price.

[21]The Patient Protection and Affordable Care Act expanded the Medicaid Drug Rebate Program to include drugs dispensed to Medicaid beneficiaries through managed care plans. Pub. L. No. 111-148, § 2501(c)(1), 124 Stat. 119, 308 (2010). Prior to the effective date of this expansion (Mar. 23, 2010), manufacturers' responsibility to pay Medicaid rebates for outpatient drugs covered was limited to drugs covered under Medicaid fee-for-service.

Table 1: Health Resources and Services Administration's (HRSA) Definition of a Patient Eligible for Discounted Drugs under the 340B Program

Criteria for patient eligibility[a]
1. The covered entity has established a relationship with the individual such that the covered entity maintains records of the individual's health care.
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.[b]
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.[c]

Source: GAO analysis of HRSA guidance. | GAO-18-480

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B Program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

[a]These criteria do not apply to Ryan White AIDS drug assistance programs, which serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals. Rather an individual enrolled in a Ryan White AIDS drug assistance program is considered a patient of the covered entity if registered as such by the state program.

[b]An individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

[c]According to HRSA, hospitals are exempt from this requirement. Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the health center program, but do not receive federal grants, are referred to as look-alikes and are eligible to participate in the 340B Program.

Contract Pharmacies

Covered entities may choose to dispense 340B drugs they purchase through contract pharmacies. The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance. HRSA's original guidance permitting the use of contract pharmacies limited their use to entities that did not have in-house pharmacies and allowed each entity to contract with only one outside pharmacy.[22] However, March 2010 guidance lifted the restriction on the number of pharmacies with which a covered entity could contract.[23] Since that time, the number of contract pharmacies has increased more than fifteen-fold, from about 1,300 to approximately 20,000. According to HRSA guidance, a covered entity is required to have a written contract in place with each pharmacy through which it intends to dispense 340B drugs, but is not

[22]See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43551, 43555 (Aug. 23, 1996).

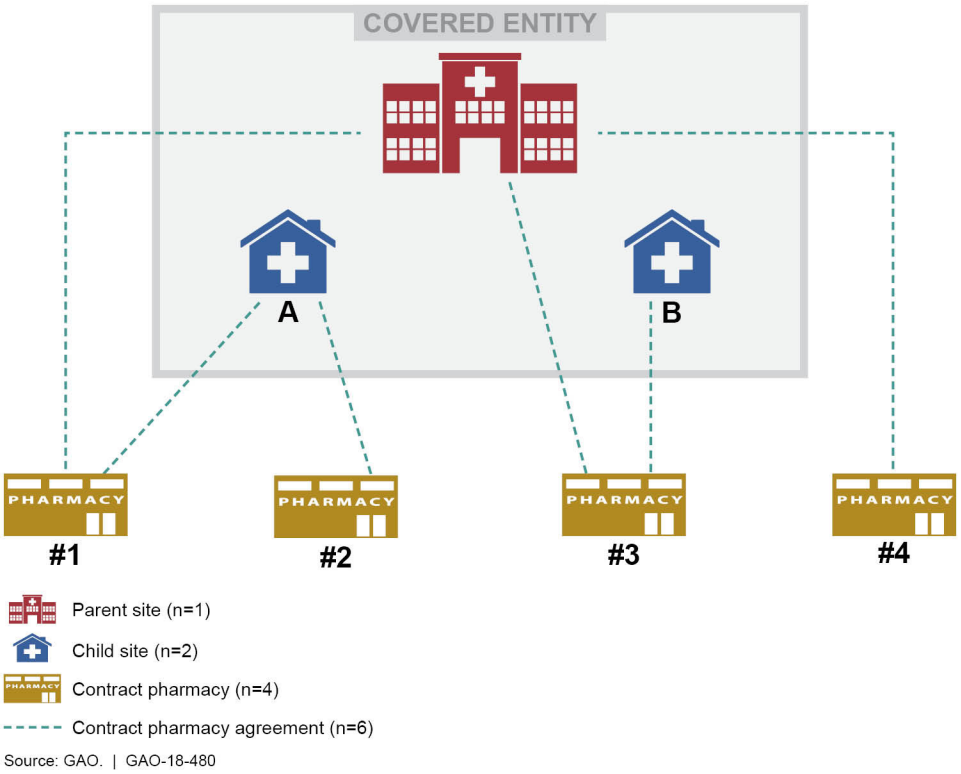
[23]See Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272, 10277 (Mar. 5, 2010).

generally required to submit its pharmacy contracts to HRSA.[24] A covered entity that has more than one site at which it provides health care may enter into separate pharmacy contracts for the parent site and each child site, or one comprehensive pharmacy contract including all sites intending to use the pharmacy.[25] It is up to the covered entity to determine which of its sites will be included in a contract with a pharmacy, and thus have what is referred to as a contract pharmacy arrangement with that pharmacy. Figure 2 provides an illustration of a covered entity that has four contract pharmacies but a total of six contract pharmacy arrangements, as not all of the entity's sites have contracts with each of the pharmacies.

[24]HRSA's guidance specifies that contracts must be provided to HRSA upon request. HRSA obtains copies of a small number of covered entities' pharmacy contracts. Specifically, HRSA collects contracts for covered entities that are audited, and in fiscal year 2017, began collecting contracts for 5 percent of new pharmacy registrations.

[25]Similarly, a contract can include multiple pharmacies from the same company, or a covered entity could have a separate contract with each pharmacy.

Figure 2: Illustrative Example of a 340B Program Contract Pharmacy Arrangement



Covered entities that choose to have contract pharmacies are required to register with HRSA the names of each of the pharmacies with which they contract. Covered entities may register their contract pharmacies in one of two ways: 1) only in relation to the parent site (use by child sites would be allowed as long as the sites were included in a comprehensive contract between the entity and the contracted pharmacies); or 2) separately for each site (parent and child) involved in a contractual arrangement with the pharmacy. As part of this registration, HRSA guidance specifies that covered entities must certify that they have signed and have in effect an agreement with each contract pharmacy and have a

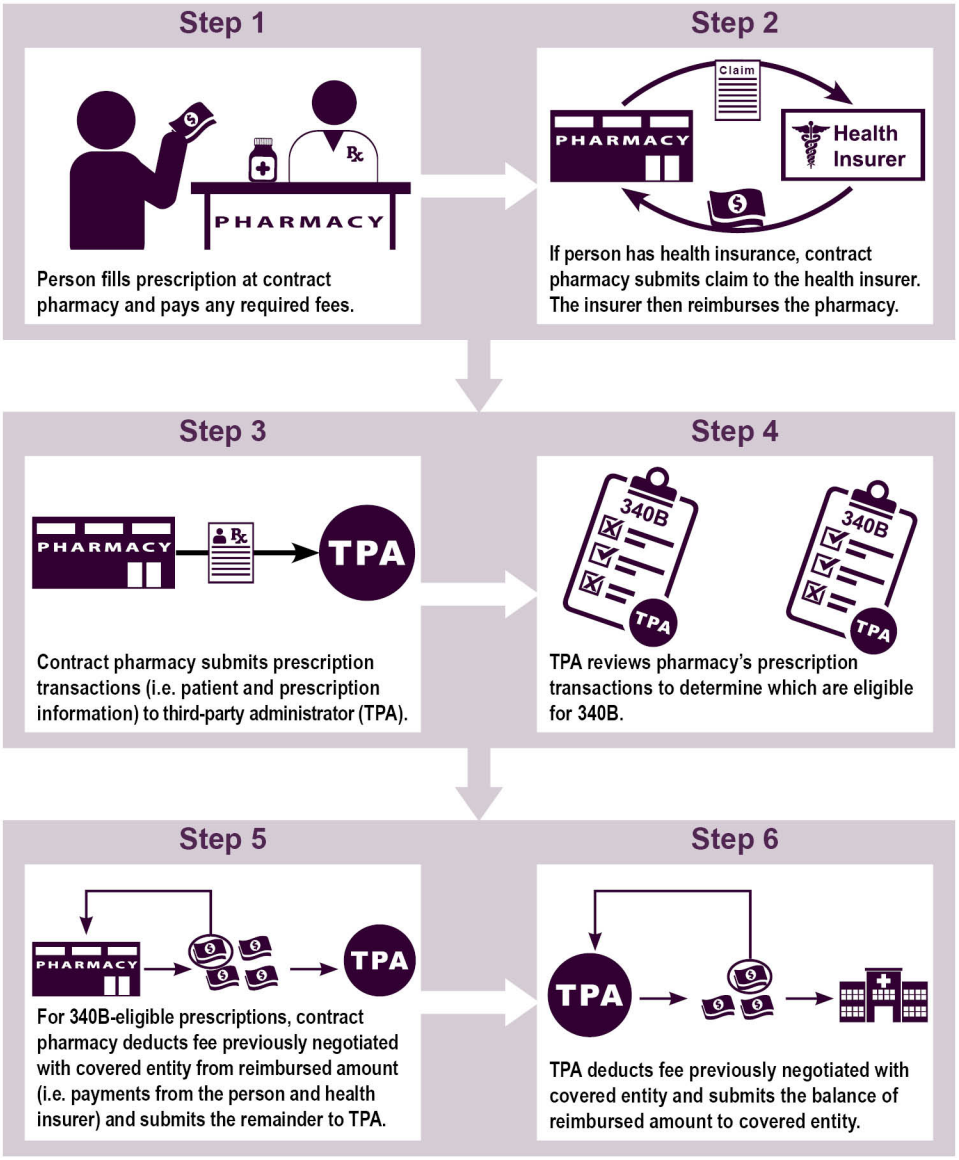
plan to ensure compliance with the statutory prohibitions on 340B drug diversion and duplicate discounts at their contract pharmacies.[26]

Like other pharmacies, when contract pharmacies fill prescriptions, they collect payments from the patient; if the patient has health insurance, the pharmacy will bill the insurer for the drug. In addition, each covered entity must determine which prescriptions are for eligible patients of the entity, and thus, can be filled with 340B drugs. One way that a covered entity could choose to do this is to employ a TPA to review all the prescriptions filled by a contract pharmacy to determine which, if any, prescriptions were issued by the covered entity to an eligible patient, and thus are eligible for the 340B discount. The covered entity then pays both the contract pharmacy and the TPA fees that they have negotiated for their roles in managing and distributing 340B drugs.[27] These fees are typically deducted from the reimbursed amounts received from patients and their health insurers by the pharmacy and TPA, and then the balance is forwarded to the covered entity. (See fig. 3 for an example of how covered entities work with contract pharmacies and TPAs to dispense 340B drugs.)

[26]For a contract pharmacy to dispense 340B drugs to patients covered under Medicaid fee-for-service, HRSA guidance requires that the covered entity, the contract pharmacy, and the state Medicaid agency have an agreement in place to prevent duplicate discounts and report the agreement to HRSA. 75 Fed. Reg. 10278 (Mar. 5, 2010).

[27]The 340B Program statute does not impose any requirements or limitations on the fees that covered entities may pay their contract pharmacies or TPAs.

Figure 3: Example of How Covered Entities, Contract Pharmacies, and Third-Party Administrators Work Together to Dispense 340B Drugs



Source: GAO. | GAO-18-480

Note: Not all covered entities employ a TPA to help manage the dispensing of 340B drugs at contract pharmacies; entities that do not may have their own staff perform the TPA duties depicted in the illustration.

HRSA's Oversight of Covered Entities

In fiscal year 2012, HRSA implemented a systematic approach to conducting audits of covered entities that is outlined on its website. HRSA has increased the number of covered entities audited since it began audits in fiscal year 2012, and now audits 200 entities per year. (See table 2.) HRSA's audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year), and covered entities that are targeted based on information from stakeholders such as drug manufacturers (10 percent of the audits conducted).[28] The criteria for risk-based audits include a covered entity's volume of 340B drug purchases, number of contract pharmacies, time in the 340B Program, complexity of its program, and history of violations or allegations of noncompliance associated with diversion and duplicate discounts.

Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), by Fiscal Year

Fiscal year	Number of audits	Percent of covered entities audited[a]
2012	51	0.5
2013	94	0.9
2014	99	0.9
2015	200	1.7
2016	200	1.7
2017	200	1.6

Source: GAO analysis of HRSA data. | GAO-18-480

[a]Determined using the number of covered entities as of January 1 of each fiscal year.

Among other things, HRSA's audits include reviews of each covered entity's policies and procedures, including those for overseeing contract pharmacies; an assessment of the entity's compliance with respect to 340B eligibility status, the prevention of duplicate discounts and diversion, and other program requirements; and reviews of a sample of prescriptions filled during a 6-month period, including prescriptions dispensed by contract pharmacies, to identify instances of non-compliance. As a result of the audits conducted, HRSA has identified instances of non-compliance with program requirements, including violations related to drug diversion and the potential for duplicate

[28]Targeted audits also include covered entities selected for a follow-up audit by HRSA as a result of findings from a prior audit. These are referred to as re-audits.

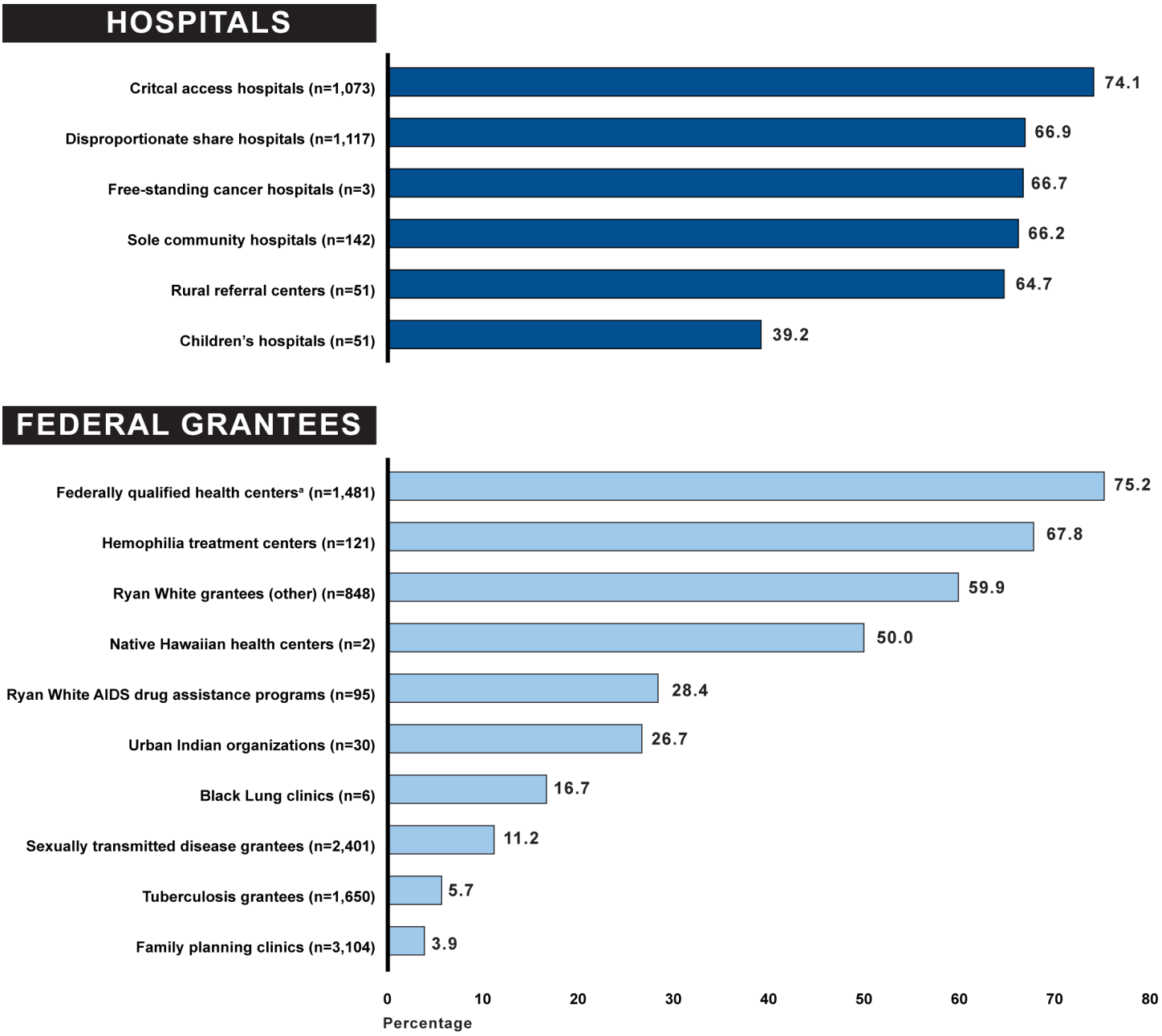
discounts.[29] Based on the audits for which results were posted on HRSA's website as of February 8, 2018, 72 percent of the covered entities audited in fiscal years 2012 through 2017 had one or more findings of noncompliance. When an audit of a covered entity has a finding of noncompliance, covered entities are required to submit a corrective action plan within 60 days of the audit being finalized for HRSA approval. HRSA closes out the audit once the entity attests that the corrective action plan has been fully implemented and any necessary repayments have been made to affected manufacturers.

About One-Third of Covered Entities Had One or More Contract Pharmacies, and Pharmacy Characteristics Varied

As of July 1, 2017, about one-third of the more than 12,000 covered entities in the 340B Program had contract pharmacies, but the extent to which covered entities had contract pharmacies varied by type of entity. Overall, a higher percentage of hospitals (69.3 percent) had at least one contract pharmacy compared to federal grantees (22.8 percent). Among the six types of hospitals, the percentage that had at least one contract pharmacy ranged from 39.2 percent of children's hospitals to 74.1 percent of critical access hospitals. Among the 10 types of federal grantees, the percentage with at least one contract pharmacy ranged from 3.9 percent of family planning clinics to 75.2 percent of FQHCs (see fig.4).

[29]The audits review covered entities' policies and practices to see if the potential for duplicate discounts exists. However, in order to determine whether duplicate discounts have actually occurred, a covered entity must check with its state Medicaid agency to see if it has received rebates for the same drugs for which the entity received a discounted price.

Figure 4: Percent of Covered Entities That Had at Least One Contract Pharmacy as of July 1, 2017, by Entity Type



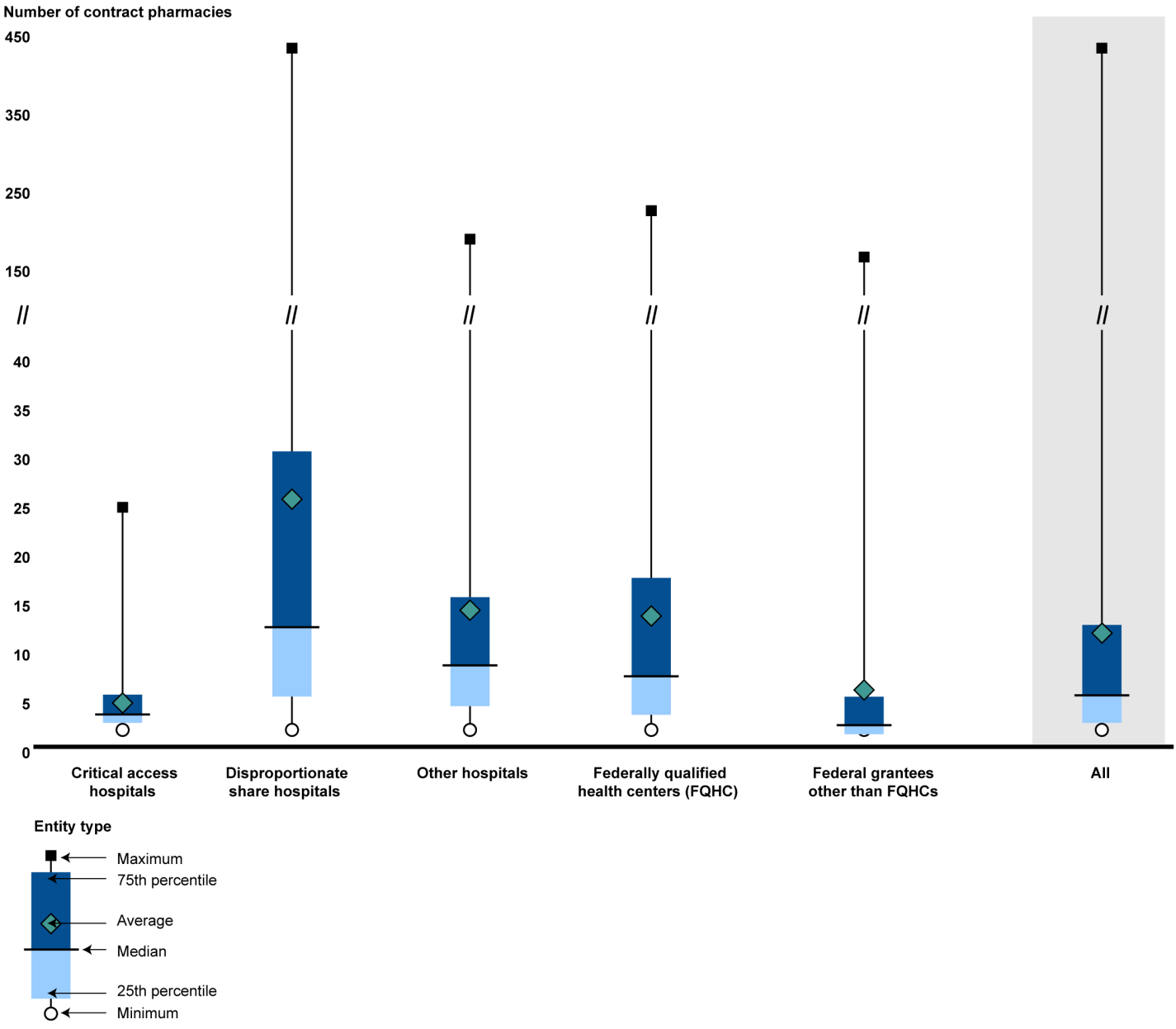
Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

[a]Not all federally qualified health centers (FQHCs) receive federal grants. Providers that meet all of the requirements for the FQHC program, but do not receive federal grants, are referred to as FQHC look-alikes and are eligible to participate in the 340B Program.

Among covered entities that had at least 1 contract pharmacy, the number of contract pharmacies ranged from 1 to 439, with an average of 12 contract pharmacies per entity. However, the number of contract pharmacies varied by covered entity type, with disproportionate share hospitals having the most on average (25 contract pharmacies), and critical access hospitals having the least (4 contract pharmacies).[30] (See fig. 5 for the distribution of contract pharmacies by covered entity type.) However, we found that a covered entity that contracts with a pharmacy may not actually use the pharmacy to dispense 340B drugs. For example, three covered entities that received our questionnaire told us that although they had one or more contract pharmacies registered with HRSA, they did not use those pharmacies to dispense 340B drugs. Moreover, officials from a covered entity we interviewed reported that while the entity maintained a contract with a specialty pharmacy, it had not dispensed 340B drugs through that pharmacy in several years. Officials explained that the covered entity maintained its contract and continued to register this pharmacy with HRSA because it would be financially beneficial should it have a patient fill a 340B-eligible specialty drug at this pharmacy in the future.

[30]Covered entities that are hospitals or FQHCs may register multiple sites as part of the entity. Across these types of covered entities, the average number of contract pharmacies per entity site ranged from a minimum of about two per critical access hospital site to a maximum of about four per disproportionate share hospital site.

Figure 5: Distribution of Contract Pharmacies as of July 1, 2017, by Covered Entity Type



Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

The actual number of 340B contract pharmacy arrangements—the number of contractual arrangements between contract pharmacies and the sites of a covered entity—is unknown because HRSA does not

require a covered entity to register pharmacies with each of its child sites. Rather, HRSA gives covered entities the option to register contract pharmacies only in relation to the parent site: child sites may use that pharmacy if included in the written contract between the entity and the pharmacy.[31] Based on our analysis of HRSA data, 1,645 covered entities that had at least one child site registered their contract pharmacies only with their parent sites. These 1,645 covered entities had a total of 25,481 registered contract pharmacy arrangements.[32] However, if the pharmacies were contracted to work with all of the covered entities' sites—the parents and all the child sites—then these 1,645 entities could have as many as 866,388 contract pharmacy arrangements.[33] Therefore, the number of contract pharmacy arrangements is likely higher than what is reported in HRSA's database.

Nearly 93 percent of the approximately 20,000 pharmacies that 340B covered entities contracted with as of July 1, 2017, were classified as community/retail pharmacies, less than 1 percent were classified as specialty pharmacies, and about 7 percent were other types of pharmacies including institutional and mail order pharmacies.[34] Furthermore, the majority (75 percent) of 340B contract pharmacies were chain pharmacies, while 20 percent were independent pharmacies and 5

[31]As previously noted, HRSA does not require covered entities to submit copies of all of their pharmacy contracts.

[32]Since the same pharmacy may have a contract to work with multiple covered entities, the number of contract pharmacy arrangements is more than the number of pharmacies that serve as 340B contract pharmacies.

[33]To determine the total possible number of arrangements, for each of the 1,645 covered entities that had multiple sites and registered their contract pharmacies only with their parent sites, we multiplied the number of sites by the number of contract pharmacies each covered entity registered with HRSA. We then summed the numbers for the 1,645 covered entities. For example, a covered entity that had five sites and 10 contract pharmacies registered only with the parent site (for a total of 10 registered contract pharmacy arrangements) could actually have a total of 50 possible arrangements.

[34]Community/retail pharmacies are defined by DataQ as those where pharmacists prepare and dispense drugs for a local patient population, counsel patients, administer vaccinations, and provide other professional services associated with pharmaceutical care such as health screenings. Specialty pharmacies are defined as pharmacies that dispense low-volume and high-cost drugs to patients undergoing intensive therapies for illnesses that are generally chronic, complex and potentially life threatening. Some of the pharmacies categorized as community/retail pharmacies may also dispense such high-cost drugs. Other pharmacies also include those where the type is unknown. About one-tenth of one percent of all contract pharmacies (26 pharmacies) were mail order pharmacies.

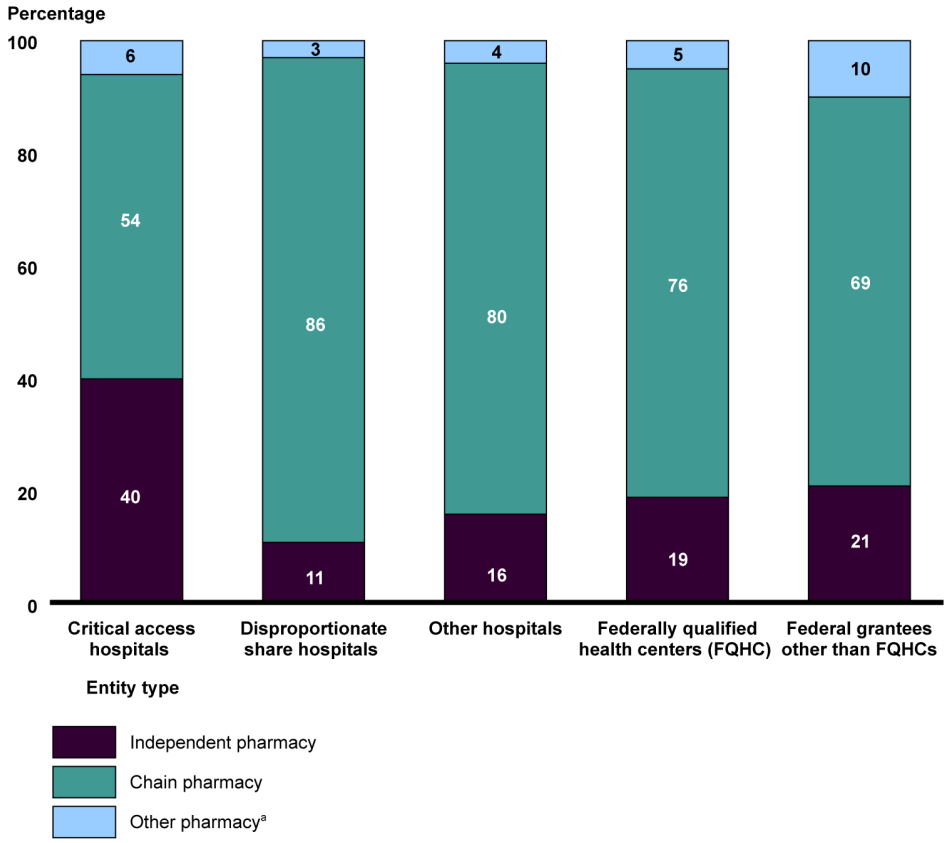
percent were other pharmacies.[35] In contrast, slightly over half of all pharmacies nationwide are chain pharmacies and about one-third are independent. The five biggest pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—represented a combined 60 percent of 340B contract pharmacies, but only 35 percent of all pharmacies nationwide.[36] Figure 6 shows how the types of pharmacies varied by type of covered entity. Critical access hospitals had a higher proportion of independent contract pharmacies (40 percent of their pharmacies) compared to other covered entity types (which ranged from 11 percent for disproportionate share hospitals to 21 percent for other federal grantees). Our analysis suggests that this is likely due, in part, to a larger proportion of critical access hospitals compared to other types of covered entities being located in rural areas; independent contract pharmacies are also more likely than other contract pharmacies to be located in rural areas.[37]

[35]Chain pharmacies are defined by DataQ as those in which four or more pharmacies are under common ownership, while independent pharmacies have three or less locations under the same ownership or are independent pharmacies that have signed a franchisor agreement. Other pharmacies include government pharmacies, alternative dispensing sites such as physician's offices, and pharmacies for which the type of pharmacy was unknown.

[36]Walgreens alone accounted for 31 percent of 340B contract pharmacies. Walgreens pharmacies account for only about 10 percent of all pharmacies nationwide.

[37]We used the addresses from the 340B database, along with the Rural Urban Commuting Area—a system for geographic classification, to determine whether covered entities and pharmacies were located in rural or urban areas.

Figure 6: Percent of 340B Program Contract Pharmacies by Pharmacy and Covered Entity Type, as of July 1, 2017



Source: GAO analysis of Health Resources and Services Administration data and DataQ data. | GAO-18-480

Note: We used the National Council for Prescription Drug Programs' DataQ to identify pharmacy type. DataQ is a database from the National Council for Prescription Drug Programs, which contains information reported by pharmacies that is used by health care payers and claims processors across the country to identify pharmacies.

[a]"Other pharmacy" includes government pharmacies, alternative dispensing sites—such as physician offices, and pharmacies for which the type of pharmacy was unknown.

Across all covered entities, the distance between the entities and their contract pharmacies ranged from 0 miles (meaning that the contract pharmacy and entity were co-located) to more than 5,000 miles; the

median distance was 4.2 miles.[38] Table 3 shows the distribution of distances between covered entities and their pharmacies overall and by entity type.

Table 3: Distance (in Miles) between Covered Entities and Their Contract Pharmacies as of July 1, 2017, by Entity Type

Entity type	Minimum	25th percentile	Median	75th percentile	Maximum
Disproportionate share hospitals	0	1.5	4.7	25.4	5,052
Critical access hospitals	0	0.6	3.6	28.7	2,495
Other hospitals	0	1.5	5.9	35.7	3,422
Federally qualified health centers (FQHC)	0	0.8	2.4	7.0	4,666
Federal grantees other than FQHCs	0	4.6	19.9	123.7	2,711
All entities	0	1.2	4.2	20.7	5,052

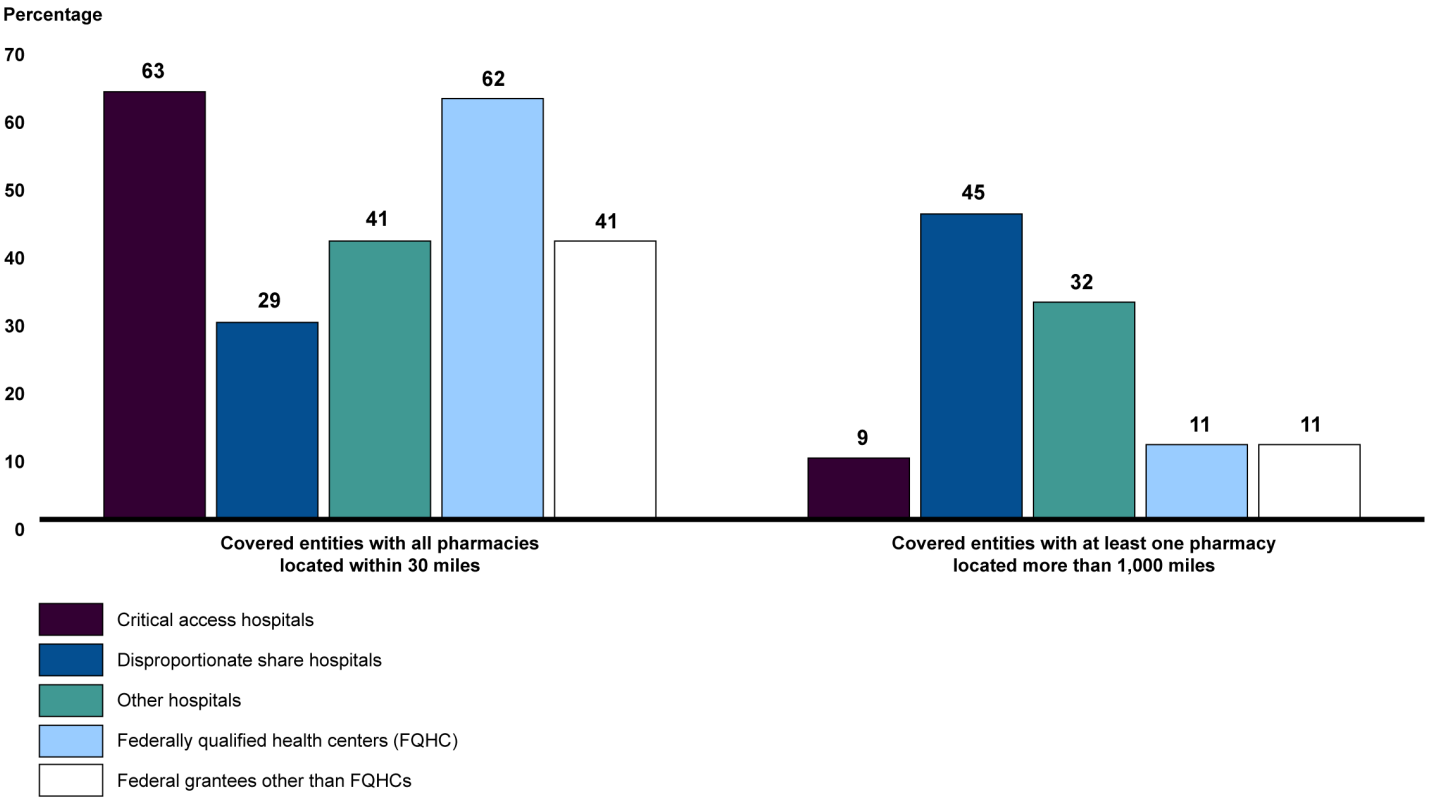
Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

Note: Distance was measured from the contract pharmacy to the closest site of the entity. Mail order pharmacies were excluded from distance calculations.

While there was a range in distances between covered entities and each of their pharmacies, about half of the entities had all their contract pharmacies located within 30 miles, but this varied by entity type. Specifically, more than 60 percent of critical access hospitals and FQHCs had all of their contract pharmacies within 30 miles. In contrast, 45 percent of disproportionate share hospitals had at least one pharmacy that was more than 1,000 miles away compared to 11 percent or less for grantees and critical access hospitals. (See fig. 7.)

[38]Distance between a covered entity and its contract pharmacies was measured from the pharmacy to the closest site of the entity. We excluded mail order pharmacies from distance calculations. The maximum distance across all covered entities was for a disproportionate share hospital located in Connecticut that contracted with a pharmacy in Hawaii. The 340B database does not provide information on why a covered entity may choose to contract with a pharmacy that is located a long distance away. When asked why contract pharmacies may be located many miles away from the covered entity, HRSA officials indicated that the pharmacies may provide prescriptions by mail (even if they are not classified as mail order pharmacies) or dispense specialty drugs. In addition, HRSA officials noted that some covered entities may serve patients who live far away from the entity and thus have contracts with pharmacies located close to where their patients reside.

Figure 7: Percent of Covered Entities with Contract Pharmacies within Given Distances as of July 1, 2017, by Entity Type



Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

Note: Distance was measured from the contract pharmacy to the closest site of the covered entity. Mail order pharmacies were excluded from distance calculations.

Selected Covered Entities Used Various Methods to Pay Contract Pharmacies and TPAs

Contracts we reviewed between selected covered entities and contract pharmacies showed that entities generally agreed to pay their contract pharmacies a flat fee per 340B prescription, with some entities also paying additional fees based on a percentage of revenue. Selected covered entities and TPAs included in our review indicated two main methods entities use to pay for TPA services: 1) per prescription processed, or 2) per contract pharmacy.

Contracts Reviewed Showed Covered Entities Agreed to Pay Contract Pharmacies a Fee per 340B Prescription; Some Also Agreed to Additional Fees

Twenty-nine of the 30 contracts we reviewed between covered entities and contract pharmacies included provisions for the entities to pay flat fees for each eligible 340B prescription. For the remaining contract, the covered entity and the contract pharmacy were part of the same hospital system, and the contract provided that the entity would not pay fees for 340B prescriptions. In addition to payment of flat fees, 13 of the 29 contracts required the covered entity to pay the contract pharmacy a fee based on a percentage of revenue generated for each 340B prescription. Among the contracts we reviewed, more federal grantees than hospitals had contracts that included both flat fees and fees based on the percentage of revenue (see fig. 8).

Figure 8: Types of Fees Included in Selected Contracts between Covered Entities and Pharmacies, by Entity Type

Source: GAO review of selected 340B contracts. | GAO-18-480

Note: We reviewed a total of 30 contracts between covered entities and pharmacies that HRSA collected during audits of entities between fiscal years 2014 and 2016. One contract was between a covered entity and a pharmacy that were part of the same hospital system, which did not require the entity to pay fees for 340B prescriptions. As a result, the total number of contracts we reviewed with fees was 29.

Example of Fees between a Covered Entity and Contract Pharmacy

In the hypothetical example below, the contract pharmacy receives a total reimbursement of $100 for providing an eligible patient with a 340B drug. Pursuant to a contract with the covered entity, the contract pharmacy deducts its fee of $15, and forwards the remaining balance of $85 to the third-party administrator (TPA).

Source: GAO. | GAO-18-480

We found a wide range in the amount of flat fees covered entities agreed to pay pharmacies in the contracts we reviewed, though they generally ranged from $6 to $15 per 340B prescription.[39] (See Appendix I for a description of fees listed in each of the contracts we reviewed.) The amount of the flat fees per 340B prescription varied by several factors according to our review, including covered entity type, type of drug, and patient insurance status:

- **Flat fees were generally higher for hospitals than federal grantees.** In general, hospitals' flat fees were higher than those for grantees, with most flat fees ranging from $15 to $25 per 340B prescription for hospitals, compared to from $6 to $13 for grantees.
- **Flat fees were sometimes higher for brand drugs.** Three of the 29 contracts we reviewed specified different flat fees for brand and generic drugs. In 2 of these contracts flat fees were $5 or $7 higher for brand drugs. In the remaining contract, the fees for some brand drugs were substantially higher, ranging from $75 to $1,750 for brand drugs, compared to $0 for generic drugs. Additionally, some contracts we reviewed only specified a fee for brand drugs, and 4 of the contracts either excluded generic drugs from being purchased at the 340B price or limited the use of the 340B Program to brand drugs.
- **Flat fees were different or substantially higher for certain specialty drugs.** For 2 of the 29 contracts we reviewed, flat fees were for drugs to treat hemophilia.[40] Given the different nature of hemophilia treatment drugs, fees for these drugs were different than those in the other contracts for other types of drugs, and provided for payments of $.06 and $.09 per unit of blood clotting factor. Additionally, 2 contracts contained substantially higher flat fees for specialty medications. In 1 contract, the flat fees were $125 per prescription for brand and generic human immunodeficiency virus drugs, and $1,750 for brand hepatitis C drugs. In another contract the flat fees were $65 for all specialty drugs, compared to $13 for other drugs.

[39]Overall, the flat fees ranged from $0 to $1,750 per eligible 340B prescription. Both ends of this range came from the same contract, which provided for a flat fee of $0 for some generic drugs, but included higher fees for other drugs, including a fee of $1,750 for brand drugs used to treat hepatitis C.

[40]Hemophilia is a bleeding disorder in which the blood does not clot normally. The main treatment for the disease is to provide patients with infusions of blood clotting factor containing a protein to aid in clotting.

- **Flat fees were sometimes higher for 340B prescriptions dispensed to patients with insurance.** Seven of the 29 contracts we reviewed specified different flat fees for prescriptions provided to patients with health insurance than for patients paying with cash or through a drug discount card provided by the covered entity.[41] The flat fees entities would pay under these contracts ranged from $1 to $16 higher per 340B prescription dispensed to insured patients compared to patients not using insurance.

As previously noted, in addition to requiring flat fees for dispensing prescriptions, 13 of the 29 contracts we reviewed included provisions for the covered entity to pay the pharmacy a fee based on the percentage of revenue generated by each prescription. These percentage fees only applied to prescriptions provided to patients with insurance, and ranged from 12 to 20 percent of the revenue generated by the prescriptions. Generally there were two methods for determining the amount of revenue generated. The first method used the reimbursement the pharmacy received for the prescription, while the second method used the net revenue after subtracting the 340B cost of the drug from the reimbursement received by the pharmacy.[42]

Selected Covered Entities Use Two Main Methods to Pay TPAs

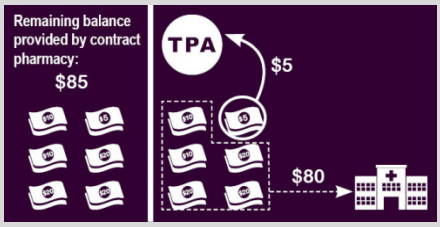
Officials from the two TPAs we interviewed and questionnaire respondents from the 39 covered entities that use TPAs described two main methods entities use to reimburse TPAs for 340B services: 1) a fee for each prescription processed by the TPA, and 2) a fee for each contract pharmacy for which the TPA processes 340B claims on behalf of the entity.

[41]Six of these contracts between grantees and a contract pharmacy had provisions for patients to use a drug discount card provided by the grantee to pay for prescriptions. When presented at the pharmacy, the pharmacy uses the discount card to verify the patient is 340B eligible and determine the amount the patient pays for the prescription.

[42]Some contracts included applicable patient copayments as part of the reimbursement, while others just used the reimbursement received from the patient's health insurance.

Example of Fees between a Covered Entity and Third-Party Administrator (TPA)

In the hypothetical example below, the TPA receives $85 from the contract pharmacy. This amount represents the total reimbursement for the 340B drug, less fees deducted by the contract pharmacy. Pursuant to an agreement with the covered entity, the TPA deducts a fee of $5, and forwards the remaining balance of $80 to the covered entity. This represents the total revenue the covered entity generated from the 340B drug.



Source: GAO. | GAO-18-480

Officials with the two TPAs we interviewed told us that their agreements with covered entities most frequently involve covered entities compensating them based on a fee for each prescription they process on behalf of the entity. Officials from one of these TPAs described three different fee-per-prescription options they offer to covered entities, with the amount of the fees varying based on the option selected:

- A small fee, for example, 20 cents, for every prescription filled by the covered entity's contract pharmacy, and reviewed and processed by the TPA. This includes prescriptions that may not have originated from the covered entity, and may not be 340B eligible, as contract pharmacies can also fill prescriptions for individuals who are not patients of the entity.
- A mid-sized fee, for example, $1.90, for each prescription filled by the covered entity's contract pharmacy that the TPA reviewed and determined originated from the covered entity. These prescriptions may or may not be 340B eligible.
- A larger fee, for example, $5 to $7, for each prescription filled by the covered entity's contract pharmacy that the TPA determined originated from the entity and is 340B eligible.

The 39 covered entities that responded to our questionnaire and reported using a TPA most frequently reported paying their TPAs a fee per each prescription processed, but the exact method varied. For example, some covered entities said they paid their TPAs for each prescription regardless of whether it was determined to be 340B eligible, others limited the fees to prescriptions that were 340B eligible, and some reported paying TPAs for 340B-eligible prescriptions dispensed to an insured patient. (See table 4.)

Table 4: Examples of Methods Used by 39 Covered Entities to Pay Third-Party Administrators (TPA) for Reviewing and Processing 340B Prescriptions

Method used to pay TPA	Number of entities reporting this method
Per prescription processed, regardless of whether the prescription was 340B-eligible	16
Per 340B-eligible prescription processed and dispensed, regardless of the patient's insurance status	15
Flat fee per contract pharmacy for which the TPA has administration responsibilities	11
Per 340B-eligible prescription processed and dispensed to an insured patient	8
Percentage of the difference between the 340B price and the reimbursement received for the drug	7
Per 340B-eligible prescription processed and dispensed to an insured patient and a percentage of the difference between the 340B price and the reimbursement received for the drug	2
Flat fee (e.g., fee per month)	3

Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, and 39 said they used TPAs to review and process 340B prescriptions. Several of the covered entities indicated that they used more than one method to pay TPAs for their services, thus the numbers in the table will not add to 39.

Among the 10 covered entities we interviewed, officials from 8 of these entities said they used TPAs; 5 said they pay their TPAs a fee per prescription, 1 reported paying a fee per contract pharmacy, and 2 reported using both options.[43] Among the covered entities that used fees per prescription and told us the amounts of the fees they pay, the fees ranged from $3.50 to $10.00 per 340B eligible prescription or $3.95 per prescription regardless of whether the prescription was 340B eligible.[44]

[43]For the two covered entities that reported using both methods to pay their TPAs, one had two TPAs, each of which they paid using a different method, while the other said it paid the TPA differently for each of its contract pharmacies.

[44]Five of the seven covered entities that reported paying their TPA a fee per prescription provided information on the amount of that fee, one of which said it paid a fee regardless of whether the prescription was 340B eligible.

For those that pay their TPA a fee per contract pharmacy, the fee was $25,000 a year per pharmacy.[45]

About Half of the Covered Entities Reviewed Provided Low-Income, Uninsured Patients Discounts on 340B Drugs at Some or All of Their Contract Pharmacies

Of the 55 covered entities responding to our questionnaire, 30 reported providing low-income, uninsured patients discounts on 340B drugs dispensed at some or all of their contract pharmacies, and 25 said they did not offer discounts at their contract pharmacies.[46] All 30 covered entities providing patients with discounts reported providing discounts on the drug price for some or all 340B drugs dispensed at contract pharmacies.[47] Federal grantees were more likely than hospitals to provide such discounts and to provide them at all contract pharmacies (see fig. 9).[48]

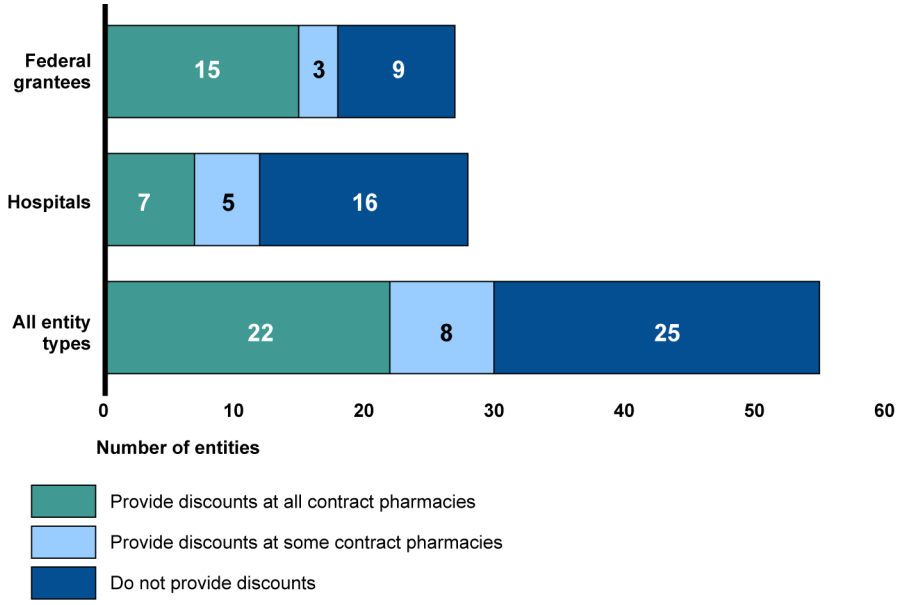
[45]Two of the three covered entities that reported paying their TPA a fee per pharmacy provided information on the amount of that fee. One of those covered entities split the fee with other covered entities that were part of the same hospital system, and thus was responsible for a smaller portion of the fee.

[46]In contrast, 17 of the 23 covered entities that had in-house pharmacies reported offering discounts at those pharmacies, including 4 entities that did not offer discounts at their contract pharmacies.

[47]In our questionnaire, a discount on the drug price was defined as charging the patient less than the wholesale price—the price that a wholesaler charges a pharmacy for a drug—or what a self-paying patient would pay.

[48]While not a requirement of the 340B Program, covered entities that became eligible for the program as a result of being federal grantees may have requirements as part of their grants related to the use of 340B revenue or the provision of discounts to patients.

Figure 9: Number of Selected Covered Entities that Reported Providing Discounts to Low-Income, Uninsured Patients on the Price of 340B Drugs Dispensed at Contract Pharmacies, by Entity Type

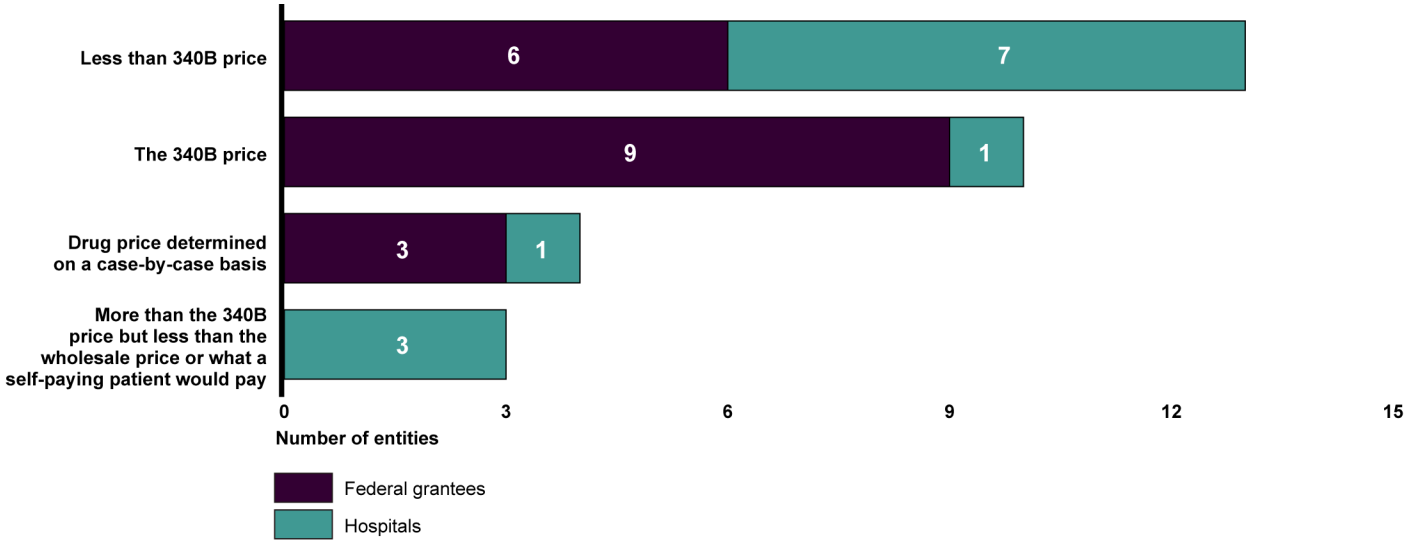


Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities; 55 entities responded.

Of the 30 covered entities that responded to our questionnaire that they provided discounts on the drug price, 23 reported providing patients the full 340B discount—the patients obtained drugs from contract pharmacies at the 340B price or less. In many cases, these covered entities indicated that patients received drugs at no cost. Some covered entities reported that patients would pay more than the 340B price, but less than the wholesale price of the drug or what a self-paying patient would pay, and others indicated they determined discounts for patients on a case-by-case basis. A larger number of federal grantees than hospitals (15 compared to 8) indicated their patients would pay the 340B price or less for their drugs at contract pharmacies where discounts were available. (See fig. 10.)

Figure 10: Prices Patients Pay for 340B Drugs for 30 Covered Entities That Reported Providing Discounts at Their Contract Pharmacies, by Entity Type



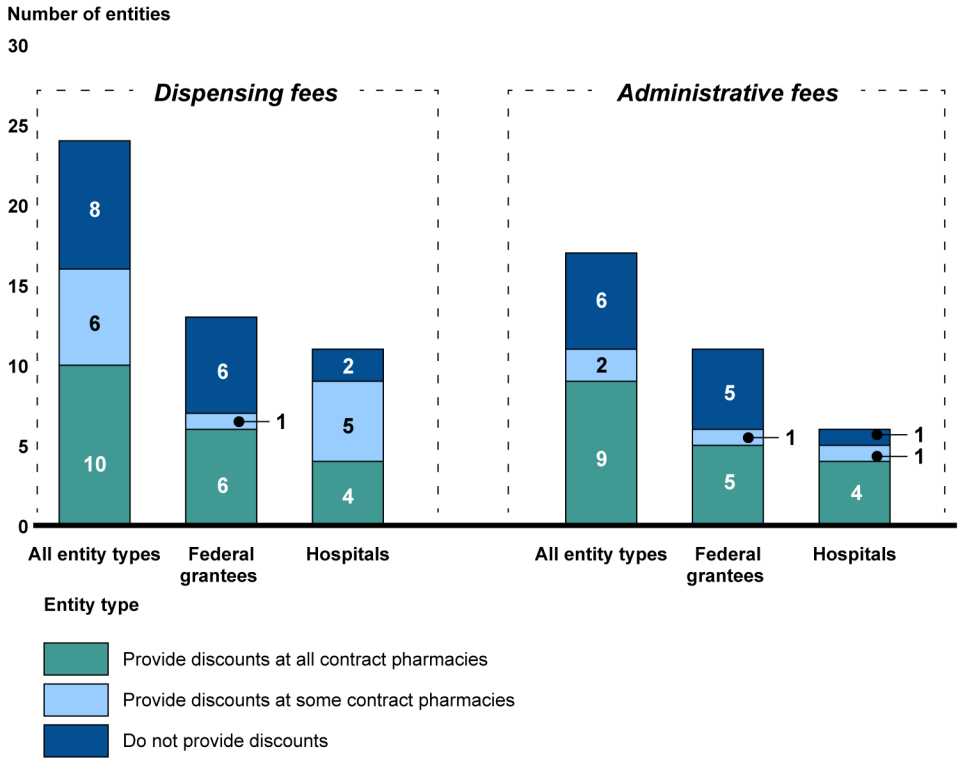
Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients.

In addition to providing discounts on the 340B drug price, some of the 30 covered entities also reported providing discounts on fees patients may pay to contract pharmacies for 340B drugs. Contract pharmacies may charge fees to dispense 340B drugs or cover administrative costs of participating in a covered entity's 340B program, including costs associated with tracking drug inventories and ordering new drugs.[49] In general, about two-thirds of the covered entities with patients who would be subject to dispensing or administrative fees at contract pharmacies reported providing discounts on the fees at some or all of their contract pharmacies. Hospitals were more likely than grantees to provide discounts on these fees when applicable. (See fig.11.)

[49]Six of the 30 covered entities indicated they did not charge patients dispensing fees through their contact pharmacies, and 13 did not charge administrative fees. Therefore, discounts on dispensing fees could be applicable to 24 covered entities (13 federal grantees and 11 hospitals), and discounts on administrative fees could be applicable to 17 covered entities (11 federal grantees and 6 hospitals).

Figure 11: Number of Selected Covered Entities That Reported Providing Discounts on Dispensing and Administrative Fees at Contract Pharmacies, by Entity Type



Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities, and 55 provided responses. Data shown are for the 30 covered entities that reported providing discounts to low-income, uninsured patients at contract pharmacies. Six of the 30 covered entities indicated they did not charge patients dispensing fees through their contact pharmacies, and 13 did not charge administrative fees. Therefore, discounts on dispensing fees could be applicable to 24 covered entities, and discounts on administrative fees could be applicable to 17 covered entities.

The 30 covered entities providing 340B discounts to low-income, uninsured patients reported using a variety of methods to determine whether patients were eligible for these discounts. Fourteen of the covered entities said they determined eligibility for discounts based on whether a patient's income was below certain thresholds as a percentage of the federal poverty level, 11 reported providing discounts to all patients, and 5 said they determined eligibility for discounts on a case-by-case basis. For those 14 covered entities determining eligibility based on income as a percentage of the federal poverty level, the threshold used to determine who was eligible for discounts varied but most reported that

patients with incomes at or below 250 percent of the federal poverty level would be eligible for discounts. (See table 5.)

Table 5: Income Thresholds Used by Selected Covered Entities to Determine Eligibility for 340B Discounts, by Entity Type

Income threshold as a percent of the federal poverty level	Number of federal grantees	Number of hospitals	Total number of entities
100	2	0	2
200	4	1	5
225	0	1	1
250	0	2	2
300	1	1	2
350	0	1	1
500	1	0	1
Total	**8**	**6**	**14**

Source: Responses to GAO's questionnaire to 340B covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients. Of those 30 covered entities, 14 reported determining eligibility for discounts based on a patient's income as a percentage of the federal poverty level. In 2018, the federal poverty level in the continental United States was $25,100 a year for a family of four.

Covered entities reported making patients aware of the availability of discounts at contract pharmacies primarily through oral communication by staff located at either the entity or the pharmacy. In addition, the covered entities reported using a variety of methods to inform contract pharmacies about which patients were eligible for discounts, including through notes in patient medical records sent to the pharmacy or by placing codes on the patient's prescriptions sent to or presented at the pharmacy. (See table 6.) Officials from one covered entity we interviewed said that it provides patients eligible for discounts with an identification card (which they referred to as a drug discount card) that patients present at the contract pharmacy; this card informs pharmacy staff of the specific discount amount. Officials from another covered entity said they place codes on electronic prescriptions which informs the pharmacy about discounts.

Table 6: Examples of Methods Used by 30 Covered Entities to Inform Contract Pharmacies of Patients' Eligibility for Discounts

Method used by covered entity	Number of covered entities
Providing patient eligibility files or electronic medical records to pharmacy	11
Placing codes or annotations on electronic prescriptions with discount information	10
Relying on pharmacist familiarity with patients, providers and medications	8
Placing stamps or notations on paper prescription	6
Using identification cards with patient information	6
Providing patients with copayment assistance cards or debit cards to present at pharmacy	3

Source: Responses to GAO's questionnaire to 340B covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients. Twelve of the 30 covered entities reported using two or more methods to inform pharmacies about patients' eligibility for discounts, thus the numbers in the table do not add to 30.

Some covered entities that did not provide discounts on 340B drugs at their contract pharmacies reported assisting patients with drug costs through other mechanisms. For example, 6 of the 10 covered entities we interviewed said that while they did not provide discounts on 340B drugs dispensed at their contract pharmacies, they provide charity care to low-income patients, including free or discounted prescriptions. Additionally, 4 of the 25 covered entities that reported on our questionnaire that they did not provide discounts at their contract pharmacies said they provided patients with discounts on 340B drugs at their in-house pharmacies.

Oversight Weaknesses Impede HRSA's Ability to Ensure Compliance at 340B Contract Pharmacies

HRSA does not have complete data on the total number of contract pharmacy arrangements in the 340B Program to inform its oversight efforts, including information that could be used to better target its audits. Additionally, weaknesses in HRSA's audit process compromise its oversight of covered entities. Finally, the lack of specificity in HRSA's guidance to covered entities potentially impedes covered entities' oversight of contract pharmacies.

HRSA Does Not Have Complete Data on Contract Pharmacy Arrangements to Use for Its Oversight

HRSA does not have complete data on all contract pharmacy arrangements in the 340B Program to inform its oversight efforts. HRSA requires covered entities to register their contract pharmacies with the agency and recertify that registration annually. Contract pharmacies registered to each covered entity are recorded in a publicly available database, which according to HRSA, is used by various stakeholders to validate the eligibility of entities and confirm shipping addresses for each contract pharmacy eligible to receive 340B drugs on an entity's behalf. However, because covered entities differ in the way they register their contract pharmacies, HRSA, and its publicly available database, does not have information on all of an entity's contract pharmacy arrangements. Specifically, because HRSA does not require covered entities to separately register contract pharmacies to each child site for which a contractual relationship exists, HRSA does not have complete information on which sites of an entity have contracted with a pharmacy to dispense 340B drugs. Our analysis of HRSA data showed that the registration of contract pharmacies for 57 percent of covered entities with child sites only specified relationships between contract pharmacies and the parent site; thus HRSA may only have information on a portion of the actual number of 340B contract pharmacy arrangements. Additionally, manufacturers do not have complete information on which covered entity sites have contracts with a pharmacy to dispense 340B drugs, according to HRSA officials. Manufacturers could use such information to help ensure that 340B discounted drugs are only provided to pharmacies on behalf of a covered entity site with a valid 340B contract with that site.

HRSA officials told us that the number of contract pharmacy arrangements recorded in HRSA's database increases a covered entity's chance of being randomly selected for a risk-based audit. However, since HRSA gives covered entities multiple contract pharmacy registration options, the likelihood of an entity being selected for an audit is dependent, at least in part, on how an entity registers its pharmacies as opposed to the entity's actual number of pharmacy arrangements. Without more complete information on covered entities' contract pharmacy arrangements, HRSA cannot ensure that it is optimally targeting the limited number of risk-based audits done each year to entities with more contract pharmacy arrangements. Federal internal control standards related to information and communication state that management should use quality information to achieve the entity's objectives, such as by obtaining relevant data that are reasonably free from error and bias and represent what they purport to represent so that

they can be used for effective monitoring.[50] Without complete information on covered entities' use of contract pharmacies, HRSA does not have the information needed to effectively oversee the 340B Program, including information that could be used to better target its audits of covered entities.

Weaknesses in HRSA's Audit Process Impede Its Oversight of 340B Program Compliance at Contract Pharmacies

HRSA primarily relies on audits to assess covered entities' compliance with 340B Program requirements, including compliance at contract pharmacies, according to HRSA officials; however weaknesses in its audit process impede the effectiveness of its oversight.[51] As a result of its audits, HRSA has identified instances of diversion and the potential for duplicate discounts at contract pharmacies, among other findings of noncompliance. Specifically, through the audits conducted since fiscal year 2012, HRSA identified at least 249 instances of diversion at contract pharmacies and 15 instances of the potential for duplicate discounts for drugs dispensed at contract pharmacies, as of February 2018. HRSA had also identified 33 covered entities with insufficient contract pharmacy oversight. (See Table 7.)

[50]GAO-14-704G.

[51]In addition to audits, other mechanisms HRSA uses to oversee compliance at contract pharmacies include the agency's registration and annual recertification process; its collection of contracts for 5 percent of newly registered contract pharmacies; and its self-disclosure process, whereby covered entities can report any material compliance breaches, and steps to address the breach, to HRSA.

Table 7: Summary of Health Resources and Services Administration's (HRSA) Audit Findings Related to Contract Pharmacies, as of February 8, 2018

Fiscal Year	Diversion Findings			Duplicate Discount Findings			Contract pharmacy oversight findings
	Total	Number at contract pharmacies	Percent at contract pharmacies	Total	Number at contract pharmacies	Percent at contract pharmacies	
2012	**16**	9	56	**18**	3	17	0
2013	**52**	22	42	**25**	1	4	5
2014	**54**	38	70	**23**	1	4	9
2015	**95**	65	68	**46**	3	7	9
2016	**94**	64	68	**55**	6	11	7
2017[a]	**69**	51	74	**39**	1	3	3
Total	**380**	**249**	**66**	**206**	**15**	**7**	**33**

Source: GAO analysis of HRSA data. | GAO-18-480

Notes: A diversion finding indicates that a covered entity dispensed 340B drugs to an individual who did not meet HRSA's definition of a patient. A duplicate discount finding indicates the potential that drugs prescribed to Medicaid beneficiaries were subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. A contract pharmacy oversight finding indicates that a covered entity did not perform any type of oversight activities for its contract pharmacies.

[a]Data for fiscal year 2017 are not complete because not all audits had been closed at the time of our review—as of February 8, 2018. Therefore, the number of findings for that fiscal year could increase depending on the results of the remaining audits.

However, we identified two areas of weaknesses in HRSA's audit process that impede its oversight of covered entities' compliance with 340B Program requirements at contract pharmacies: 1) the process does not include an assessment of all potential duplicate discounts, and 2) the process for closing audits does not ensure all covered entities have fully addressed any noncompliance identified.

Medicaid Delivery Systems

States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, states reimburse providers directly for each service delivered. For example, a pharmacy would be paid by the state for each drug dispensed to a Medicaid beneficiary. Under a capitated managed care model, states typically contract with managed care organizations to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pays each organization a set amount per beneficiary per month to provide or arrange those services.

Source: GAO. | GAO-18-480

Not all potential duplicate discounts are assessed. HRSA's audits only assess the potential for duplicate discounts in Medicaid fee-for-service. They do not include a review of covered entities' processes to prevent duplicate discounts for drugs dispensed through Medicaid managed care.[52] The potential for duplicate discounts related to Medicaid managed care has existed since 2010 when manufacturers were required to pay Medicaid rebates under managed care, and currently, there are more Medicaid enrollees, prescriptions, and spending for drugs under managed care than fee-for-service.[53]

HRSA officials told us that they do not assess the potential for duplicate discounts in Medicaid managed care as part of their audits because they have yet to issue guidance as to how covered entities should prevent duplicate discounts in Medicaid managed care.[54] They agreed that the lack of Medicaid managed care guidance for covered entities was problematic, and HRSA's December 2014 policy release stated, "HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care, and is working with the Centers for Medicare & Medicaid Services (CMS) to develop policy in this regard."[55] According to HRSA, in the absence of formal guidance, covered entities should work with their states to develop strategies to prevent duplicate discounts in Medicaid managed care. However, 8 of the 10 covered entities we spoke with described challenges working with their

[52]While HRSA does not include an assessment for duplicate discounts related to Medicaid managed care claims as part of its audit process, beginning April 1, 2018, if the agency becomes aware of the potential for such duplicate discounts during the course of an audit, then it will note this in the audit report for the covered entity. If the audit of the covered entity results in findings, then the entity would be required to indicate how it will address the duplicate discounts.

[53]According to analysis from the Medicaid and CHIP Payment and Access Commission, in fiscal year 2016, almost 60 percent of Medicaid gross spending for drugs and almost 70 percent of Medicaid drug prescriptions were in managed care. Additionally, as of July 2015, about 65 percent of Medicaid enrollees received their medical care services through managed care.

[54]Federal law directs HRSA to provide guidance to covered entities regarding the prevention of duplicate discounts. 42 U.S.C. § 256b(d)(2)(B)(iii). In 1993, HRSA issued final guidance for the prevention of duplicate discounts in Medicaid fee-for-service, establishing that HHS will provide covered entity Medicaid provider numbers to the state Medicaid agencies on a regular basis. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (Jun. 23, 1993). This information is referred to as the Medicaid Exclusion File.

[55]See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014). CMS is the HHS agency responsible for overseeing state Medicaid programs.

states and local Medicaid managed care organizations to ensure that duplicate discounts were not occurring or expressed the need for more guidance from HRSA on how to comply with 340B requirements related to duplicate discount prevention. As a result of these challenges, some covered entities acknowledged that they did not have assurance that duplicate discounts were not occurring with their Medicaid managed care claims, while other entities told us that they did not seek discounts for the drugs of managed care patients due to compliance challenges.

Federal internal control standards related to control activities and monitoring state that agencies should 1) implement control activities through policies, such as by determining the necessary policies based on the objectives and related risks for the operational process; and 2) establish and operate monitoring activities to monitor the internal control system and evaluate results, such as by establishing and operating monitoring activities that are built into each entity's operations, performed continually, and responsive to change.[56] In addition, federal law directs the agency to develop detailed guidance describing methodologies and options for avoiding duplicate discounts.[57] Until HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance. As a result, manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions.

Audit closure process does not ensure all identified issues of noncompliance are addressed. Under HRSA's audit procedures, covered entities with audit findings are required to 1) submit corrective action plans to HRSA that indicate that the entities will determine the full scope of any noncompliance (beyond the sample of prescriptions reviewed during an audit); 2) outline the steps they plan to take to correct findings of noncompliance, including any necessary repayments to manufacturers; and 3) specify the timelines for implementing the corrective action plans.[58] HRSA closes the audit when a covered entity

[56]GAO-14-704G.

[57]42 U.S.C. § 256b(d)(2)(B)(iii).

[58]As part of its audit, HRSA reviews a sample of prescriptions filled with 340B drugs during a 6-month period. In the 20 audit files we reviewed, HRSA sampled a total of 1,073 out of 2,286,862 prescriptions (0.05 percent). This included 511 out of 260,839 prescriptions filled at the selected covered entities' contract pharmacies during the audit time frame.

submits a letter attesting that its corrective action plan, including its assessment of the full scope of noncompliance, has been implemented and any necessary repayments to manufacturers have been completed.[59]

However, we identified two specific deficiencies in HRSA's approach. First, although HRSA requires that covered entities determine the full scope of noncompliance found in audits, it does not provide guidance as to how entities should make this assessment. Specifically, HRSA does not specify how far back in time covered entities must look to see if any related noncompliance occurred and instead, relies on each entity to make this determination. For example, a document from a fiscal year 2017 audit revealed that a covered entity that had participated in the 340B Program for 3 years only reviewed 5 months of claims to determine whether any other instances of diversion had occurred, diminishing the likelihood that its efforts identified the full scope of noncompliance. Additionally, until April 2018, HRSA did not require covered entities that were audited to communicate the methodology used to assess the full scope of noncompliance, or the findings of their assessments, including how many or which manufacturers were due repayment. Beginning April 1, 2018, HRSA requires covered entities subject to targeted audits to document their methodology for assessing the full scope of noncompliance. However, as previously noted, only 10 percent of the 200 audits HRSA currently conducts each year are targeted audits. Consequently, the vast majority of covered entities audited are not required to provide HRSA with information on their methodology for assessing the full scope of noncompliance. Furthermore, HRSA officials told us that they believe determining the scope of noncompliance is a matter between the covered entities and manufacturers. Thus, HRSA relies on manufacturers to determine the adequacy of a covered entity's effort to assess the full scope of noncompliance. However, covered entities only contact the manufacturers that they determine were affected by the noncompliance based on the methodology they choose to apply; thus, it is unclear how manufacturers not contacted would be in a position to negotiate an acceptable assessment of the scope of noncompliance and any applicable repayment.

Federal internal control standards related to control activities state that agencies should implement control activities through policies, such as by

[59]Beginning April 1, 2018, HRSA requires covered entities with audit findings to submit a copy of their revised policies and procedures that reflects changes made in response to the audit prior to HRSA closing the audit.

documenting policies in the appropriate level of detail to allow management to effectively monitor the control activity.[60] As HRSA does not provide guidance on how covered entities are to assess the full scope of noncompliance and does not review most entities' methodology for making such assessments, the agency does not have reasonable assurances that entities have adequately identified all instances of noncompliance.

Second, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity is now in compliance with 340B Program requirements. Beginning April 1, 2018, HRSA requires the 10 percent of covered entities that are subject to targeted audits to provide documentation that they implemented their corrective action plans prior to HRSA closing the audits. However, it still relies on the remaining 90 percent of audited covered entities to self-attest to their compliance with program requirements.

HRSA officials told us they believe that a covered entity providing a description of the corrective actions is sufficient, and that the self-attestation of corrective action plan implementation provides HRSA with the information necessary to close the audit. However, aside from the self-attestation, HRSA's only mechanism to ensure that the majority of audited covered entities have implemented their corrective action plans is to re-audit the entities—in other words, subject the entity to a targeted audit. To date, the agency told us that it has re-audited 21 covered entities, and based on those re-audits, determined that 1 entity did not fully implement its corrective action plan from the original audit. However, we found that of the 19 re-audited covered entities for which results were available, 12 had similar findings of noncompliance in their second audits, as were identified in their original audits (e.g., diversion findings in both audits), 3 of which were caused by the same issue, according to information provided to us by HRSA.

Federal internal control standards for monitoring specify that agencies should establish and operate monitoring activities to monitor the internal control system and evaluate the results, for example by using ongoing monitoring to obtain reasonable assurance of the operating effectiveness of the service organization's internal controls over the assigned process.[61]

[60]GAO-14-704G.

[61]GAO-14-704G.

By only reviewing evidence of corrective action plan implementation for the limited number of covered entities subject to targeted audits, HRSA does not have reasonable assurance that the majority of covered entities audited have corrected the issues identified in the audit, and are not continuing practices that could lead to noncompliance, thus increasing the risk of diversions, duplicate discounts, and other violations of 340B Program requirements.

HRSA's Guidance for Covered Entities' Oversight of Contract Pharmacies Lacks Specificity

HRSA guidance for covered entities on their oversight of contract pharmacies lacks specificity and thus provides entities with considerable discretion on the scope and frequency of their oversight practices. Specifically, HRSA's 2010 guidance on contract pharmacy services specifies that covered entities are responsible for overseeing their contract pharmacies to ensure that drugs the entity distributes through them comply with 340B Program requirements, but states that, "the exact method of ensuring compliance is left up to the covered entity."[62] The guidance also states that, "annual audits performed by an independent, outside auditor with experience auditing pharmacies are expected," but HRSA officials told us that covered entities are not required to conduct independent audits and instead are expected to do some form of periodic oversight of their contract pharmacies.[63] Thus, according to HRSA officials, if a covered entity indicates that it has performed oversight in the 12 months prior to a HRSA audit, then HRSA considers the entity to have met HRSA's standards for conducting contract pharmacy oversight regardless of what the oversight encompassed.

Due, at least in part, to a lack of specific guidance, we found that some covered entities performed minimal contract pharmacy oversight.

- Officials from a grantee reported auditing claims of 5 randomly selected patients quarterly, despite treating approximately 900 patients each month.
- Officials from a critical access hospital that serves about 21,000 patients a year at its outpatient clinics reported that the annual independent audit of their hospital system reviewed five claims.

[62]75 Fed. Reg. 10278 (Mar. 5, 2010).

[63]75 Fed. Reg. 10278 (Mar. 5, 2010). HRSA indicated that it does not have statutory authority to require covered entities to conduct annual independent audits of their contract pharmacies.

- Officials from two entities reported that they did not contract for an independent audit of their 340B Program, despite HRSA's expectation to do so.

Additionally, of the 20 covered entities whose audits we reviewed, 6 had no documented processes for conducting contract pharmacy oversight.

The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices. Specifically, 66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies, and 33 of the 813 audits for which results were available had findings for lack of contract pharmacy oversight.[64] However, the number of contract pharmacy oversight findings may be limited by the fact that officials from HRSA's contractor said that its auditors rely on verbal responses from entity officials about any internal review or self-audits conducted by the entity. This is despite the fact that HRSA officials told us that the agency requires auditors to review documentation of covered entities' oversight activities.[65]

Federal internal control standards related to control activities state that agencies should implement control activities through policies, such as by documenting the responsibility for an operational process's objectives and related risks, and control activity design, implementation, and operating effectiveness. The standards also specify that management should periodically review policies, procedures, and related control activities for continued relevance and effectiveness in achieving its objectives or addressing related risks.[66] As a result of the lack of specific guidance and its numerous audit findings of noncompliance, HRSA does not have assurance that covered entities' contract pharmacy oversight practices are sufficiently detecting 340B noncompliance.

Conclusions

The 340B Program provides covered entities with discounts on outpatient drugs and the ability to generate revenue on drugs purchased under the

[64]These figures are based on the 813 audits conducted by HRSA from fiscal year 2012 to fiscal year 2017 for which results were posted on HRSA's website as of February 8, 2018.

[65]HRSA officials told us that they are updating their policy and protocols to more clearly define HRSA's expectations for its contracted auditor.

[66]GAO-14-704G.

program. Use of contract pharmacies enables covered entities to increase the use of 340B drugs by expanding their distribution networks, thereby increasing the volume of 340B drugs dispensed and generating associated savings and revenue. The expansion of contract pharmacies presents an opportunity for entities to fill more prescriptions with discounted 340B drugs, but it also increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts. Although covered entities and HRSA have taken steps to ensure that 340B Program requirements are being met at contract pharmacies, HRSA's audits continue to identify instances of noncompliance.

As currently structured, weaknesses in HRSA's oversight impede its ability to ensure compliance with 340B Program requirements at contract pharmacies. HRSA cannot ensure that its limited number of audits target covered entities with the most complex 340B programs, and thus the greatest risk of noncompliance, because the agency does not have complete data on entities' contract pharmacy arrangements. Additionally, HRSA's audit process does not adequately identify compliance issues, nor does it ensure that identified issues are corrected. HRSA's audits do not assess compliance with a key 340B Program requirement (the prohibition regarding duplicate discounts) as it relates to Medicaid managed care, and HRSA does not provide audited entities with guidance for determining the full scope of noncompliance, which reduces the effectiveness of HRSA's audits in identifying drug diversion and duplicate discounts. Moreover, where audits identify instances of noncompliance, HRSA's process does not confirm that all covered entities successfully correct the deficiencies and take steps to prevent future noncompliance. Although HRSA made improvements to its process for targeted audits during the course of our review, the agency does not require most covered entities subject to an audit to provide evidence of corrective actions taken.

Moreover, the lack of specificity in HRSA's guidance to covered entities on the methods through which they should ensure compliance may impede the effectiveness of entities' oversight. For example, without guidance instructing covered entities how to prevent duplicate discounts in Medicaid managed care, entities are left to individually navigate the policies and practices of states and private insurers. Furthermore, by not clearly communicating expectations for covered entities' oversight of their contract pharmacies, HRSA faces the risk that instances of noncompliance, such as diversion, at contract pharmacies will not be identified and addressed. As the 340B Program continues to grow, it is essential that HRSA address these shortcomings.

Recommendations for Executive Action

We are making the following seven recommendations to HRSA:

- The Administrator of HRSA should require covered entities to register contract pharmacies for each site of the entity for which a contract exists. (Recommendation 1)
- The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs. (Recommendation 2)
- The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities. (Recommendation 3)
- The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit. (Recommendation 4)
- The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance. (Recommendation 5)
- The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit. (Recommendation 6)
- The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight. (Recommendation 7)

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report, which are reproduced in app. II, and technical comments, which we have incorporated as appropriate. In its written comments, HHS concurred with four of our seven recommendations, did not concur with three of our

recommendations, and stated that it had concerns with some of the other information in our report.

In concurring with four of our recommendations, HHS stated that HRSA is making changes to its audit process to strengthen oversight of the 340B Program. Regarding our recommendation related to guidance on duplicate discounts, HHS concurred, but commented that the recommendation did not account for the critical role that CMS would play in its successful implementation. We agree that CMS would play an important role in ensuring compliance with the prohibition on duplicate discounts in Medicaid managed care, which is why we recommended that HRSA coordinate with CMS on the guidance. HHS indicated that HRSA and CMS are strategizing on effective ways to address this issue. HHS also concurred with our recommendations to issue guidance related to identifying the full scope of noncompliance and covered entities' oversight of their contract pharmacies, although it noted that HRSA would face challenges in issuing guidance related to areas where it does not have explicit regulatory authority. While we recognize that HRSA's authority to issue regulations governing the 340B Program may be limited, our recommendations were focused on HRSA clarifying certain program requirements through whatever format the agency deems appropriate. Since the establishment of the 340B Program, HRSA has used interpretative guidance and statements of policy to provide guidance to covered entities regarding compliance with program requirements. HRSA has also used certain of its audit procedures, such as the template provided to covered entities for the development of corrective action plans, to provide such clarifications. Our recommendations are intended to expand the availability of information HRSA provides to covered entities to help them improve compliance with existing program requirements. As such, we continue to believe that further clarification, whether provided as interpretive guidance, audit procedures, or another format, is necessary to help ensure compliance with program requirements.

Among the recommendations with which HHS did not concur was our recommendation to require covered entities to register contract pharmacies for each site of the entity for which a contract exists. HHS stated that its current registration process is responsive to our concerns for all covered entity types other than hospitals and health centers. However, as we note in the report, hospitals and FQHCs are typically the covered entity types that have multiple sites, and are generally more likely to have contract pharmacies. HHS cited administrative burden for both covered entities and HRSA as a reason not to require covered entities to

provide more complete information about contract pharmacy arrangements. However, given that HRSA requires covered entities to register both their sites and their contract pharmacies with the agency, it is unclear why there would be significant additional burden for covered entities to indicate which of the previously registered sites had contracts with which contract pharmacies. It is also important to note that contract pharmacy use by covered entities is voluntary, and covered entities that choose to have contract pharmacies are required to oversee those pharmacies to ensure compliance with 340B Program requirements. Therefore, the use of contract pharmacies inherently comes with additional administrative responsibilities for the covered entity, and we believe that the requirement to register each contract pharmacy arrangement with HRSA should present limited additional burden on covered entities.

Rather than implementing our recommendation, HHS stated that HRSA will make changes to its audit selection process; HRSA will assume that all contract pharmacies registered with the parent site would also be used by all sites of the covered entity prior to selecting entities for risk-based audits. Although this may be a good step forward, it does not provide information on the actual number of contract pharmacy arrangements for each covered entity. As such, we continue to believe that HRSA needs more complete information on contract pharmacy arrangements to best target its limited number of audits to covered entities with the most complex 340B programs. This is also important information to provide manufactures to help ensure that 340B discounted drugs are only provided to pharmacies on behalf of a covered entity site with a valid 340B contract with that site.

HHS also did not concur with our two recommendations to require covered entities to specify their methodologies for identifying the full scope of noncompliance identified during their audits as part of their corrective action plans, and to provide evidence that these plans have been successfully implemented prior to HRSA closing audits. In its response, HHS noted that on April 1, 2018, HRSA implemented these requirements for entities subject to targeted audits (including re-audits), which represent 10 percent of all entities audited. However, HRSA indicated that implementing these requirements for all covered entities that are audited would create a significant burden for these entities. As we previously noted, HRSA already requires covered entities with audit findings to determine the full scope of noncompliance and to submit corrective action plans. Thus, it is unclear how requiring covered entities to include written descriptions of their methodologies for identifying the full

scope of noncompliance, which should already be formulated, and to provide evidence that the corrective actions that entities developed have been implemented, would create significant additional burden for these entities.

HHS also expressed concern that these additional steps would significantly delay the audit process and repayments to manufacturers. We recognize that reviewing these documents may create some additional work for HRSA and possibly require additional time to close audits. However, we believe this additional work and time is necessary for the audits to be effective at adequately identifying compliance issues and ensuring that those issues are corrected. Furthermore, these additional actions could reduce the need for re-audits which are burdensome in terms of cost and time, for both the covered entity and HRSA.

Finally, HHS also expressed concerns about some of the other information included in the draft report.

- HHS stated that disclosing actual fees paid by covered entities to pharmacies and TPAs could cause disruptions in the drug pricing market and fluctuations in fees entities pay. Our report provides fees for a small and nongeneralizable sample of contracts, covered entities, and TPAs. For example, we provide contract pharmacy fees for 30 of the thousands of contracts that exist between covered entities and pharmacies. It is unclear how this information could cause disruptions in the drug pricing market or lead to fluctuations in fees covered entities may pay, and HHS did not provide any evidence to support its assertion. Additionally, HHS has raised questions about the effect of the 340B Program on drug pricing.[67] As such, we believe that our discussion of fees brings enhanced transparency to the 340B Program, and provides Congress with important information it requested to gain a better understanding of the program and enhance its oversight.
- Regarding the distance between contract pharmacies and covered entities, HHS noted that the longest distance was for a specialty pharmacy that was registered for 17 days. As noted in our scope and methodology, our analysis was of covered entities and contract pharmacies participating as of July 1, 2017. Additionally, there were

[67]Department of Health and Human Services, *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,* (Washington, D.C.: May 2018).

other contract pharmacy arrangements of similarly long distances. HHS also expressed concern that the draft report did not note that such specialty pharmacies may be needed due to restricted distribution by a manufacturer, which would be outside a covered entity's control. In our report, we noted that the 340B database does not provide information on why a covered entity may choose to contract with a pharmacy that is located a long distance away. However, the report does include some potential reasons HRSA provided us as to why this may occur.

- HHS also commented that our table on the number and percent of covered entities audited does not fully reflect HRSA's auditing efforts because it does not include the number of entity sites and contract pharmacies included within each audit. However, HRSA's audits of covered entities generally do not include visits to multiple covered entity sites, or all contract pharmacies that distribute 340B drugs on a covered entity's behalf. Additionally, while the audits include a review of a sample of 340B drugs distributed, that sample may not include prescriptions written at, or dispensed from, all of the covered entity's sites or contract pharmacies. As a result, information in our report highlights the number of entities that were audited.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, the Administrator of HRSA, and other interested parties. In addition, the report will be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at DraperD@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix III.

Debra A. Draper
Director, Health Care

Appendix I: Summary of Fees Included in 340B Pharmacy Contracts Reviewed

Table 8 provides a brief description of the fees that covered entities pay pharmacies with which they contracted to dispense 340B drugs based on our review of 30 contracts.

Table 8: Fees That 30 Selected Covered Entities Pay to Contract Pharmacies for Dispensing 340B Drugs, by Entity Type

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Hospitals		
Critical access hospital	Chain	• Flat fee of $24 for each brand drug prescription • Flat fee of $15 for each prescription patient pays with cash • Generic drugs excluded
Critical access hospital	Chain	• Flat fee of $15 for each prescription
Critical access hospital	Chain	• Flat fee of $28 for each brand drug prescription for patients with insurance coverage • Limited to brand drugs
Critical access hospital	Independent	• Flat fee of $17 for each prescription
Critical access hospital	Independent	• Flat fee of $15 for each prescription
Critical access hospital	Not available[a]	• Flat fee of $24 for each brand drug prescription • Generic drugs excluded
Critical access hospital	Not available[a]	• Fee of $0 for each prescription
Disproportionate share hospital	Chain	• Flat fee of $15 for each prescription when patient has insurance coverage • Up to 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments • The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	• Flat fee of $15 for each prescription when patient has insurance coverage • Up to 15 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug • The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	• Flat fee of $15 for each prescription when patient has insurance coverage • 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments • The covered entity does not pay any fees if the patient does not have insurance coverage

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Disproportionate share hospital	Chain	• Flat fee of $15 for each prescription when patient has insurance coverage • 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug • The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	• Flat fee of $18 for each generic drug prescription • Flat fee of $25 for each brand drug prescription
Disproportionate share hospital	Chain	• Flat fee of $30 for each brand drug prescription
Disproportionate share hospital	Chain	• Flat fee of $22 for each brand and generic drug prescription
Disproportionate share hospital	Independent	• Flat fee of $5 for each generic drug prescription • Flat fee of $10 for each brand drug prescription
Federal grantees		
Federally qualified health center	Chain	• Flat fee of $28 for each brand drug prescription for patients using a drug discount card[b] or insurance • Limited to brand drugs
Federally qualified health center	Chain	• Flat fee of $6 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $7 for each brand and generic prescription when patient has insurance coverage • 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Federally qualified health center	Chain	• Flat fee of $6 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $7 for each brand and generic prescription when patient has insurance coverage • 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Federally qualified health center	Chain	• Flat fee of $8 for each brand prescription for patients using a drug discount card[b] • Flat fee of $24 for each brand prescription when patient has insurance coverage
Federally qualified health center	Chain	• Flat fee of $8 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $9 for each brand and generic prescription when patient has insurance coverage • 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Federally qualified health center	Independent	• Flat fee of $8 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $10 for each prescription when patient has insurance coverage • 14 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments
Federally qualified health center	Independent	• Flat fee of $6 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $7 for each brand and generic prescription when patient has insurance coverage • 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Other federal grantee	Alternate dispensing site[c]	• Flat fee of $0.06 per international unit of factor[d]
Other federal grantee	Chain	• Flat fee of $13 for each prescription when patient has insurance coverage • Up to 18 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug • The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Chain	• Flat fee of $0.09 per international unit of factor[d]
Other federal grantee	Chain	• Flat fee of $13.50 for each prescription when patient has insurance coverage • Up to 13 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug • The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Chain	• Flat fee of $13 or $65 (for specialty drugs) for each prescription when patient has insurance coverage • 13 percent, or up to 13 percent (for specialty drugs), of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments • The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Independent	• Flat fee of $3 for each prescription
Other federal grantee	Independent	• Flat fee of $125 for each brand and generic human immunodeficiency virus drug • Flat fee of $1,750 for each brand Hepatitis C drug • Fee of $0 for each generic Hepatitis C drug • Flat fee of $75 for each brand and $0 for each generic drug not included above

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Other federal grantee	Not available[a]	• Flat fee of $10 for each prescription when patient does not have insurance coverage • Flat fee of either $10 when patient has insurance coverage or 12 percent of the of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments, whichever is greater

Source: GAO review of selected 340B contracts and DataQ data. | GAO-18-480

Note: Information on pharmacy type comes from the National Council for Prescription Drug Programs' DataQ, a database containing information reported by pharmacies that is used by health care payers and claims processors across the country to identify pharmacies.

[a]For these pharmacies information was not available in DataQ on pharmacy type.

[b]Some covered entities provide their patients with a drug discount card that the patient can present at the contract pharmacy. The pharmacy then uses the discount card to verify the patient as 340B eligible and determine the amount the patient will pay for the prescription.

[c]An alternate dispensing site is a pharmacy or dispensing site such as a physician's office or emergency department.

[d]Factor refers to blood clotting factor, which is the main treatment used for hemophilia—a bleeding disorder in which the blood does not clot normally. Patients with hemophilia are provided with infusions of blood clotting factor containing a protein to aid in clotting.

Appendix II: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 04 2018

Debra Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*" (GAO-18-480).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

for

Matthew D. Bassett
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

HHS places the highest priority on the integrity of the 340B Program and continually works to strengthen oversight of the Program, including ongoing improvement of its audit process. HHS appreciates GAO's examination of 340B covered entities use of contract pharmacies. During the course of the study, HRSA took the opportunity to make improvements to the program and has already implemented some of GAO's recommendations. While GAO's work will continue to inform our program integrity efforts, implementing some of the other recommendations in this report are not feasible at this time; they would require significant resources, currently not available under the Program's funding authorities. Successful implementation would require significant expansion of the Program's current information technology systems to account for new audit functions as well as strengthened enforcement authority and additional staff to oversee these efforts. In addition, HHS notes that some of the recommendations would impose additional audit requirements— and by extension, significant burden – on covered entities, especially smaller entities who are often resource constrained.

HHS also has significant concerns regarding many of the findings in the draft report. While discussion of the fees that covered entities pay their contract pharmacies and third party administrators (TPA) to dispense 340B drugs is within scope of the study's objectives, disclosing the actual fees, which are not widely available, could cause disruptions in the drug pricing market and lead to fluctuations in the fees that covered entities are charged. Further, it is important to note that HRSA has no legal authority to address the fees that a contract pharmacy or TPA may charge a covered entity for dispensing drugs to patients of the entity, as the fees are a private business matter between the parties involved. Covered entities utilize contract pharmacies and TPAs as an access point for patients to obtain 340B drugs. Without an explicit statement that HRSA lacks statutory authority to address these fees, the reader could be led to believe that fees are within the purview of the Program.

In addition, the GAO found in its analysis that the distance between a covered entity and its contract pharmacies was measured from the pharmacy to the closest site of the entity and that mail order pharmacies were excluded from distance calculations. GAO also explains that the maximum distance across all covered entities was for a disproportionate share hospital located in Connecticut contracting with a specialty pharmacy in Hawaii. Important context missing from GAO's report is the rationale for why a specialty pharmacy may be needed in the first place – such as the case of restricted distribution by a manufacturer, which would be outside a covered entity's control. HRSA also notes that the hospital in Connecticut that contracted with a specialty pharmacy in Hawaii was registered for 17 days and the pharmacy contract was subsequently terminated by the covered entity on July 17, 2017.

GAO's analysis was also not fully reflective of HRSA's auditing efforts which was a central objective of the study. "Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), by Fiscal Year," lists the number of audits by fiscal year and the percent of covered entities audited. While the numbers are accurate,

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it does not fully capture the significant number of sites included within each audit. HRSA notes the total number of audited sites below to provide the reader with the full scope of HRSA's oversight efforts.

- FY 12 – 51 audits, 410 outpatient/sub-grantee sites, 860 contract pharmacies
- FY 13 – 94 audits, 718 outpatient/sub-grantee sites, 1937 contract pharmacies
- FY 14 – 99 audits, 1476 outpatient/sub-grantee sites, 4028 contract pharmacies
- FY 15 – 200 audits, 2720 outpatient/sub-grantee sites, 4443 contract pharmacies
- FY 16 – 200 audits, 4011 outpatient/sub-grantee sites, 3531 contract pharmacies
- FY 17 – 200 audits, 2046 outpatient/sub-grantee sites, 4052 contract pharmacies

Finally, GAO makes several recommendations directing HRSA to issue guidance on specific policy matters. While HHS appreciates the recommendations to issue guidance, we would face challenges with issuing guidance on 340B policy matters in cases where our enforcement authority is quite limited. HHS notes that HRSA currently lacks explicit general regulatory authority in the 340B statute to issue regulations on most aspects of the 340B Program. Exceptions to this include the calculation of the ceiling price, manufacturer civil monetary penalties, and administrative dispute resolution. A regulation is a binding, enforceable document that would dictate specific 340B Program requirements and provide the clarity necessary for stakeholders to be fully compliant. HHS notes that the 2011 GAO report also included a recommendation related to hospital eligibility; however, HRSA remains unable to address the report's two recommendations without legislative changes, including the expansion of regulatory authority.

HHS notes that the FY 2019 President's Budget includes a proposal to amend the 340B statute to provide HRSA explicit general regulatory authority. If this proposal were enacted by Congress, HRSA could conduct rulemaking for all provisions in the 340B statute, affording it explicit, general regulatory authority, which would be most effective in facilitating HRSA's oversight over the 340B Program. In addition, explicit general regulatory authority would allow HRSA to provide greater clarity and specificity to Program requirements necessary for implementing GAO's 2011 recommendations and the recommendation in this report.

HRSA continues to support the development of program policy as a general matter and is working with the Administration to determine next steps on several aspects of Program policy.

Recommendation 1

The Administrator of the Health Resources and Services Administration (HRSA) should require covered entities to register contract pharmacies for each site of the entity for which a contract exists.

HHS Response

HHS non-concurs with GAO's recommendation.

- HRSA notes that its current process is already responsive to GAO's recommendation for covered entity types other than hospitals and health centers. Because HRSA recognizes

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

relationships of hospitals and health centers in a different manner (parent and child), and for administrative burden reasons, HRSA only requires that a contract pharmacy register with the parent covered entity, notwithstanding that child sites can still utilize that pharmacy. HRSA does require all covered entity sites and contract pharmacy sites to be listed on the written contract, and this information is audited by HRSA.

- For the FY 2019 audit cycle, HRSA will strengthen this risk-based audit strategy by including an assumption that all contract pharmacies registered with the parent entity would also be used by the child sites, prior to randomly selecting covered entities for audit. Adding this assumption to the methodology, rather than requiring registration for all contract pharmacy contracts, will preclude having to strain HRSA's IT system and, more importantly, it will avoid placing significant burden on covered entities that only list their contract pharmacy with the parent organization.
- GAO explains that because HRSA allows covered entities to utilize multiple contract pharmacy registration options, the likelihood of being selected for an audit is dependent on how an entity registers its pharmacies. HRSA does not believe that requiring entities to register each contract pharmacy in the database is the appropriate mechanism to address the GAO's specific concern. In assessing the scope and effectiveness of implementing this proposed recommendation, HRSA conducted an internal analysis in line with GAO's scenario where all contract pharmacies listed under the parent entity (for hospitals and health centers) are also listed under all of their child sites. HRSA concludes that its existing risk-based selection method is effective and efficient in selecting covered entities with the most contract pharmacy arrangements.

Recommendation 2

The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS, as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs.

HHS Response

HHS concurs with GAO's recommendation.

- While HRSA recognizes the need for guidance, GAO's recommendation as currently stated does not account for the critical role that CMS would play in its successful implementation. Development of effective and comprehensive guidance would require that HRSA and CMS work closely together under the guidance of departmental leadership. In this regard, HRSA continues to hold calls with CMS and discuss concerns and strategize on effective ways to address the issue for both the Medicaid and 340B Program.

Recommendation 3

The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities.

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HHS Response
HHS concurs with GAO's recommendation.

- HRSA notes that this recommendation can only be accomplished after guidance has been issued as outlined in recommendation 2.
- While HRSA does not currently audit Medicaid managed care claims and has no policy on preventing duplicate discounts in this context, we encourage covered entities and manufacturers to work on strategies to ensure compliance with the duplicate discount prohibition. After reviewing our policy in this area, beginning April 1, 2018, HRSA now includes an area for improvement (AFI) in audits where Medicaid managed care claims are identified as potential risks. Further, HRSA has since updated its policy on April 1, 2018 to add that all entities with findings are required to provide information regarding their plan to implement any areas for improvement.

Recommendation 4
The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit.

HHS Response
HHS concurs with GAO's recommendation.

- The ability for HRSA to issue guidance is predicated on the challenges of issuing guidance versus regulations that are discussed above. HRSA supports the development of program policy and is working with the Administration to determine next steps.

Recommendation 5
The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope on noncompliance.

HHS Response
HHS non-concurs with GAO's recommendation.

Now on p. 41.

- As indicated by the GAO in the draft report (page 35), beginning April 1, 2018, HRSA requires entities that are subject to target audits and re-audits to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of non-compliance.
- Covered entities must work in good faith with manufacturers to remedy any repayment owed after the entity determines the compliance. Covered entities and manufacturers have

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

access to the necessary data needed to resolve any repayment, which is a private matter between the two parties due to their established business relationship.

- HRSA notes that if this recommendation were implemented for all audits, it would create a significant burden for covered entities to comply with the additional documentation they would need to produce as part of the audit. In addition, the timeframe it would take HRSA to review GAO's recommended methodology for identifying the full scope of noncompliance and to close an audit would be significantly extended.
- HRSA has established an efficient audit process to ensure that if there is a compliance issue, particularly involving repayment to a manufacturer, covered entities are able to resolve the issue quickly and notify the manufacturer in order to work out repayments that may be owed in good faith. Additional requirements related to document submission will significantly delay the process and repayment to manufacturers due to program violations.

Recommendation 6

The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessment of the full scope of noncompliance identified during an audit.

HHS Response

HHS non-concurs with GAO's recommendation.

- For all audits, HRSA requires covered entities to describe in detail their plan for corrective action. If during the course of review of the CAP concerns arise, HRSA would request additional documentation that would describe the steps taken to correct any noncompliance. As indicated by the GAO in the draft report (page 35), beginning April 1, 2018, HRSA took additional action to require evidence and documentation as outlined in the recommendation for entities that are subject to target audits and re-audits.
- Requiring all entities to providence evidence and documentation as outlined in the recommendation, would create a significant burden for covered entities to comply with the additional materials they would need to produce as part of the audit.
- In addition, the timeframe it would take HRSA to review GAO's recommended methodology for identifying the full scope of noncompliance and to close an audit would be extended. HRSA has established an efficient audit process to ensure that if there is a compliance issue, particularly involving repayment to a manufacturer, covered entities are able to resolve the issue quickly and notify the manufacturer in order to work out repayments that may be owed in good faith. Additional requirements related to document submission will delay the audit process significantly, thus delaying repayment to affected manufacturers due to program violations.

Recommendation 7

The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.

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Now on p. 42.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

HHS Response

HHS concurs with GAO's recommendation.

- HRSA's ability to issue guidance is predicated on the challenges with issuing guidance versus regulations discussed above. HRSA supports the development of program policy and is working with the Administration to determine next steps.

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contact

Debra A. Draper (202) 512-7114 or DraperD@gao.gov

Acknowledgments

In addition to the contact named above, Michelle Rosenberg (Assistant Director), N. Rotimi Adebonojo (Analyst in Charge), Jennie Apter, George Bogart, Amanda Cherrin, David Lichtenfeld and Dan Ries made key contributions to this report. Also contributing were Julianne Flowers and Vikki Porter.

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Exhibit J

REVIEW OF THE 340B DRUG PRICING PROGRAM

Table of Contents

I. Executive Summary

The 340B Drug Pricing Program (340B program) was established by Congress in 1992, and mandates that, to remain eligible for participation in the Medicaid program, drug manufacturers must provide outpatient drugs to eligible health care providers—also known as covered entities—at reduced prices. Covered entities include certain nonprofit organizations such as qualifying hospitals and federal grantees identified in the Public Health Services Act (PHSA). The Health Resources and Services Administration (HRSA) is the Operating Division within the U.S. Department of Health and Human Services (HHS) that administers and oversees the 340B program.

The 340B program is an important program that enjoys strong bipartisan support in Congress. The program helps reduce the prices of covered drugs for certain participating entities who, in turn, provide care for patients. Numerous covered entities have stated the 340B program has helped ensure that underserved and indigent patients have access to affordable medicines and health care. On numerous occasions, including during the Energy and Commerce Committee's (the committee's) most recent hearing in October 2017, the committee has emphasized the importance of the 340B program in providing care to vulnerable Americans.[1]

Over the past 25 years, the nation's health care system has changed in some significant ways. For example, in 1992, there were roughly 29 million people enrolled in Medicaid and the program spent $120 billion that year. Comparatively, in 2016, there were more than 72 million people enrolled in Medicaid and the program cost more than $575 billion.[2] In that same period, the 340B program has also grown substantially—not only in the number of covered entities and contract pharmacies, but also in the amount of money saved by covered entities. HRSA estimates that covered entities saved approximately $6 billion on approximately $12 billion in discounted purchases in Calendar Year (CY) 2015 by participating in the 340B program.[3] It is estimated that discounted drug purchases made by covered entities under the 340B program totaled more than $16 billion in 2016—a more than 30 percent increase in 340B program purchases in just one year.[4]

The committee has been examining the operation and oversight of the 340B program over the past two years. Through stakeholder meetings, hearings, and document requests, the committee has identified several weaknesses in program administration and oversight.

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[1] *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, at 84 (Oct. 11, 2017).

[2] Medicaid and CHIP Payment and Access Commission, *MACStats: Medicaid and CHIP Data Book, Exhibit 10* (Dec. 2017), *available at* https://www.macpac.gov/wp-content/uploads/2017/12/MACStats-Medicaid-and-CHIP-Data-Book_December-2017.pdf.

[3] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).

[4] Aaron Vandervelde and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2012-2017*, BERKELEY RESEARCH GROUP (July 2017), *available at* https://www.thinkbrg.com/media/publication/928_Vandervelde_Measuring340Bsize-July-2017_WEB_FINAL.pdf.

Congress did not clearly identify the intent of the program and did not identify clear parameters, leaving the statute silent on many important program requirements. According to the 1992 House Report accompanying the legislation, the 340B program was intended "to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[5] It is unclear whether Congress intended low-income and uninsured individuals to directly benefit from the reduced drug prices offered under the 340B program. Congress should clarify the intent of the 340B program and, in doing so, evaluate how developments in the health care landscape over the past 25 years have affected, if at all, the structure and goals of the 340B program.

HRSA lacks sufficient regulatory authority to adequately oversee the program and clarify program requirements. In 2014, a federal court ruled that HRSA's regulatory authority is limited to three specific areas, including (1) establishing and implementing a binding Administrative Dispute Resolution (ADR) process for the resolution of certain disputes relating to compliance with 340B program requirements, (2) providing for the imposition of civil monetary penalties (CMPs) against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug, and (3) issuing precisely defined standards of methodology for calculation of 340B ceiling prices. As a result, HRSA is unable to issue rules that would clarify certain program requirements. In addition, HRSA has not fully implemented guidance or regulations in the three areas where the agency has regulatory authority, nor has HRSA issued guidance on fundamental aspects of the program such as the definition of an eligible patient. Consequently, important aspects of the program have remained vague, as the statute is silent on many key aspects of the program, resulting in variation in the way covered entities use the program. HRSA should finalize regulations in the areas in which it has regulatory authority, and Congress should provide HRSA with more regulatory authority to adequately administer and oversee the 340B program, including the ability to improve program integrity, clarify program requirements, monitor and track program use, and ensure that low-income and uninsured patients directly benefit from the 340B program.

HRSA's primary compliance mechanism is the agency's annual audit process. HRSA began auditing covered entities in 2012. HRSA conducted 51, 94, and 99 audits in the first three years of auditing, and since 2015 has conducted approximately 200 audits annually. HRSA's annual audits uncovered a high level of non-compliance by covered entities. Given HRSA's limited authority, HRSA only conducts a limited review of the covered entity's use of the program during the audit process. Specifically, HRSA audits entities only for program eligibility, duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting. HRSA also conducts audits of manufacturers to determine whether they are offering drugs at prices no higher than the 340B ceiling price.

The Patient Protection and Affordable Care Act (PPACA) dramatically increased the size and scope of this program by expanding eligibility to more types of hospitals, such as critical access hospitals and sole community hospitals, and expanded Medicaid eligibility. Program participation has more than quadrupled over the past decade. While HRSA's authorities and resources have increased over the same period, they do not appear sufficient to meet the demands of this program. Although HRSA has increased the number of covered entity audits it conducts

[5] H.R. Rep. 102-384, Pt. 2 (1992).

per year, the percentage of covered entities audited in 2016 was below two percent of total entities participating in the program. Program growth has outpaced HRSA's ability to effectively oversee the program. Congress should equip HRSA with the resources and staff necessary to conduct more rigorous oversight of the program. In addition, Congress should consider whether the permissible scope of HRSA's audits should be expanded, and HRSA should work toward auditing covered entities and manufacturers at approximately the same rate. To further aid HRSA in its administration of the program, Congress should require certain covered entities to conduct independent audits of program compliance, including of any contract pharmacies.

The 340B statute does not require covered entities to track or report program savings or how they are used. As a result, covered entities use program savings in a variety of ways. While some covered entities (*i.e.*, federal grantees) are restricted in the way they can use program funds due to other federal grant requirements, most entities are not required to use program savings in any specific way. Further, the 340B statute does not require covered entities to report the level of charity care that they provide to patients. The absence of reporting requirements in the 340B statute has resulted in a lack of data and transparency on how covered entities use the program and the value of the program, both to entities themselves and to the patients these entities serve.

The term "340B savings" refers to the cost saved by the covered entity by purchasing a drug at a reduced price. Because covered entities can purchase medicines at 340B prices for patients that have insurance, entities can also use the program to generate "340B revenue" by collecting insurance payments that exceed the acquisition price paid by the covered entity under the 340B program. Examples of ways a covered entity may maximize its 340B revenue include prescribing expensive drugs purchased at a significantly discounted 340B price and then receiving a higher insurance reimbursement rate for the drug, or hospitals acquiring private oncology clinics that prescribe expensive oncology drugs and then increasing the cost of care for the patient through facility fees, even though the treatment that the patient receives has not changed. Committee staff also heard directly from doctors and administrators about how some unintended consequences of the 340B program may negatively impact the quality of patient care.

In the committee's opinion, increasing transparency in the 340B program would allow for an accurate accounting of the full scope of the program's use and benefits. Congress, or HRSA where HRSA already has authority to make such changes, should promote transparency in the 340B program, including by ensuring that covered entities and other relevant stakeholders have access to ceiling prices and requiring covered entities to disclose information about annual 340B program savings and/or revenue. Congress should also establish a mechanism to monitor the level of charity care provided by covered entities. This should include a clear definition of charity care such that the data can be used to fairly compare care provided across entities.

While the 340B program only applies to certain *outpatient* drugs, eligibility is determined by using an *inpatient* metric. The current metric used to determine hospital eligibility for the 340B program does not necessarily reflect the amount of charity care offered by the hospital or the 340B patient population for the hospital. Congress should consider whether an inpatient metric remains an appropriate measure for program eligibility, or whether another metric is more appropriate.

The report concludes with a series of recommendations that, in the opinion of the committee, would improve the administration of the 340B program, primarily through changes in HRSA's regulatory authority and requiring transparency and accountability from covered entities. If implemented, these changes would strengthen the 340B program.

II. Table of Acronyms

Acronym	Description
ADR	Administrative Dispute Resolution
AMP	Average Manufacturer Price
ANPRM	Advanced Notice of Proposed Rulemaking
CAP	Corrective Action Plan
CAHS	Cook Area Health Services
CMP	Civil Monetary Penalty
CMS	Centers for Medicare and Medicaid Services
COA	Community Oncology Alliance
CY	Calendar Year
DSH	Disproportionate Share Hospital
EPI	Erlanger Pharmacies Inc.
EHS	Erlanger Health System
FFS	Fee-For-Service
FTE	Full Time Employees
FQHC	Federally Qualified Health Centers
FY	Fiscal Year
GAO	U.S. Government Accountability Office
GPO	Group Purchasing Organization
HHS	U.S. Department of Health and Human Services
HHS OIG	Office of Inspector General. U.S. Department of Health and Human Services
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HRSA	Health Resources and Services Administration, U.S. Department of Health and Human Services
IT	Information Technology
JHH	Johns Hopkins Hospital
LPN	Licensed Practical Nurses
MCO	Managed Care Organization
MedPAC	Medicare Payment Advisory Commission
MEF	Medicaid Exclusion File
NPI	National Provider Identifier
NPRM	Notice of Proposed Rulemaking
NYULH	NYU Langone Health
OPA	Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services
OPAIS	Office of Pharmacy Affairs Information System
PPA	Pharmaceutical Pricing Agreement
PHSA	Public Health Services Act
PPACA	Patient Protection and Affordable Care Act
RN	Registered Nurse
SSI	Supplemental Security Income
URA	Unit Rebate Amount
WAC	Wholesale Acquisition Cost

III. Findings

- HRSA has started, but after several years not completed, the process to issue and enforce regulations pertaining to the Administrative Dispute Resolution Process, the calculation of ceiling prices, and manufacturer civil monetary penalties. HRSA has not fully implemented these regulations in a timely manner.

- HRSA lacks sufficient authority to adequately oversee the program and clarify program requirements. HRSA needs more regulatory authority to promote compliance and ensure program integrity. Key aspects of the program have remained vague, resulting in variation in the way covered entities use the 340B program.

- Although HRSA has increased the number of covered entity audits it conducts per year, the audit process still needs improvement. Given HRSA's limited regulatory authority over the 340B program, HRSA only conducts a limited review of the covered entity's use of the program during the audit process. Covered entities would benefit from clearer guidance on the audit process.

- HRSA's annual audits uncovered a high level of non-compliance by covered entities. The HRSA audits from FY 2012 to FY 2016 demonstrate that non-complying entities violate program requirements in a variety of different ways, including duplicate discounts, diversion to ineligible patients and facilities, incorrect database reporting, and violation of the Group Purchasing Organization (GPO) prohibition (if applicable).

- HRSA audits manufacturers and in their audits to date found no manufacturers out of compliance with the statute. However, without access to ceiling prices, covered entities may not know that they should report to HRSA that they are not getting an accurate price.

- The PPACA significantly increased the scope of the Medicaid program by expanding eligibility to certain low-income, non-disabled, non-elderly, non-pregnant adults. Medicaid expansion under the PPACA has likely increased the number of hospitals eligible for the 340B program because some hospitals' eligibility is based, in part, on the number of the hospital's inpatients who are Medicaid and low-income Medicare patients by virtue of their DSH (disproportionate share hospital) percentage. Overall, program participation has more than quadrupled over the past decade. HRSA's limited oversight ability does not appear to be sufficient to conduct adequate oversight of this program.

- Congress did not clearly identify its intent for the program and did not clearly identify the program's parameters, leaving the statute silent on many important program requirements. Moreover, given the vastly changed health care landscape and 340B program environment, it is unclear whether, and to what degree, the program's original structure is still relevant.

- Congress did not establish any mechanisms to monitor or calculate program savings or specify how they are used. As a result, covered entities use program savings in a variety of different ways. Some covered entities are restricted in the way they can use program funds due to other federal grant requirements.

- The 340B statute does not require covered entities to report the level of charity care provided. As a result, there is a lack of data on how much charity care is provided by covered entities. Further, because there is no universally accepted definition of charity care, drawing a fair comparison of charity care provided across covered entities is difficult, if not impossible. Finally, while charity care spending often exceeds program savings, charity care levels have been on the decline at some hospitals, even as program savings increase.

- There is a financial incentive for 340B hospitals to prescribe more, and/or more expensive drugs to Medicare Part B beneficiaries, and prescribing trends indicate that 340B hospitals do prescribe more and more expensive drugs to Medicare Part B beneficiaries as compared to non-340B hospitals.

- There has been a marked increase in consolidation of private oncology practices, which, in some instances, negatively impacts the quality of patient care and can result in increased patient cost.

- The current metric used to determine hospital eligibility for the 340B program does not necessarily reflect the amount of charity care offered by the hospital or the outpatient population for the hospital. Hospitals have a financial incentive to open child sites in areas that do not reflect the DSH percentage of the parent entity, thus enabling the hospital to gain access to a higher number of commercially insured patients.

IV. Background

A. Overview of the 340B Program's Development and Growth

Congress established the 340B Drug Pricing Program (340B program) through the Veterans Health Care Act of 1992.[6] The 340B program mandates that, to remain eligible for participation in the Medicaid program, drug manufacturers provide covered outpatient drugs to eligible health care providers at reduced prices.[7] More specifically, the statute requires that, as a condition of participation in the Medicaid program, drug manufacturers enter into pharmaceutical pricing agreements (PPAs) that require those manufacturers to sell their product at a discount to certain health care providers, known as covered entities.[8] Covered entities include certain nonprofit organizations such as qualifying hospitals and federal grantees identified in the Public Health Services Act (PHSA).[9]

According to the 1992 House Report accompanying the original legislation, the 340B program was established, in part, to respond to the increase in prescription drug prices for the Department of Veterans Affairs and some federally-funded clinics and public hospitals following the enactment of the 1990 Medicaid Drug Rebate Program (created through the Omnibus Budget Reconciliation Act of 1990 (OBRA)).[10] Before the enactment OBRA, many drug manufacturers voluntarily sold medicines to the Veterans Health Administration and other federal entities (including public health service grantees) at significant discounts and drug manufacturers also bargained with large purchasers.[11] Because the Medicaid Drug Rebate Program requires that pharmaceutical manufacturers provide Medicaid with the manufacturers' lowest or "best price" for outpatient drugs, some stakeholders were concerned that after the program was implemented, manufacturers might limit discounts to federal, non-Medicaid purchasers. The 1992 House Report indicated that, "[i]n giving these 'covered entities' access to price reductions the committee intends to enable these entities to stretch scarce [f]ederal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[12] Beyond these statements in the 1992 House Report, it is unclear exactly how Congress intended covered entities to use the 340B program. Congress remained silent in the statute on many important questions regarding the structure and scope of the 340B program.

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[6] Veterans Health Care Act of 1992 (VHCA), P.L. 102-585.

[7] The definition of a covered outpatient drug is set forth in section 1927(k) of the Social Security Act. According to Apexus, the 340B program generally includes the following outpatient drugs: (1) FDA-approved prescription drugs; (2) Over-the-counter (OTC) drugs written on a prescription; (3) biological products that can be dispensed only by a prescription (other than vaccines); or (4) FDA-approved insulin. Apexus, *340B Price/Covered Outpatient Drugs* (last accessed Jan. 3, 2018), https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs.

[8] Public Health Service Act, 42 U.S.C. 256b. A sample 340B program Pharmaceutical Pricing Agreement is available on HRSA's website. *See* U.S. Dep't of Health and Human Services, Health Services and Resources Administration, *General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)* (last accessed Jan. 3, 2018), https://www.hrsa.gov/sites/default/files/opa/manufacturers/pharmaceuticalpricingagreement.pdf.

[9] *See* Health Resources and Services Administration, *340B Eligibility & Registration* (last accessed Dec. 1, 2017), https://www.hrsa.gov/opa/eligibility-and-registration/index.html.

[10] H.R. Rep. 102-384, Pt. 2 (1992).

[11] U.S. Senate, Committee on Labor and Human Resources, *Hearing on Public Health Clinic Prudent Pharmaceutical Purchasing Act (S. 1729)* (Oct. 16, 1991) (statement of Stephen Schondelmeyer, Pharm.D., Ph.D.).

[12] H.R. Rep. 102-384, Pt. 2 (1992).

The 340B program is an important program that helps reduce the prices of covered drugs for certain participating entities who, in turn, provide care for patients. On numerous occasions, including during the committee's most recent hearing in October 2017, the committee has emphasized the importance of the 340B program in further enabling covered entities to provide care to vulnerable Americans.[13]

The Health Resources and Services Administration (HRSA) is the Operating Division within the U.S. Department of Health and Human Services (HHS) that administers and oversees the 340B program. According to HRSA's Fiscal Year (FY) 2018 Budget Justification, HRSA budgeted $10.2 million and 22 Full Time Employees (FTEs) to administer the 340B program in FY 2017.[14] HRSA and manufacturers have had the authority to audit covered entities since the 340B program was established in 1992.[15] Initially, however, HRSA primarily relied on covered entities to self-monitor and ensure compliance with 340B program requirements.[16] In 2012, following a 2011 Government Accountability Office (GAO) report recommending HRSA begin auditing covered entities to monitor for program violations, provide additional program oversight, and prevent diversion and duplicate discounts, HRSA began conducting selective audits of covered entities.[17] HRSA also conducts audits of manufacturers to ensure compliance with program requirements.[18]

Participation in the 340B program is voluntary for covered entities and drug manufacturers, but there are incentives to participate. Participating manufacturers remain eligible for the Medicaid program, meaning that their pharmaceuticals are covered by Medicaid. Covered entities are eligible to receive discounts on certain outpatient prescription drugs from participating manufacturers and save between 25 and 50 percent of the average wholesale price for covered outpatient drugs.[19] The 340B price for a drug paid by covered entities—sometimes referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities.[20] HRSA calculates the ceiling price for each 340B drug as the difference between the drug's average manufacturer price (AMP) and its unit rebate amount (URA), obtaining both the AMP and URA from the Centers for Medicare and Medicaid Services (CMS) as part of quarterly reporting for the Medicaid Drug Rebate

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[13] *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Oct. 11, 2017).
[14] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees*, at 244 (2018).
[15] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program Notice: Clarification of HRSA Audits of 340B Covered Entities*, Release No. 2012-1 (Mar. 5, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/auditclarification030512.pdf.
[16] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong., at 19 (Mar. 24, 2015).
[17] *Id.*
[18] U.S. Dep't of Health and Human Services, *Health Resources and Services Administration, FY 2017 Manufacturer Audit Results* (last updated Dec. 12, 2017), https://www.hrsa.gov/opa/program-integrity/audit-results/fy-17-manufacturer-audit-results.html.
[19] 340B Prime Vendor Program, *340B Price/Covered Outpatient Drugs* (last accessed Dec. 1, 2017), *available at* https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/.
[20] Manufacturers may sell a drug at a price that is lower than the ceiling price, so covered entities may negotiate prices below the ceiling price.

Program.[21] AMP is defined as the average price paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.[22] The URA is based on the formula used to calculate Medicaid drug rebates as specified in Section 1927 of the Social Security Act.[23] Currently, the Medicaid Drug Rebate Program rebate is 23.1 percent for single-source and innovator drugs and 13 percent for generic drugs. Occasionally, the formula results in a negative price for a 340B drug. In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA's penny pricing policy.[24]

Covered entities do not receive discounts on *inpatient* drugs under the 340B program, but can realize substantial savings through 340B price discounts and generate 340B revenue by selling eligible outpatient drugs at a higher price than the discounted price at which the covered entity obtained the drug. Moreover, while covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA's current definition of a patient,[25] these entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, regardless of whether they are low income, uninsured, or underinsured. Both the Office of Inspector General at the U.S. Department of Health and Human Services (HHS OIG) and GAO have criticized HRSA's failure to provide adequate clarity on the definition of a patient.[26] HRSA does not have regulatory authority to clarify the definition of an eligible patient, and after a decision by a federal court limiting HRSA's regulatory authority, HRSA withdrew their guidance on this topic.[27] HRSA could issue guidance clarifying important program requirements and providing information about best practices for program participants, but to date, the agency has not released such guidance.

Recent years have seen significant changes and expansions to the program (see Appendix A for a complete list of major legislation affecting the 340B program). HRSA estimates that covered entities saved $3.8 billion on outpatient drugs through the program in FY 2013,[28] $4.5

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[21] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *340B Ceiling Price Calculation* (last reviewed April 2017), https://www.hrsa.gov/opa/updates/2015/may.html; Medicare Payment Advisory Commission, *Report to Congress: Overview of the 340B Drug Pricing Program*, at 6 (May 2015).
[22] *See* Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016).
[23] Medicare Payment Advisory Commission, *Report to Congress: Overview of the 340B Drug Pricing Program*, at 6 (May 2015).
[24] Medicaid and CHIP Payment and Access Commission, *Issue Brief: Medicaid Payment for Outpatient Prescription Drugs* (March 2017), *available at* https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.
[25] For current definition of a patient, see HRSA's website. U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Eligibility & Registration* (last accessed Dec. 1, 2017), *available at* http://www.hrsa.gov/opa/eligibilityandregistration/index.html.
[26] *See, e.g.*, *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017).
[27] *See, e.g.*, *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Capt. Krista M. Pedley, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, Health Resources and Services Administration, U.S. Dep't of Health and Human Services).
[28] *Examining the 340B Drug Discount Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 114th Cong. (March 24, 2015) (statement of Diana Espinosa, Deputy Administrator, Health Resources and Services Administration).

billion in FY 2014,[29] and approximately $6 billion in Calendar Year (CY) 2015.[30] In CY 2015, approximately $12 billion in discounted purchases were made by covered entities.[31] It is estimated that discounted drug purchases made by covered entities under the 340B program totaled more than $16 billion in 2016—a more than 30 percent increase in 340B program purchases in just one year.[32] As of October 1, 2017, 12,722 covered entities are participating in the program and, as of January 2, 2018, 743 pharmaceutical manufacturers are participating in the program.[33]

While many covered entities contract with multiple external pharmacies in operating their 340B programs, this structure is a relatively recent arrangement born out of administrative guidance, not the statute. The statute itself is silent on pharmacy arrangements for covered entities. In March 2010, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies, referred to as contract pharmacies. Prior to 2010, covered entities could contract with only one pharmacy if they did not have an in-house pharmacy.[34] The growth and oversight of contract pharmacies since 2010 has been identified as an issue of concern by HHS OIG, and GAO is planning an upcoming report examining that issue. According to HRSA's FY 2018 Budget Justification, 27 percent of covered entity sites have contract pharmacy arrangements, and there are about 18,078 unique pharmacy locations in the 340B Office of Pharmacy Affairs Information System (OPAIS).[35] Contract pharmacies may have arrangements to dispense drugs for more than one entity. HRSA data indicates that there were 46,174 contract pharmacy arrangements—arrangements between a covered entity site and a pharmacy—as of January 1, 2017.[36] As GAO noted, however, "the total number of contract pharmacy arrangements is likely higher, as HRSA does not require entities to report all arrangements to the agency."[37]

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[29] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2017* (2016), *available at* https://www.hrsa.gov/about/budget/budgetjustification2017.pdf.

[30] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).

[31] *Id*.

[32] Aaron Vandervelde and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2012-2017*, BERKELEY RESEARCH GROUP (July 2017), *available at* https://www.thinkbrg.com/media/publication/928_Vandervelde_Measuring340Bsize-July-2017_WEB_FINAL.pdf.

[33] U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Email from U.S. Department of Health and Human Services Staff to Committee Staff (Dec. 21, 2017); U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program Manufacturers* (last accessed Dec. 13, 2017), https://340bopais.hrsa.gov/manufacturersearch.

[34] Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,274-10,278 (March 5, 2010).

[35] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, at 245-46 (2017), *available at* https://www.hrsa.gov/about/budget/budgetjustification2018.pdf.

[36] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., at footnote 19 (Jul. 18, 2017) (statement of Debra Draper, Director, Health Care, Government Accountability Office).

[37] *Id*. HRSA does not require covered entities to report contract pharmacy arrangements by entity sites. Instead, covered entities may just report the contract pharmacy arrangements for the main parent site even if some, or all, of the child sites also have an arrangement with the same pharmacy. If entities were required to report all arrangements, the percent of sites with contract pharmacy arrangements could be higher.

Many 340B program covered entity parent organizations have multiple associated "child sites." Child sites can include satellite clinics or facilities, hospital departments, outpatient treatment units, and other facilities. Child sites are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on a hospital's most recently filed Medicare cost report. As of October 1, 2017, 42,029 registered covered entity sites were participating in the 340B program, including 12,722 covered entity (parent) sites and 29,307 associated (child) sites participating in the program.[38]

Over the past 25 years, the health care landscape has changed dramatically. According to HHS's National Health Interview Survey, over 35 million Americans under the age of 65 did not have health insurance in 1992.[39] In 2016, about 28 million Americans under the age of 65 were uninsured.[40] Moreover, in 1992, there were about 29 million people enrolled in Medicaid and the program spent $120 billion that year, whereas in 2016, there were more than 72 million people enrolled and the program cost more than $575 billion.[41] In addition to changes in coverage, the structure of hospitals has also evolved dramatically. In a recent report, the National Academies Press indicated that nonprofit hospitals are increasingly displaying characteristics of for-profit hospitals.[42] Indeed, a recent press article highlighted how some, particularly large non-profit hospitals, have become quite profitable and "now resemble and act like Fortune 500 companies instead of the charities they were often built as."[43]

B. Types of Covered Entities

HRSA is tasked with reviewing applications for participation in the 340B program, determining program eligibility, and overseeing covered entities. Covered entities must recertify their eligibility for the 340B program annually. Eligibility is statutorily defined and is limited to certain qualifying hospitals and federal grantees.[44] Congress has expanded program eligibility over time, most recently through the PPACA.[45]

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[38] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program Covered Entities* (last accessed Dec. 1, 2017), https://340bopais.hrsa.gov/coveredentitysearch; U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Email from U.S. Dep't of Health and Human Services Staff to Committee Staff (Dec. 21, 2017).

[39] U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, *National Health Interview Survey: Long-term Trends in Health Insurance Coverage* (Oct. 2017), *available at* https://www.cdc.gov/nchs/data/nhis/health_insurance/TrendHealthInsurance1968_2016.pdf.

[40] *Id.*

[41] Medicaid and CHIP Payment and Access Commission, *MACStats: Medicaid and CHIP Data Book, Exhibit 10* (Dec. 2017), *available at* https://www.macpac.gov/wp-content/uploads/2017/12/MACStats-Medicaid-and-CHIP-Data-Book_December-2017.pdf.

[42] National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 6 (Nov. 2017).

[43] Bob Herman, *Hospitals are making a fortune on Wall Street*, AXIOS (Dec. 7, 2017), *available at* https://www.axios.com/hospitals-are-making-a-fortune-on-wall-street-2513530266.html.

[44] 42 U.S.C. § 256b.

[45] The PPACA added the following to the list of covered entities entitled to discounted drug prices under the 340B program: (1) certain children's and free-standing cancer hospitals excluded from the Medicare prospective payment system; (2) critical access hospitals; and (3) certain rural referral centers and sole community hospitals. These 340B-eligible facilities also must meet other specified 340B participation requirements, including but not limited to, having a minimum disproportionate share adjustment percentage to qualify for program participation (Critical

Federal grantees include various types of health centers, HIV/AIDS program grantees, and specialized clinics, including Federally Qualified Health Centers (FQHC), Federally Qualified Health Center Look-Alikes,[46] Native Hawaiian Health Centers, Tribal/Urban Indian Health Centers, Ryan White HIV/AIDS Program Grantees, Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Sexually Transmitted Disease Clinics, Tuberculosis Clinics, and Title X Family Planning Clinics.[47] These entities typically are subjected to additional requirements and federal oversight because of their status as federal grantees. For example, HRSA (which oversees the Ryan White HIV/AIDS Program) has established that any revenue a Ryan White grantee generates through participation in the 340B program is Ryan White program income and therefore subject to HRSA restrictions on how Ryan White program income may be spent.[48]

Hospitals that are eligible to participate in the 340B program include certain disproportionate share hospitals (DSH hospitals), children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Eligible hospitals must meet certain additional requirements to participate in the program. First, an eligible hospital typically must have a minimum disproportionate share adjustment percentage to qualify for program participation (which is based on the share of a hospital's inpatients who are Medicaid and low-income Medicare patients).[49] Furthermore, each eligible hospital must be: (1) owned and operated by a state or local government; (2) a public or private nonprofit corporation that is formally delegated governmental powers by a unit of state or local government; or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare.[50]

Additionally, as shown in Figure 1 below, certain eligible hospitals must certify that they will not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangements (referred to as the "GPO prohibition").[51]

Access Hospitals are not required to have a minimum disproportionate share adjustment percentage to participate in the 340B program). See Figure 1: Hospital Eligibility for additional details regarding hospital eligibility requirements in the 340B program.

[46] "Federally Qualified Health Center Look-Alikes are community-based health care providers that meet the requirements of the HRSA Health Center Program, but do not receive Health Center Program funding. They provide primary care services in underserved areas, provide care on a sliding fee scale based on ability to pay and operate under a governing board that includes patients. The defining legislation for Federally Qualified Health Center Look-Alikes (under the Consolidated Health Center Program) is Section 1905(l)(2)(B) of the Social Security Act." *See* U.S. Department of Health and Human Services, Health Resources and Services Administration, *Federally Qualified Health Center Look-Alike* (last accessed Jan. 2, 2018), *available at* https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc-look-alikes/index.html.

[47] Health Resources and Services Administration, Eligibility & Registration (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/eligibilityandregistration/index.html.

[48] Health Resources and Services Administration, *15-03 Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income, Policy Clarification Notice (PCN) #15-03, Relates to Policy #15-04* (last accessed Dec. 1, 2017), https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf.

[49] Public Health Service Act, 42 U.S.C. 256b(a)(4)(L)(ii).

[50] Public Health Service Act, 42 U.S.C. 256b(a)(4)(L)(i).

[51] Public Health Service Act, 42 U.S.C. 256b(a)(4)(L)(iii).

Figure 1: Hospital Eligibility[52]

Hospital Type	Nonprofit/Government Contract Requirement	DSH %	Subject to GPO Prohibition
Disproportionate Share Hospital	Yes	> 11.75%	Yes
Children's Hospital	Yes	> 11.75%	Yes
Free-Standing Cancer Hospital	Yes	> 11.75%	Yes
Critical Access Hospital	Yes	N/A	No
Rural Referral Center	Yes	≥ 8%	No
Sole Community Hospital	Yes	≥ 8%	No

Participation by hospitals in the 340B program has grown markedly in recent years—faster than that of federal grantees—increasing almost three-fold in the number of participants from 2005 to 2011.[53] According to a 2011 report by GAO, one third of all hospitals participated in the program, and DSH hospitals alone represented about 75 percent of all spending by covered entities on 340B drugs.[54] Similarly, in 2015, GAO found that about 40 percent of all U.S. hospitals participate in the 340B program and that the majority of 340B drugs are sold to hospitals.[55] Indeed, according to the Medicare Payment Advisory Commission (MedPAC), as of the first quarter of 2015, DSH hospitals represented about 78 percent of all 340B drug purchases.[56]

C. Background on the Committee's Investigation

The committee has been examining the operation and oversight of the 340B program for over two years. During this review, committee staff have interviewed more than 50 stakeholders including but not limited to HRSA, CMS, GAO, HHS OIG, covered entities, drug manufacturers, pharmacies, third party administrators, and physicians. The committee has held three hearings examining the 340B program and sent letters to HRSA and covered entities requesting documents and information about the program. The committee has also requested that GAO examine certain aspects of the 340B program. The findings in this report are primarily grounded in the committee's work over the past two years.

The first two hearings—on March 24, 2015[57] and July 18, 2017[58]—included federal

[52] Apexus, 340B University, *340B Hospital Eligibility Criteria* (2015), *available at* https://docs.340bpvp.com/documents/public/resourcecenter/Hospital_Eligibility_Criteria.pdf.
[53] U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).
[54] *Id.*
[55] U.S. Gov't Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (Jun. 2015).
[56] Medicare Payment Advisory Commission, *Report to Congress: Overview of the 340B Drug Pricing Program*, at 12 (May 2015).
[57] *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong. (Mar. 24, 2015).
[58] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017).

witnesses from GAO, HHS OIG, and HRSA. During the 2015 hearing, the witnesses testified that while HRSA had taken some steps to strengthen the agency's oversight of the 340B program, there were additional opportunities for enhanced program integrity that were restricted by HRSA's limited authority over the program.[59] HRSA noted that the agency's regulatory authority was limited to three specific topics (as discussed in more detail in Section V.A-B, these three areas include calculation of the 340B ceiling price, imposition of manufacturer civil monetary penalties, and implementing an administrative dispute resolution process), and since HRSA does not have regulatory authority over many aspects of the program, they cannot be as clear or definitive on the program requirements given the different enforcement authority associated with guidance documents.[60] Similarly, during the 2017 hearing, GAO and HHS OIG testified that while HRSA has strengthened their oversight of the 340B program, several weaknesses in program oversight remain. HRSA testified that their limited regulatory authority over the 340B program hinders their ability to oversee program integrity, and that regulatory authority would allow HRSA to provide greater clarity and specificity of program requirements.[61] For example, the 340B statute does not require that entities report their savings or how those savings are used. HRSA therefore does not have data on how much each entity saves through program participation and how the savings are used. In addition, HRSA lacks the authority to promote transparency or direct how covered entities use program savings.

The third hearing was held on October 11, 2017, and included representatives from different types of covered entities participating in the 340B program, including DSH hospitals, a FQHC, a Ryan White grantee, and critical access hospitals.[62] The witnesses provided information about how they use the 340B program to serve vulnerable populations, including whether the program savings are passed directly on to the most vulnerable patients. During the hearing, covered entities discussed the importance of program flexibility. While some covered entities track their program savings regularly to determine how those funds should be used, others testified that they do not track their savings on a regular basis.[63] Moreover, the covered entities did not track program savings in a consistent manner, thereby making it hard to compare the value of the program across different entities.[64] Similarly, the covered entities had varying ways in which they calculated the charity care that they provided to vulnerable populations thereby making it difficult to compare the amount of charity care provided by an entity to examine how savings are being used to improve patient care.[65]

The committee sent a letter to HRSA on June 1, 2017, requesting documents and information about the agency's audits of covered entities. The committee explained the basis of the request:

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[59] *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong., at 51 (Mar. 24, 2015).
[60] *Id.* at 53.
[61] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., at 26 (Jul. 18, 2017).
[62] *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Oct. 11, 2017).
[63] *Id.* at 50-54.
[64] *Id.*
[65] *Id.* at 59-64.

> The Committee is concerned about the 340B program's rapid growth without additional and proportional oversight. Provisions in the Patient Protection and Affordable Care Act (PPACA) expanded the definition of eligible entities to include 'free-standing cancer, community and critical access hospitals on the basis of their disproportionate share hospital (DSH) percentage,' which has increased program enrollment substantially. 340B drug sales more than doubled between 2010 and 2015 and expanded by 66 percent between 2013 and 2015 alone. As of 2011, nearly a third of all U.S. hospitals participated in the program.
>
> Although HRSA began auditing covered entities and publishing its findings in 2012, the lack of reporting requirements presents additional challenges. HRSA does not track how much covered entities make through [the] 340B program, nor how they use program savings. Further, there is no legislative requirement that requires hospitals to use 340B savings in a specific way…. Given the program's ability to generate revenue for covered entities, HRSA has a vested interest in ensuring that those funds are used to benefit patients. The Committee is concerned about reports that uninsured and underinsured patients at 340B hospitals often pay the full list price for a drug while the hospital receives that same drug at a severely discounted price.[66]

After negotiations with committee staff, HRSA produced a sample of 20 audits, selected by HRSA, from different types of covered entities with different characteristics. Committee staff received the entire audit file for these sample audits, including, but not limited to, the audit findings, the covered entity's policies and procedures relating to the 340B program, and contract agreements between pharmacies and covered entities. HRSA subsequently provided an additional 12 audit files to the committee.

In light of the limited information that HRSA was able to provide about the ways in which different covered entities utilize the program, the committee sent a letter on September 8, 2017, to a diverse group of covered entities, 19 in total, requesting information about the entity's participation in the 340B program.[67] Given how differently each covered entity approaches the

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[66] Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, and Hon. Michael C. Burgess, M.D., Chairman, Subcomm. on Health of the H. Comm. on Energy and Commerce, to Mr. George Sigounas, Administrator, Health Resources and Services Administration, U.S. Dep't of Health and Human Services (June 1, 2017).

[67] Information provided by these covered entities is discussed throughout the report. The covered entities that received the committee's September 8, 2017 letter and are discussed in this report include: ARcare (P.O. Box 497, August, Arkansas 72006), Cedars-Sinai Medical Center (8700 Beverly Boulevard, Los Angeles, California 90048), Cook Area Health Services, Inc. (20 Fifth Street SE, Cook, Minnesota 55723), Duke University Health System (14209 red zone, Duke South, Durham, NC 27710), Emory University Hospital Midtown (550 Peachtree Street NE, Atlanta, Georgia 30308), Erlanger Health System (975 East Third Street, Chattanooga, Tennessee 37403), Grady Health System (80 Jesse Hill Drive SE, Atlanta, Georgia 30303), Hudson Headwaters Health Network (9 Carey Road, Queensbury, New York 12804), Primary Children's Hospital (owned and operated by Intermountain Healthcare) (100 North Mario Capecchi Drive, Salt Lake City, Utah 84113), Johns Hopkins Hospital (600 North Wolfe Street, Baltimore, Maryland 21287), Massachusetts General Physicians Organization (Hemophilia Treatment Center Designation) and Massachusetts General Hospital (55 Fruit Street, Boston, Massachusetts 02114), Mission Health (509 Biltmore Avenue, Asheville, North Carolina 28801), Northern Nevada HOPES (580 West 5th Street,

340B program, the committee wanted to hear from a variety of covered entities across the country. The committee explained:

> Congress has only limited visibility into how covered entities use program savings. A recent survey conducted by an association of hospitals participating in the program – 340B Health – indicates that many covered entities use program savings in ways that include but are not limited to, using savings to increase services to uninsured or underinsured patients, improve pharmacy services by funding patient assistance programs and patient counseling, and help fund community service initiatives…. Over the years, however, the program has grown substantially and reports indicate that some hospitals may be abusing the program and may be failing to pass program savings on to the intended beneficiaries.[68]

Information sought by the committee included estimated amount of savings each entity generates through 340B program participation, how each entity calculates, tracks, and spends the program savings, drugs purchased through the program, number of registered child sites, number of contract pharmacy arrangements, patient population served, and how patients benefit from the entities' participation in the program. In addition to requesting information in the letter, committee staff was briefed by each entity, during which staff asked detailed follow-up questions about how each entity uses the program.

D. GAO and HHS OIG Reports on the 340B Program

HHS OIG and GAO have both closely examined various aspects of the 340B program and identified weaknesses in program oversight. In response to Congressional requests, GAO issued reports in 2011[69] and 2015[70] regarding the 340B program. Recently, during the

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Reno, Nevada 89503), Northland Cares (3112 Clearwater Drive Suite A, Prescott, Arizona 86305), Northside Hospital (1000 Johnson Ferry Road NE, Atlanta, Georgia 30342), NYU Langone Health (One Park Avenue 3rd Floor, New York, New York 10016), Parkland Health and Hospital System (5200 Harry Hines Boulevard, Dallas, Texas 75235), UC San Francisco (UCSF) Medical Center (500 Parnassus Avenue, San Francisco, California 94143), and the University of Washington Medicine (Box 356340, Seattle, Washington 98195-6340). Copies of the letters and recipient responses are available on the committee's website. *See* Committee on Energy and Commerce, U.S. House of Representatives, *Letters to a Series of Covered Entities Participating in the 340B Drug Pricing Program* (Sept. 8, 2017), *available at* https://energycommerce.house.gov/news/letter/letters-series-covered-entities-participating-340b-drug-pricing-program/.

[68] *See*, *e.g.*, Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, to Mr. Thomas A. Priselac, President and Chief Executive Officer, Cedars-Sinai Medical Center (Sept. 8, 2017).

[69] In 2011, GAO issued a report entitled, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. GAO found that the 340B program allows certain providers within the U.S. health care safety-net to stretch federal resources to reach more eligible patients and provide more comprehensive services. However, GAO cautioned that HRSA's then-current approach to oversight did not ensure 340B program integrity, and raised concerns that this vulnerability may be exacerbated by changes within the program. U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).

[70] In 2015, GAO issued a report entitled, *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*. The report identified the characteristics of 340B DSH hospitals as compared to non-340B hospitals, and found that hospitals participating in the 340B program have a financial incentive to prescribe more drugs, and more expensive drugs to Medicare beneficiaries. U.S. Gov't Accountability Office, *Medicare Part B*

committee's July 2017 hearing, GAO testified that HRSA has implemented some, but not all, of the recommendations to improve program integrity.[71] Similarly, HHS OIG issued reports examining different aspects of the 340B program in 2011[72] and 2014.[73] At the July 2017 hearing before the committee, HHS OIG testified that some of the weaknesses they identified have been addressed through legislation or by HRSA directly. HHS OIG also noted, however, that long-standing fundamental vulnerabilities continue to exist, including: (1) a lack of transparency that prevents accurate payments by 340B providers, state Medicaid programs, and pharmaceutical manufacturers; and (2) a lack of clarity regarding program rules that creates uncertainty and results in uneven program implementation and limited accountability.[74] Moreover, HHS OIG testified that HRSA needed additional authority to increase transparency and clarity around program rules.[75]

GAO is currently reviewing issues related to contract pharmacies and characteristics of 340B covered entities at the request of the committee. The committee will determine whether to undertake additional work with respect to these issues upon receiving the GAO's reports.

Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442 (June 2015).

[71] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript* (Jul. 18, 2017) (statement of Debra Draper, Director, Health Care, Government Accountability Office).

[72] In 2011, HHS OIG issued a report entitled, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*. HHS OIG found that states lacked pricing information needed for oversight and that nearly half of states did not have written 340B program policies. Office of Inspector General, U.S. Dep't of Health and Human Services, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321 (June 2011).

[73] In 2014, HHS OIG issued a report entitled, *Contract Pharmacy Arrangements in the 340B program*. HHS OIG found that contract pharmacy arrangements create complications in preventing diversion and duplicate discounts. HHS OIG also found that "some covered entities in [their] study [did] not offer the discounted 340B price to uninsured patients in their contract pharmacy arrangements." In the report, HHS OIG noted that the number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent. Office of Inspector General, U.S. Dep't of Health and Human Services, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 4, 2014).

[74] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, Assistant Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services).

[75] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 50 (Jul. 18, 2017).

V. HRSA Administration and Oversight of the 340B Program

A. HRSA's Implementation of 340B Regulations

Finding: HRSA has started, but after several years not completed, the process to issue and enforce regulations pertaining to the Administrative Dispute Resolution Process, the calculation of ceiling prices, and manufacturer civil monetary penalties. HRSA has not fully implemented these regulations in a timely manner.

HRSA is the Operating Division within HHS that administers and oversees the 340B program. HRSA is the principal federal agency responsible for increasing access to effective and efficient basic health care for individuals who are medically underserved or face barriers (*e.g.*, economic, geographic, linguistic, and cultural) to health care.[76] In addition to administering the 340B program, HRSA supports other programs and services including the Health Center Program, and the Ryan White HIV/AIDS Program, among others.[77] The President's FY 2018 Budget Proposal requested $9.9 billion, including $4.4 billion in mandatory funding, for HRSA to invest in programs that provide these health care services.[78]

According to HRSA's FY 2018 Budget Justification, HRSA budgeted $10.2 million and 22 FTEs to administer the 340B program in FY 2017.[79] HRSA testified in July 2017 that there were currently 16 FTEs overseeing the 340B program and that the amount requested in the agency's budget proposal was necessary to maintain their current level of oversight of the 340B program.[80] The amount of funding for the 340B program has stayed relatively constant since 2014 despite the significant amount of program growth over the past few years.

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[76] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees* (2018).
[77] U.S Dep't of Health and Human Services (HRSA), *HRSA Program Areas* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov.
[78] *Id.*
[79] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees*, at 244 (2018).
[80] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 56 (Jul. 18, 2017).

Figure 2: HRSA Funding for the 340B Program

Year	Funding History (in millions)	FTEs
2010[81]	$2.22 million *(actual)*	--
2011[82]	$4.48 million *(enacted)*	1
2012[83]	$4.47 million *(enacted)*	3
2013[84]	$4.19 million *(final)*	3
2014[85]	$10.21 million *(final)*	4
2015[86]	$10.24 million *(final)*	11
2016[87]	$10.24 million *(enacted)*	24
2017[88]	$10.22 million *(annualized CR)*	22
2018[89]	$10.22 million *(requested)*	22

In 2014, Congress increased HRSA's budget for the 340B program by $6 million to expand the agency's oversight of the program. HRSA used the funding to support program integrity efforts and to develop information technology (IT) systems supporting program compliance.[90] To ensure that both covered entities and pharmaceutical manufacturers are in compliance with program requirements, HRSA, among other things: (1) conducts initial eligibility checks of all entities seeking to register with the program; (2) recertifies covered entities on an annual basis; (3) performs audits of covered entities and manufacturers; and (4) provides additional compliance support.

HRSA has prioritized rulemaking in the three specific areas where the D.C. Circuit has clearly recognized the agency's regulatory authority[91]: (1) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices; (2) imposition of manufacturer civil monetary penalties; and (3) establishment of an administrative dispute resolution process.[92] However, HRSA has not yet fully implemented regulations addressing any of these issues. The limits established by the D.C. Circuit on HRSA's regulatory authority, and

[81] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2012 Justification of Estimates for Appropriations Committees* (2012).
[82] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2013 Justification of Estimates for Appropriations Committees* (2013).
[83] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2014 Justification of Estimates for Appropriations Committees* (2014).
[84] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2015 Justification of Estimates for Appropriations Committees* (2015).
[85] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2016 Justification of Estimates for Appropriations Committees* (2016).
[86] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2017 Justification of Estimates for Appropriations Committees* (2017).
[87] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees* (2018).
[88] *Id.*
[89] *Id.*
[90] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong. (Mar. 24, 2015).
[91] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 26 (Jul. 18, 2017).
[92] *Id.* at 81.

the impact this has on HRSA's ability to oversee the 340B Program, are discussed in Section V.B.

To resolve disputes between covered entities and manufacturers regarding the 340B program in an expeditious manner, in 1996, HRSA established a voluntary administrative dispute resolution (ADR) process for resolving these claims.[93] In 2010, the PPACA required HHS to promulgate regulations to establish and implement a binding ADR process for resolution of certain disputes concerning compliance with the 340B program.[94] The purpose of the ADR process is to resolve assertions by covered entities that they have been overcharged for 340B drugs and claims by manufacturers that a covered entity has violated the prohibitions on duplicate discounts and diversion. In 2010, HHS issued an advanced notice of proposed rulemaking (ANPRM) requesting comments on the development of the ADR process.[95] After being under development for a number of years,[96] during which time HRSA considered the 14 comments the agency received regarding the ANPRM, HHS issued a notice of proposed rulemaking (NPRM) on the ADR process on August 12, 2016.[97] The comment period for the NPRM closed on October 11, 2016.[98] On August 1, 2017, HHS withdrew the NPRM.[99] Accordingly, HRSA has not yet developed an ADR process, some seven years after the law requiring them to do so was enacted.

The PPACA required HHS to provide for the imposition of civil monetary penalties (CMPs) against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug.[100] Because HHS had never had CMP authority to address overcharging by manufacturers in the 340B program, HHS issued an ANPRM entitled *340B Drug Pricing Program Manufacturer Civil Monetary Penalties* in 2010 to solicit public feedback on this requirement.[101] After considering the 15 comments on the ANPRM regarding the imposition of CMPs for manufacturers that knowingly and intentionally overcharge covered entities under the 340B program, on June 17, 2015, HHS issued a NPRM on the calculation of ceiling prices, the imposition of manufacturer CMPs, and to establish the requirement that a manufacturer charge a $0.01 (penny pricing policy) for 340B drugs if the ceiling price equals zero.[102]

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[93] Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406 (Dec. 12, 1996).
[94] 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sept. 20, 2010).
[95] *Id.*
[96] *See*, *e.g.*, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (stating that "The administrative dispute resolution process remains under development and is not included in this notice of proposed rulemaking.").
[97] 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016).
[98] *See* Docket for 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016), *available at* https://www.regulations.gov/document?D=HRSA-2016-0002-0001.
[99] *See* Office of Management and Budget, *340B Drug Pricing Program; Administrative Dispute Resolution Process* (last accessed Dec. 12, 2017), *available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90.
[100] 340B Drug Pricing Program Manufacturer Civil Monetary Penalties, 75 Fed. Reg. 57,230 (Sept. 20, 2010).
[101] *Id*.
[102] 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (Jun. 17, 2015).

On January 5, 2017, HHS finalized this rule and established an effective date of October 1, 2017.[103] The final rule requires that manufacturers calculate the 340B ceiling price on a quarterly basis, requires that manufacturers charge $0.01 per unit of measure if the 340B ceiling price calculation results in a ceiling price that equals zero, establishes the methodology manufacturers must use when estimating the ceiling price for a new 340B drug, establishes how a CMP will be imposed on a manufacturer that knowingly and intentionally overcharges a covered entity, and establishes what constitutes an instance of overcharging that triggers a CMP.[104] On August 21, 2017, however, HRSA published a NPRM to further delay the effective date of the final rule.[105] Shortly thereafter, on September 29, 2017, HRSA formally delayed the effective date and the enforcement date of the final rule to July 1, 2018, and expressed their intent to engage in further rulemaking.[106] Thus, HRSA has not yet effectuated their regulation on this issue, some seven years after the law requiring them to do so was enacted.

Consistent with HHS OIG's recommendation for HRSA to improve program transparency surrounding the ceiling prices set by manufacturers in accordance with the statutory formula, the PPACA authorized HRSA to share confidential ceiling price information with covered entities.[107] HRSA used part of the increased funding it received in 2014 to develop an IT system to share ceiling prices with covered entities, and has since testified that it is continuing to work on the development of that system.[108] While HRSA testified that they were "getting very close to the release of [this] system," covered entities still do not have access to ceiling price information.[109] As discussed in Section V.D., without this data, covered entities are unable to ensure they are paying an appropriate price for 340B drugs.[110] Accordingly, they may not know that they should report to HRSA that they are not receiving an accurate price from a manufacturer.

HHS OIG also has recommended that state Medicaid programs have access to information about ceiling prices for 340B drugs to help ensure state Medicaid programs can effectively enforce Medicaid payment policies for 340B drugs.[111] While the PPACA provided HRSA with the authority to share ceiling prices with covered entities, HRSA does not have the authority to share ceiling prices with the state Medicaid programs. HRSA testified in July 2017

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[103] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017).
[104] Health Resources and Services Administration, *Office of Pharmacy Affairs Update* (Jan. 2017), *available at* https://www.hrsa.gov/sites/default/files/opa/updates/2017/170106monthlyupdate.pdf.
[105] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 39,553 (Aug. 21, 2017).
[106] *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 45,511 (Sept. 29, 2017).
[107] *See Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, U.S. Dep't of Health and Human Services, Office of Inspector General).
[108] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 86 & 101 (Jul. 18, 2017).
[109] *Id*. at 102.
[110] *Id.* at 31.
[111] *See Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, U.S. Dep't of Health and Human Services, Office of Inspector General).

that while providing access to ceiling prices would not address any issues relating to duplicate discounts, state Medicaid agencies could use this information to ensure compliance with CMS reimbursement requirements:

> Q: Do you have sufficient statutory authority to carry out that recommendation of providing ceiling prices to state Medicaid agencies?
>
> A: The statute is very specific to allow HRSA to provide ceiling prices to covered entities. Therefore, we would need a legislative change to provide that information to the states. We are currently in discussion with CMS regarding some possible administrative options. But we would need up front a legislative –
>
> Q: Okay. So let us talk about that for a second. Let us assume that state Medicaid agencies have the ability to learn of the ceiling prices. Can you share for this subcommittee how that would positively impact program integrity?
>
> A: So in terms of providing the ceiling to states, it would not address any issues around duplicate discounts under the 340B statute. The ceiling prices would be in place to help inform the prices being paid for those drugs so that the states could reimburse the covered entity according to CMS rules.[112]

According to a February 2016 final rule, CMS requires that states adopt a Medicaid reimbursement methodology based on Actual Acquisition Cost that reflects the actual price that a provider paid to acquire the medicine.[113] In a February 11, 2016 letter to State Medicaid Directors, CMS explained that "[f]or drugs purchased through the 340B program, reimbursement should not exceed the 340B ceiling price."[114] However, many State agencies are unable to effectively enforce their Medicaid payment policies for 340B drugs because they do not have access to ceiling prices.[115]

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[112] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 107 (Jul. 18, 2017).
[113] Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016).
[114] Letter from Vikki Wachino, Director, Centers for Medicare and Medicaid Services, to State Medicaid Directors re Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program (Feb. 11, 2016).
[115] *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong. (Mar. 24, 2015) (statement of Ann Maxwell, Assistant Inspector General, Office of Evaluation and Inspections, Office of Inspector General, U.S. Dep't of Health and Human Services).

B. HRSA's Authority to Clarify Program Requirements

Finding: HRSA lacks sufficient authority to adequately oversee the program and clarify program requirements. HRSA needs more regulatory authority to promote compliance and ensure program integrity. Key aspects of the program have remained vague, resulting in variation in the way covered entities use the 340B program.

HRSA continues to face challenges in overseeing the 340B program, primarily because the agency has limited regulatory authority over the 340B program. HRSA has encountered numerous oversight hurdles since a federal court established limits on HRSA's rulemaking authority in 2014, ruling that the 340B statute provides HRSA with explicit regulatory authority in only three specific areas: (1) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices; (2) imposition of manufacturer civil monetary penalties; and (3) establishment of an administrative dispute resolution process.[116]

The federal court decision limiting HRSA's regulatory authority regarded a 2013 final rule relating to the circumstances in which an orphan drug must be offered at a discounted price under the 340B program.[117] In a suit brought by the Pharmaceutical Research and Manufacturers of America, the D.C. District Court concluded that HRSA lacked the statutory authority to promulgate the orphan drug regulations and vacated the rule.[118] The court reasoned that Congress provided HRSA with limited explicit regulatory authority in three specific areas and the agency therefore could not promulgate regulations regarding other provisions in the 340B program statute.[119] The court noted "[t]he 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 provisions of the 340B program."[120] Shortly thereafter, in June 2014, HRSA announced they continued to stand by their interpretation described in the published final rule, and in July 2014, HRSA issued an interpretive rule pertaining to the statutory requirement for inclusion of drugs with orphan drug designations in the 340B drug pricing program.[121] These agency actions were also challenged, and, in October 2015, the D.C. District Court held that the interpretive rule was contrary to the language of the 340B statute.[122]

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[116] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 81 (Jul. 18, 2017).

[117] The orphan drug rule HRSA issued allowed 340B covered entities affected by the orphan drug exclusion (critical access hospitals, freestanding cancer hospitals, sole community hospitals and rural referral centers) to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation. Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 78 Fed. Reg. 44,016 (Jul. 23, 2013).

[118] *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health and Human Serv.*, 43 F. Supp. 3d 28, 42-5 (D.D.C. 2014).

[119] *Id.*

[120] *Id*.

[121] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Covered Entities Under the 340B Program* (Jul. 23, 2014), *available at* https://www.hrsa.gov/sites/default/files/opa/programrequirements/interpretiverule/interpretiverule.pdf.

[122] *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health and Human Serv.*, case no. 14-1685 (D.D.C. 2015).

Consequently, HRSA has struggled to provide stakeholders with specific information about program requirements.[123]

In 2014, HRSA had planned to issue an omnibus regulation for the 340B program to strengthen the agency's oversight of covered entities and manufacturers and establish additional policies, including clarifying the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities. Because of the May 2014 federal court decision invalidating the orphan drug regulation, however, HRSA withdrew the omnibus 340B regulation from Office of Management and Budget (OMB) review in November 2014 to re-evaluate the proposed omnibus regulation given the court's ruling.[124] HRSA subsequently released a proposed 340B Drug Pricing Program Omnibus Guidance, commonly referred to as the "Mega-Guidance," in August 2015.[125] HRSA ultimately withdrew the Mega-Guidance on January 30, 2017, shortly after the Trump administration issued a regulatory freeze requiring agencies to retract any regulations currently under review.[126] In July 2017, HRSA testified that they were "working on next steps to address these policy issues."[127]

HRSA has requested additional regulatory authority for the 340B program under both President Obama and President Trump.[128] For example, in the overview of President Obama's FY 2017 Budget, the administration proposed a user fee to be imposed on covered entities to support operation of the program, and noted it was "committed to program integrity in the 340B program, and the FY 2017 Budget [sought] new rulemaking authority to ensure adherence to the program's principles, compliance with the law, and the most effective use of this critical safety-net program."[129] The Obama administration also proposed the use of fees to support the program in the FY 2015 and FY 2016 budgets.[130] Similarly, in HRSA's congressional budget justification

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[123] *See, e.g., Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong. (Mar. 24, 2015).

[124] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, U.S. Dep't of Health and Human Services, Office of Inspector General).

[125] *340B Drug Pricing Program Omnibus Guidance* 80 Fed. Reg. 52,300 (Aug. 28, 2015).

[126] Executive Office of the President, Office of Management and Budget, Office of Information and Regulatory Affairs, *340B Program Omnibus Guidance*, RIN 0906-AB08 (last accessed Dec. 1, 2017), *available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AB08.

[127] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 26 (Jul. 18, 2017).

[128] U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Committee Staff Phone Briefing with U.S. Dep't of Health and Human Services, Health Resources and Services Administration (Jul. 13, 2017); *See also* U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees* (2018).

[129] *See* U.S. Dep't of Health and Human Services, *HHS FY 2017 Budget in Brief – HRSA* (last accessed Dec. 19, 2017), *available at* https://www.hhs.gov/about/budget/fy2017/budget-in-brief/hrsa/index.html.

[130] *See* U.S. Dep't of Health and Human Services, *HHS FY 2015 Budget in Brief – HRSA*, https://www.hhs.gov/about/budget/fy2015/budget-in-brief/hrsa/index.html ("The Budget includes $17 million for the 340B program, an increase of $7 million above FY 2014, through a new cost recovery fee, which will help improve the program's operations, oversight and integrity.") (last accessed Dec. 19, 2017); U.S. Dep't of Health and Human Services, *HHS 2016 Budget in Brief – HRSA*, https://www.hhs.gov/about/budget/fy2016/budget-in-

for President Trump's FY 2018 Budget, HRSA stated: "HHS will work with Congress to develop a legislative proposal to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations. This proposal would provide regulatory authority."[131]

In July 2017, HRSA testified "[s]pecific legislative authority to conduct rule making for all provisions in the 340B statute would be more effective for facilitating HRSA's oversight and management of the program. Specifically, regulatory authority would also allow HRSA to provide greater clarity and specificity of program requirements."[132] HRSA also noted that the agency has struggled to clarify some of the program requirements since they lack explicit regulatory authority for other provisions of the 340B statute:

> Q: So let me ask you then what you think then are the key – Captain Pedley, the key areas that we ought to be looking at to support your work in making sure that your audits are as effective as they can be and that this program is as effective as it can be.
>
> A: As proposed in the – in the fiscal year '18 president's budget, HRSA only, again, has regulatory authority in three specific areas and we have proposed guidance in all other areas. The regulatory authority across the program is critical for us to be able to provide clarity in our program requirements and assist HRSA in our oversight efforts to be able to then enforce those requirements. So regulatory authority is key.[133]

Similarly, in March 2015, HRSA testified that if the agency had additional tools to clarify program requirements, they would certainly use those tools.[134] Moreover, HRSA said that rulemaking authority would allow the agency to provide more specificity about program requirements:

> Q: And then what about the difficulties, other difficulties with enforcing guidance in the absence of rule-making authority?
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> A: Generally rule making allows an agency to be more specific about its requirements and that is clearly something that has been identified by both the GAO and IG. So greater specific, clarity on the requirements. It also

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brief/index.html ("In addition, it proposes a new user fee totaling $7.5 million as a long-term financing strategy to support the program's activities) (last accessed Dec. 19, 2017).

[131] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees*, at 246 (2018).

[132] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 26 (Jul. 18, 2017).

[133] *Id.* at 90.

[134] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong., at 60 (Mar. 24, 2015).

> has a stronger enforcement ability than guidance. So yes, overall, rule making is a stronger enforcement tool than guidance.[135]

Likewise, HHS OIG testified during the committee's July 2017 hearing that HRSA needs additional regulatory authority to effectively administer and oversee the 340B program:

> Q: And Ms. Bliss, I just wanted to ask you quickly what tools or authorities do you believe HRSA needs in order to efficiently administer the 340B program?
>
> A: Thank you. We believe that increasing transparency and clarity around the program rules is very important, and while I can't offer a legal opinion on HRSA's authority, our understanding is they may need additional authority from Congress to do this.[136]

GAO has also identified vulnerabilities in HRSA's oversight of the 340B program in some of their work. For example, in 2011, GAO issued a report entitled *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*.[137] In the report, GAO found that HRSA's oversight of the 340B program was inadequate to ensure compliance with program rules, and GAO made recommendations for HRSA to improve program integrity. HRSA has addressed two of GAO's four recommendations in the report by beginning to conduct audits of covered entities and providing more specific non-discrimination guidance for manufacturers on handling cases in which distribution of drugs is restricted.[138] HRSA, however, has not clarified guidance on the definition of an eligible patient and hospital eligibility criteria for program participation as recommended in GAO's report.[139] The committee therefore asked GAO about these findings during the July 2017 hearing, and asked whether there were any remaining concerns about program integrity:

> Q: Now, so, Dr. Draper, I understand that in the GAO audits you found some weaknesses in HRSA's ability to oversee the program and also you found that the agency needs to issue guidance that defines a 340B patient and clarity the standard for hospital eligibility. Are those in general your concerns?
>
> A: Well, to give you an example, the definition of a patient is very ambiguous. It is that the patient has an established relationship with the entity and the

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[135] *See, e.g., Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong., at 26 & 62 (Mar. 24, 2015).
[136] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 50 (Jul. 18, 2017).
[137] U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).
[138] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Debra Draper, Director, Health Care, Government Accountability Office).
[139] *Id*.

> entity maintains the medical records and that the entity – the provider of services for that entity is either employed or under contract arrangement or some other type of arrangement. So we had concerns about the language about like some other type of arrangement –
>
> Q: Right.
>
> A: -- what specifically does that mean, and I think it has been interpreted very broadly.
>
> Q: So let me ask you, do you think the agency has authority under the current statutory language to tighten those definitions up or do you think that we need to do something with the statute?
>
> A: Well, since 1992 the agency has issued program guidance to try and clarify the rules of the program. So we are not – we are a little confused about why. I think there is some concern that they need some regulatory authority versus having guidance and –
>
> Q: Okay. So we might have to – we might have to go and look at the statute.
>
> A: Perhaps.[140]

Despite these limitations on HRSA's regulatory authority, the agency has attempted to clarify program requirements in a variety of ways. This process, however, oftentimes has been inadequate and made it difficult for some covered entities to comply with the program. In the Questions for the Record for the October 2017 hearing, one covered entity, Mission Health, told the committee that HRSA's inability to issue clear guidance on program requirements has resulted in varying interpretations of program requirements:

> [Over the last 25 years], HRSA has, due to the state of the applicable statutes, at times, dictated or ushered compliance through the issuance of 'frequently asked questions' posed on the 340B website and/or through audit findings (instead of issuing regulations and/or through rulemaking), leading to varying interpretations of permissible/impermissible use across the 340B program. This process has made it more difficult to optimally achieve compliance in an already complex program.
>
> By way of example, 340B providers have asked the question as to whether, in owned or contracted community pharmacies, a Medicaid Managed Care patient is eligible for 340B-priced medications. In multiple forums, the verbal answer from HRSA has been that only fee-for-service Medicaid duplicate discounts are prohibited, and a Medicaid Managed Care patient, is therefore, 340B eligible. The Apexus website 'frequently asked question' does not include an answer to this

[140] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcommittee. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 50 (Jul. 18, 2017).

> question. The 'eligible patient definition' in this situation is not clear, and accordingly, hospitals must make a decision that could ultimately result in audit findings. Situations like this example are what Mission references as a lack of regulatory clarity, and it is a clear opportunity for improvement.[141]

Mission Health continued: "The issuance of clear, statutory language supported by a formal and consistent regulatory and/or rule-making process regarding the 'patient' definition would strengthen the 340B Program and help 340B hospitals meet program requirements in consistent manner."[142]

HHS OIG has also highlighted concerns with the current lack of clarity in program requirements and commented on how covered entities might interpret program requirements in different ways. For example, in 2015, HHS OIG testified that health care providers use different definitions of eligible patient:

> Let's imagine a doctor sees a patient at a community health center. Later that same doctor sees the same patient at her private practice. If that doctor prescribes a drug to that patient at her private practice, is that prescription eligible for the 340B discount? One provider we talked to in our study said yes. Another provider in our study said no. And yet another said maybe. So who is right? We couldn't tell based on current guidance.[143]

Likewise, at the same hearing in 2015, GAO testified that "[b]ecause of the complex nature of and significant growth in the program, it is also critical that program requirements are clearly and explicitly laid out in guidance or regulations. Otherwise, much is left to interpretation, increasing the risk of misuse of the 340B Program."[144]

C. HRSA's Audits of Covered Entities

Finding: Although HRSA has increased the number of covered entity audits it conducts per year, the audit process still needs improvement. Given HRSA's limited regulatory authority over the 340B program, HRSA only conducts a limited review of the covered entity's use of the program during the audit process. Covered entities would benefit from clear guidance on the audit process.

Under 42 USC 256b(a)(5)(C), HRSA has the authority to audit covered entities for compliance with 340B program requirements. The relevant provision in the PHSA provides:

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[141] Letter from Ronald A. Paulus, M.D., President and Chief Executive Officer, Mission Health System, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, *Additional Questions for the Record* (Nov. 21, 2017).
[142] *Id*.
[143] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong., at 36-37 (Mar. 24, 2015).
[144] *Id*. at 19.

> (C) AUDITING. ---A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

Subparagraph (A) under 42 USC 256(b)(a)(5) prohibits requiring manufacturers to pay discounts or rebates under both the 340B program and the Medicaid Drug Rebate Program (*i.e.*, duplicate discounts). Subparagraph (B) under 42 USC 256(b)(a)(5) prohibits the resale of 340B drugs to a person who is not a patient of the entity (*i.e.*, diversion).

HRSA and manufacturers have had the authority to audit covered entities since the 340B program was established in 1992.[145] Until 2012, however, HRSA primarily relied on covered entities to self-monitor and ensure compliance with 340B program requirements. In response to a 2011 GAO report recommending HRSA begin auditing covered entities to monitor for program violations, provide additional program oversight, and prevent diversion and duplicate discounts, HRSA began conducting selective audits of covered entities in 2012.[146] Since FY 2012, HRSA has slowly increased the number of audits it conducts each year of covered entities—conducting 51 audits in 2012,[147] 94 in 2013,[148] 99 in 2014,[149] 200 in 2015,[150] 200 in 2016,[151] and 132 in 2017 (as of December 12, 2017).[152]

As of October 2016, there were 12,148 covered entities participating in the 340B program.[153] HRSA therefore audited fewer than 2 percent of covered entities participating in the

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[145] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program Notice: Clarification of HRSA Audits of 340B Covered Entities*, Release No. 2012-1 (Mar. 5, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/auditclarification030512.pdf.

[146] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong., at 19 (Mar. 24, 2015).

[147] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY12 Results* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/audit-results/fy-12-results.html.

[148] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY13 Results* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/audit-results/fy-13-results.html.

[149] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY14 Results* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/audit-results/fy-14-audit-results.html.

[150] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY15 Results* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/audit-results/fy-15-audit-results.html.

[151] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY16 Results* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/audit-results/fy-16-results.html.

[152] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY17 Results* (last updated Dec. 12, 2017) (last accessed Jan. 3, 2018), *available at* https://www.hrsa.gov/opa/program-integrity/audit-results/fy-17-results.html.

[153] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees* (2018).

program in 2016. HRSA conducts selective and targeted audits of covered entities. For the first selective model, HRSA selects covered entities through a risk-based approach whereby the agency factors in certain risk factors and then randomly selects covered entities to audit based on those factors.[154] In the targeted model, HRSA specifically targets certain covered entities to audit based on either specific allegations HRSA has received about compliance issues with the covered entities or information HRSA has indicating that a covered entity is not in compliance with program requirements.[155] For example, HRSA considers if a previous audit had findings, and may consider re-auditing the covered entity once the Corrective Action Plan (CAP) is fully processed so the agency can assess whether the covered entity fully implemented the CAP.[156]

During audits of covered entities, HRSA reviews covered entity compliance with respect to eligibility status and program requirements, including compliance with the GPO prohibition as applicable, incorrect database, duplicate discounts, and diversion. In certain instances, HRSA also will make non-binding recommendations to the covered entity in an "Area for Improvement" section in the final audit report issued to the covered entity.[157] When HRSA is auditing for duplicate discounts and diversion, HRSA follows a standard auditing process whereby the agency only audits a sample of the 340B drugs purchased by the covered entity rather than all 340B drugs purchased by that entity.[158] To ensure the entire program is in compliance with program requirements, HRSA also reviews all other aspects of the program including looking at their policies and procedures, interviewing staff, reviewing software systems, and examining any other relevant documents and information.[159]

HRSA also examines the covered entity's off-site facilities and contract pharmacies participating in the program. During the committee's July 2017 hearing, HRSA testified that the more than 800 covered entity audits conducted by the agency since 2012 included reviews of nearly 11,000 offsite facilities and 18,000 contract pharmacy locations.[160]

> Q: But why the great expansion in the number of contract pharmacies? Is it just because we lifted the cap of one or how did that happen?
>
> A: The 340B statute is silent on how these covered entities dispense and get these drugs to their patients. We had understood that through state law entities were contracting with pharmacies. So in recognition of that, we did

[154] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 88 (Jul. 18, 2017).
[155] *Id*.
[156] U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Committee Staff Phone Briefing with U.S. Dep't of Health and Human Services, Health Resources and Services Administration (Jul. 13, 2017).
[157] *See* HRSA audit records on file with the Committee.
[158] U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Committee Staff Phone Briefing with U.S. Dep't of Health and Human Services, Health Resources and Services Administration (Jul. 13, 2017).
[159] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 89-90 (Jul. 18, 2017).
[160] *Id.* at 27. HRSA's review of contract pharmacies is limited due to HRSA's narrow authority.

develop guidance in 2010 that stated if they were going to have these contract pharmacies they needed to ensure they were also complying with the statutory requirements of diversion and duplicate discounts and we audit that information on those contract pharmacies when we go in to audit a covered entity.

Q: All right…. But I have also heard that the contract pharmacies are not only allowed to charge a dispensing fee but some of them ask for part of the savings on the drug. Is that correct or is that incorrect?

A: I don't have the information on that. That's a business matter between the parties and their contract.

Q: But it is not prohibited?

A: It is – it is not prohibited.

Q: Okay. Now let us get back to the audits.... Do you suspend the pharmacy or do you suspend the entity if they are not doing the proper oversight of the contracting pharmacies?

A: So we have audited now over 800 covered entities but it doesn't stop there. We also do conduct the audits within those of their contract pharmacies. So we have audited over 18,000 contract pharmacy arrangements related to those audits. We do ensure the covered entity is providing oversight. We sample 340B drugs dispensed from those pharmacies to ensure that they have not been diverted or have a duplicate discount, and if we do find the entity is not providing oversight of those contracts pharmacies we will remove the pharmacies from the program.

Q: All right. Now, that raises an interesting issue. If you have done the audits, and you touched on 18,000 contract pharmacies, those audits didn't reveal to you if some of them were getting a split of the savings with the entity?

A: That is a matter outside of our authority so we don't review it when we – when we audit them.[161]

Typically, if there is a finding during HRSA's audit process such as diversion or duplicate discounts, the covered entity is required to submit a CAP to HRSA. HRSA will review and approve the CAP, and then HRSA will continue to monitor the covered entity to ensure the CAP is properly implemented. The covered entity also may be required to offer the manufacturers repayment if there are certain findings and HRSA may remove the covered entity from the 340B program. HRSA posts summaries of the audit findings for each covered entity on their website

[161] *Id.* at 116-118.

and information about whether the covered entity is under a CAP.[162] HRSA rarely terminates covered entities from the 340B program through the audit process. In July 2017, the agency testified that they had terminated one covered entity for not submitting a corrective action plan following an audit.

> Q: Have you ever terminated an entity?
>
> A: We have terminated one covered entity for not submitting a corrective action plan. We were able to terminate them through that mechanism. We have terminated contract pharmacies through the program where a covered entity was not providing oversight and there were a few cases where we terminated a child or offsite clinic of a hospital because they were not eligible for the program. But that is just through the audit process. We also terminate through our recertification process and some other quarterly integrity checks that we do to ensure compliance.[163]

HRSA can terminate an entity from the 340B program through the audit process if HRSA finds that the GPO prohibition is applicable to that entity and the covered entity is not complying with the GPO prohibition.[164]

While HRSA examines a covered entity's policies and procedures and interviews staff during an audit, audits are limited in scope as HRSA does not audit any information that is not within their explicit statutory authority.[165] For example, as previously noted, HRSA does not examine whether a covered entity is sharing program revenue with its contract pharmacy. Similarly, HRSA does not examine how covered entities use program savings:

> Q: Do we or do we not know or audit how the savings are spent? That seems to be one of the issues. We all believe that everybody is a good actor and the money is going to the people most in need, as well as savings. But I

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[162] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/index.html.

[163] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 72-73 (Jul. 18, 2017).

[164] Section 340B(a)(4)(L)(iii) of the PHSA provides that, to be eligible for the 340B program, certain covered entities may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." HRSA's long-standing policy is that if a covered entity subject to this prohibition participates in a GPO or other group purchasing arrangement, the covered entity "will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices." 340B Drug Pricing Program Omnibus Guidance, 59 Fed. Reg. 25,110 at 25,113 (May 13, 1994). *See* Health Resources and Services Administration, *340B Drug Pricing Program Notice: Statutory Prohibition on Group Purchasing Organization Participation*, Release No. 2013-1 (February 7, 2013) (indicating that "[s]ince the GPO prohibition is an eligibility requirement, covered entities found in violation will be considered ineligible and immediately removed from the 340B Program. Covered entities may also be subject to repayment to manufacturers for the time period for which the violation occurred.").

[165] *See, e.g., Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 44 (Jul. 18, 2017).

also am not clear that HRSA actually – that there is a clear definition of how the money should be spent or that we track the money. Is that correct?

A: So the statute is silent as to how savings are used. Therefore, HRSA does not audit or have access to that information.[166]

If HRSA audits beyond the scope of their authority, the findings can easily be challenged by the covered entity.[167] If a covered entity disagrees with HRSA's audit findings, the entity has 30 days in which to notify HRSA of their disagreement and provide supporting documentation.[168] OPA then reviews the entity's response and may reissue the audit Final Report if appropriate.[169]

i. Audit Findings

Finding: HRSA's annual audits uncovered a high level of non-compliance by covered entities. The HRSA audits from FY 2012 to FY 2016 demonstrate that non-complying entities violate program requirements in a variety of different ways, including duplicate discounts, diversion to ineligible patients and facilities, incorrect database reporting, and violation of the Group Purchasing Organization (GPO) prohibition (if applicable).[170]

Figure 3: Program Requirement Violations*:[171]

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Duplicate Discounts	18	16	18	36	48
Drug Diversion	16	54	54	95	94
Incorrect Database	15	46	51	96	60
GPO Prohibition	0	1	9	18	9
No Adverse Findings	19	22	19	45	62
Total Audits	51**	94**	99**	200**	200**

**Numbers provided represent the number of entities that committed this type of violation. In some cases, an entity may have committed one type of violation multiple times.*
***Numbers do not sum because several entities had more than one type of violation.*

[166] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript* (Jul. 18, 2017).
[167] U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Committee Staff Phone Briefing with U.S. Dep't of Health and Human Services, Health Resources and Services Administration (Jul. 13, 2017).
[168] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *340B Audit Process* (last accessed Dec. 14, 2017), *available at* https://www.hrsa.gov/opa/updates/july-2014.html.
[169] *Id*.
[170] Duplicate discounts, diversion, and incorrect reporting will be discussed later in this section.
[171] *See* U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/index.html.

ii. Duplicate Discounts

Covered entities are prohibited from receiving duplicate discounts.[172] A duplicate discount occurs when a covered entity receives a 340B discount on drugs provided to Medicaid patients *and* the state Medicaid agency also receives a rebate for the drug dispensed to the Medicaid beneficiary through the Medicaid Drug Rebate Program. When an entity enrolls in the 340B program, it must determine whether it will "carve-in" or "carve-out" for Medicaid prescriptions. Entities that "carve-in" agree to buy Medicaid drugs through the 340B program without seeking a Medicaid rebate, while entities that "carve-out" agree to buy Medicaid drugs through the Medicaid Drug Rebate Program or otherwise. Duplicate discounts occur because there is overlap in eligibility for the Medicaid Drug Rebate Program and the 340B program. While Medicaid rebates benefit state Medicaid programs and 340B discounts benefit 340B-covered entities, both of these programs target the same safety-net population.[173] The significant overlap in prescription eligibility makes discount errors likely, and HRSA's audits found duplicate discounts to be quite common. Further, 340B discounts are often determined retrospectively, which can also increase the rate of discount errors. At least 17 percent of 340B-covered entities audited had duplicate discount errors each year since 2012, when HRSA began conducting audits, as shown above in Figure 3.

In 2013, HRSA created the 340B Medicaid Exclusion File (MEF) as a strategy to prevent duplicate discounts for drugs subject to both Medicaid rebates and 340B prices for fee-for-service (FFS) claims.[174] The MEF is a list of Medicaid provider numbers or national provider identifiers (NPI) of each entity that has agreed to purchase all drugs billed to Medicaid through the 340B program. The MEF is intended to prevent duplicate discounts by notifying states and manufacturers which drug claims are not eligible for Medicaid rebates. This measure counts on the integrity and continued participation of covered entities to disclose accurate and current information.

HRSA lacks a centralized mechanism similar to the MEF to prevent duplicate discounts for Medicaid Managed Care Organizations (MCOs).[175] This is a very significant and growing problem because an increasing number of Medicaid programs rely on MCOs to deliver Medicaid benefits. In 2014, 76 percent of Medicaid enrollees were in some type of managed care.[176] HHS OIG released a report in June 2016 finding that duplicate discounts are a severe issue for Medicaid MCOs.[177] The data that most states collect for MCO drugs is not granular enough to detect all individual drug claims. Many states still used the MEF for MCO drugs, despite

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[172] Public Health Service Act, 42 U.S.C. 256b(a)(5)(A)(i).
[173] Jason Hardaway, *340B Program Puts Manufacturers At Risk of Duplicate Drug Discounts*, 41 PHARMACY AND THERAPEUTICS 1, 38 (2016).
[174] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File,* Release No. 2014-1, 3 (Dec. 2014).
[175] 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300, 52309 (Aug. 2015); *See* Office of Inspector General, U.S. Dep't of Health and Human Services, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates,* OEI-05-14-00430 (June 2016).
[176] *Medicaid Managed Care Enrollment and Program Characteristics, 2014*, Centers for Medicare and Medicaid Services, *available at* https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/medicaid-managed-care/downloads/2014-medicaid-managed-care-enrollment-report.pdf.
[177] U.S. Dep't of Health and Human Services, *Office of Inspector General, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016).

HRSA's guidance to develop alternate strategies, since the MEF only works for FFS drugs.[178] Overall, this dynamic results in the risk of duplicate discounts for a majority of Medicaid patients, since a majority of Medicaid beneficiaries receive their benefits through MCOs.

Duplicate discounts for MCOs participating in the Medicaid Drug Rebate Program is a growing problem. Prior to the PPACA, only Medicaid FFS claims were eligible for rebates. The PPACA extended the Medicaid Drug Rebate program to expenditures made for drugs under managed care but did not create a centralized mechanism to help prevent duplicate discounts for MCOs.

The volume of duplicate discounts likely occurring in the Medicaid and 340B programs due to this dynamic may be far greater than has been previously realized. That is because the majority of Medicaid beneficiaries are enrolled in MCOs. According to MACPAC, the percentage of Medicaid enrollees in comprehensive managed care as of July 1, 2015 was about 65 percent—a number that has likely only increased as more states adopt managed care delivery systems.[179] Additionally, most Medicaid expenditures for covered outpatient drugs currently occur under managed care.[180] While there are some safeguards in place to prevent duplicate discounts in Medicaid FFS, HRSA audits do not include the same review of Medicaid managed care. This problem will only grow over time to the degree states increasingly rely on MCOs to deliver Medicaid benefits.

The committee's review of HRSA's audit files revealed that, while there are some safeguards in place to prevent duplicate discounts in FFS Medicaid, some covered entities fail to adequately protect against the risk of duplicate discounts.[181] For example, in one final audit report for a covered entity audited by HRSA, HRSA indicated that the covered entity and its off-site outpatient facilities did not accurately appear on the 340B MEF at the time of the audit.[182] Similarly, in a final audit report for a different covered entity, HRSA found that the covered entity was billing Medicaid contrary to the information contained in the 340B MEF.[183] In the final report, HRSA noted that:

> Duplicate discounts are prohibited by section 340B(a)(5)(A) of the of the PHSA; that is, a drug purchase shall not be subject to both a discount under section 340B and a Medicaid rebate under section 1927 of the Social Security Act. HRSA has created the 340B Medicaid Exclusion File as a mechanism for covered entities to

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[178] To remedy this issue, some stakeholders have suggested the inclusion of 340B-specific claims identifiers, the provision of claims-level identifiers, and the provision of claims level data by covered entities to states as well as manufacturers sufficient to identify claims. Since the Centers for Medicare and Medicaid Services (CMS) provides oversight of State Medicaid programs, separate regulations pertaining to this issue may need to be issued by CMS. However, since 340B drugs are determined retrospectively, stakeholders have informed the committee that the IT infrastructure is not currently equipped to resolve the issue of identifying Medicaid managed care claims under 340B.

[179] *See* Medicaid and CHIP Payment and Access Commission, *MACStats: Medicaid and CHIP Data Book* (December 2017) at 83, *available at* https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-CHIP-Data-Book-December-2017.pdf.

[180] *See id*. at 80.

[181] *See* HRSA audit records on file with the committee.

[182] *See* HRSA audit records on file with the committee.

[183] *See* HRSA audit records on file with the committee.

> comply with the duplicate discount prohibition. [The covered entity] must ensure it is appropriately listed on the 340B Medicaid Exclusion File and follow any additional state Medicaid laws. [The covered entity] responded "no" to the question "Will you bill Medicaid for drugs purchased at the 340B price?" which was contrary to the entity's practice at the time of the audit. Since [the covered entity] failed to appear on the 340B Medicaid Exclusion File, this action may have resulted in duplicate discounts, prohibited under 340B(a)(5)(A) of the PHSA.[184]

iii. Diversion

HRSA prohibits the resale or transfer of 340B drugs to ineligible patients, known as diversion. Only individuals who are patients of covered entities are eligible to receive 340B drugs.[185] To be considered a patient of a covered entity, the individual must maintain his or her records with the covered entity, and receive health care services from providers employed by the covered entity.[186] As shown in Figure 3, a large percentage of HRSA's audited entities diverted drugs to ineligible patients in FY 2012 through FY 2016.

In FY 2012, FY 2015, and FY 2016, close to half of HRSA's audited entities diverted benefits to ineligible patients—31 percent of covered entities in FY 2012, 47 percent of covered entities in FY 2015, and 47 percent of covered entities in FY 2016 were found to have diverted drugs. Diversion violations reached 54 percent in FY 2014 and a 57 percent high in FY 2013, when more than 50 audited entities offered drug pricing benefits to ineligible patients.

The lack of a clear definition of "patient" may be directly connected to the high number of covered entities who committed diversion violations, since HRSA's definition of "patient" has been criticized widely for its vagueness. HHS OIG has stated that "[there is] a lack of clarity on how HRSA's patient definition should be applied in contract pharmacy arrangements."[187] GAO has also offered criticism, explaining that "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B."[188]

To identify which 340B-eligible patients received prescriptions, contract pharmacies often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In their 2014 report, HHS OIG found wide variation in these eligibility

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[184] *See* HRSA audit records on file with the committee.
[185] There is one exception: individuals registered in state-operated or funded AIDS Drug Assistance Program who are automatically eligible for 340B benefits. *See* 340B Prime Vender Program, *Patient Definition* (last accessed Jan. 8, 2018), *available at* https://www.340bpvp.com/resource-center/faqs/patient-definition/.
[186] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207 (Oct. 24, 1996).
[187] Office of Inspector General, U.S. Dep't of Health and Human Services, *Memorandum report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014).
[188] Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

determinations. Depending on the interpretation of HRSA's patient definition, some 340B provider eligibility determinations would be considered diversion and others would not.[189]

The committee's review of HRSA's audit files revealed that many entities have engaged in diversion by dispensing a 340B drug to an ineligible individual. Moreover, in at least eight of the 32 audit files reviewed by committee staff, HRSA recommended that the covered entity improve its oversight of each contract pharmacy arrangement to prevent diversion of 340B drugs at the contract pharmacy.[190] For example, in the "Areas for Improvement" section of one final audit report for a covered entity, HRSA wrote:

> Covered entities are required to oversee each contract pharmacy arrangement used to dispense 340B drugs (75 Fed. Reg. 10272 (Mar. 5, 2010)).
>
> While [the covered entity] has written 340B Program policies and procedures for contract pharmacy arrangements, such policies and procedures do not currently reflect all of the actions that [the covered entity] is taking to ensure 340B Program compliance and oversight activities of their contract pharmacies. More specifically, current 340B Program policies and procedures do not include all controls to verify 340B-eligibility or prevent diversion of 340B drugs at the contract pharmacy. [The covered entity's] 340B Program policies and procedures should describe monitoring procedures to include effective procedures for eligibility determination process used at contract pharmacies and reconciliation of dispensing and purchasing records to ensure that diversion has not occurred.
>
> Covered entities must ensure 340B Program compliance at the entity, off-site outpatient facilities, and contract pharmacies. [Covered entity] remains responsible for ensuring their contract pharmacies meet statutory obligations to ensure against diversion or duplicate discounts of [covered entity's] 340B drugs. At the time of the audit [covered entity] relied on [third party vendors] to monitor contract pharmacies' 340B dispenses. HRSA expects that all covered entities perform annual <u>independent</u> audits (or more frequent as necessary) of all their contract pharmacies to ensure 340B Program compliance, although the exact method of ensuring compliance is left up to the entity.[191]

HRSA's suggestions in the "Areas for Improvement" section of audit documents, however, are not binding and thus to not require the covered entity to take the recommended course of action. As is alluded to above, the exact method of ensuring compliance is left up to the entity.

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[189] Office of Inspector General, U.S. Dep't of Health and Human Services, *Memorandum report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014).
[190] *See* HRSA audit records on file with the Committee.
[191] *Id*.

iv. Incorrect Reporting

The administration of the 340B program depends on accurate database information. HRSA audits reveal that many covered entities are not fulfilling their obligations of maintaining current database information. With the exception of FY 2012, at least half of the audited entities kept incorrect records all other years, as shown above in Figure 3. The audits show that many times, records include clinic locations or outpatient facilities that are no longer in service. During the committee's review of HRSA's audit files, the committee found that covered entities also did not always register all off-site outpatient facilities in the 340B database that used 340B drugs.[192] HHS OIG investigators have warned that incorrect reporting could hide program violations.[193]

v. GPO Prohibition and Program Termination

Certain eligible hospitals must certify that they will not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement (referred to as the "GPO prohibition").[194] HRSA can terminate an entity from the 340B program through the audit process if HRSA finds that the GPO prohibition is applicable to that covered entity and the entity is not complying with the GPO prohibition.[195] In one of the audit files produced to the committee, HRSA found that the entity did not comply with the GPO prohibition as the entity obtained covered outpatient drugs through a GPO during a certain period of time.[196] HRSA did not, however, terminate the covered entity from the 340B program "based upon the information provided to HRSA that [covered entity] is currently in compliance with the GPO prohibition." In the final audit report, HRSA wrote:

> A DSH hospital must meet the requirement in section 340B(a)(4)(L)(iii) of the PHSA to be eligible for the 340B Program, which states the entity may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." HRSA's longstanding policy is that if a covered entity subject to this prohibition participates in a GPO, the covered entity "will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices." 59 Fed. Reg. 25110 at 25113 (May 13, 1994). HRSA published 340B Drug Pricing Program Notice (Release No. 2013-1) on February 7, 2013 to clarify HRSA's position on violations of the prohibition against

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[192] *See* HRSA audit records on file with the committee.

[193] U.S. Dep't of Health and Human Services, Office of Inspector General, *State Efforts to Exclude 340B Drugs From Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016) https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.

[194] Public Health Service Act, 42 U.S.C. 256b(a)(4)(L)(iii).

[195] 340B Drug Pricing Program Omnibus Guidance, 59 Fed. Reg. 25,110 at 25,113 (May 13, 1994). *See* Health Resources and Services Administration, *340B Drug Pricing Program Notice: Statutory Prohibition on Group Purchasing Organization Participation*, Release No. 2013-1 (February 7, 2013) (indicating that [s]ince the GPO prohibition is an eligibility requirement, covered entities found in violation will be considered ineligible and immediately removed from the 340B Program. Covered entities may also be subject to repayment to manufacturers for the time period for which the violation occurred.").

[196] *See* HRSA audit records on file with the committee.

> purchasing covered outpatient drugs through a GPO and gave covered entities until August 7, 2013, to come into compliance with the prohibition.
>
> Based upon the information provided by [the covered entity], [the covered entity] began purchasing covered outpatient drugs through a GPO on [Date]. [The covered entity's] use of a GPO to purchase covered outpatient drugs violates section 340B(a)(4)(L)(iii) of the PHSA. Violation of the GPO prohibition is grounds for removal from the 340B Program. However, based upon the information provided to HRSA that [covered entity] is currently in compliance with the GPO prohibition, OPA will not remove [the covered entity] from the 340B Program at this time. [The covered entity] may be required to repay impacted manufacturers for 340B purchases made while [the covered entity] was in violation of the GPO prohibition. [The covered entity] may be liable to manufacturers for any purchases or transfers of covered outpatient drugs under the 340B Program during the period of ineligibility from [Date] until [Date].[197]

Similarly, the committee heard from one covered entity that expressed concerns with the lack of guidance and information available regarding HRSA's audit process, especially with respect to a finding of non-compliance with the GPO prohibition. This covered entity was found to be non-compliant with the GPO prohibition during an audit. While the finding of non-compliance was ultimately reversed, the covered entity expressed concerns that they were not given an opportunity to respond to HRSA's finding before they received a letter from HRSA recommending that they stop purchasing outpatient drugs through the 340B program. Instead, according to the covered entity, HRSA conducted an on-site audit and then over three months later HRSA sent a "Final Report" to the covered entity indicating the agency had found that the covered entity, its off-site outpatient facilities, and its contract pharmacies were no longer eligible to participate in the 340B program and were required to make any necessary repayments to affected manufacturers. At the time HRSA conducted the audit of the entity, the entity believed, based upon discussions with auditors, that the audit went well. In the "Final Report" HRSA sent to the covered entity, HRSA provided the covered entity 30 days to dispute the findings and demonstrate to HRSA that the covered entity was in compliance with the GPO prohibition. HRSA did not, however, provide the covered entity with any information about why the agency believed that the covered entity was not in compliance with the GPO prohibition. HRSA also recommended the entity immediately stop purchasing 340B drugs. After multiple exchanges, the covered entity ultimately resolved the issue by presenting evidence to HRSA that it was in compliance with the GPO prohibition and HRSA ultimately reversed their findings, leaving the covered entity with no findings regarding eligibility, duplicate discounts, or diversion.

[197] *Id.*

D. HRSA's Audits of Manufacturers

Finding: HRSA audits manufacturers and in their audits to date found no manufacturers out of compliance with the statute. However, without access to ceiling prices, covered entities may not know that they should report to HRSA that they are not getting an accurate price.

Under Section 340B(a)(1) of the PHSA, manufacturers of covered outpatient drugs that participate in the 340B program must offer all covered outpatient drugs at no more than the 340B ceiling price to a covered entity listed on HRSA's public 340B database if such drug is made available to any other purchaser at any price. Under 340B(d)(1)(B)(v), HRSA has the authority to audit manufacturers to ensure compliance with program requirements. HRSA does not appear to audit manufacturers at the same rate as covered entities. According to HRSA's website, HRSA has audited 10 manufacturers since FY 2015 and has not had any adverse findings.[198] If a manufacturer fails to comply with 340B pricing requirements, the manufacturer may be liable to covered entities for refunds of overpriced 340B drugs.[199]

In 2015, HRSA testified that they have efforts in place for manufacturer compliance, but the requirements for manufacturers under the law are much narrower as they only have to offer the ceiling price.[200] HRSA made similar comments in 2017:

> Q: What have the audits found so far?
>
> A: Thus far, we do post the audits on our website and we have not had any findings whereby the manufacturers are not in compliance with the statute. The manufacturers only have – they have a more narrow focus than the 340B-covered [entities] and that is to provide the drug at or below the ceiling price and that is what we audit. But that is only one tool we use for manufacture[r] compliance. We also ensure that once they are in the Medicaid program that they appropriately sign an agreement with HRSA to provide the drugs at or below the ceiling price. We also issue regulation and guidance in the program related to manufacturer compliance. We also review all allegations that we receive if a covered entity is not receiving a price at or below the ceiling price and we investigate each of those situations.[201]

As previously mentioned in Section V.A, HRSA is working on, but has not yet released, an information system that will allow covered entities to view ceiling prices. In July 2017,

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[198] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/index.html.
[199] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity* (last accessed Dec. 1, 2017), *available at* https://www.hrsa.gov/opa/program-integrity/index.html.
[200] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong., *Preliminary Transcript*, at 99 (Mar. 24, 2015).
[201] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 67 (Jul. 18, 2017).

HRSA indicated the system would be released in the "coming months."[202] Since covered entities do not yet have access to ceiling prices, they do not necessarily know whether they are getting a fair ceiling price on the 340B drugs.[203] A covered entity therefore may not know they should report to HRSA that they are not getting an accurate price. HHS OIG testified in July 2017 that "[a]lthough Congress authorized HRSA to share confidential ceiling prices with 340B providers in 2010, HRSA has not yet done so" and "340B providers need to know the 340B ceiling prices to determine whether they are paying the accurate price."[204] The committee has previously expressed concern about this lack of transparency. For example, during the committee's 2005 hearing entitled *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency*, the then-Chairman of the Subcommittee on Oversight and Investigations noted it was "nonsensical" that covered entities did not have access to the ceiling prices:

> [T]he common theme of all of the subcommittee's drug pricing work, has been transparency. The 340B program certainly fits that mold. It is nonsensical to me that the entities entitled to the 340B discount, the 340B institutions and the prime vendor, do not have access to ceiling prices. Imagine going to a grocery store which advertises a special discounted price, only to find that when you go to the register to check out, no one can tell you what that discount is.[205]

E. Program Growth and HRSA's Ability to Keep Up

Finding: The PPACA significantly increased the scope of the Medicaid program by expanding eligibility to certain low-income, non-disabled, non-elderly, non-pregnant adults. Medicaid expansion under the PPACA has likely increased the number of hospitals eligible for the 340B program because some hospitals' eligibility is based, in part, on the number of the hospital's inpatients who are Medicaid and low-income Medicare patient by virtue of their DSH (disproportionate share hospital) percentage. Overall, program participation has more than quadrupled over the past decade. HRSA's limited oversight ability does not appear to be sufficient to conduct adequate oversight of this program.

The 340B program has grown drastically since its inception, particularly after the PPACA expanded the list of eligible entities in 2010 and expanded Medicaid eligibility. The PPACA added the following to the list of covered entities entitled to discounted drug prices under the 340B program: (1) certain children's and free-standing cancer hospitals excluded from the Medicare prospective payment system; (2) critical access hospitals; and (3) certain rural referral centers and sole community hospitals. As discussed above, these 340B-eligible facilities

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[202] *Id*. at 102.
[203] *Id*. at 102.
[204] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, Assistant Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Dep't of Health and Human Services).
[205] *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 109th Cong., at 2 (Dec. 15, 2005).

also must meet other specified 340B participation requirements.[206]

Historically, Medicaid was only available for certain low-income children, pregnant women, parents of dependent children, the elderly, and individuals with disabilities.[207] The PPACA expanded Medicaid eligibility in 2014 by giving states the option to extend Medicaid coverage to all adults under age 65 (including adults without dependent children) with incomes below 138 percent of the federal poverty level.[208] The largest growth in Medicaid enrollment between July/September 2013 and September 2017 has been in states that expanded Medicaid to include the newly eligible adult group.[209] Since 2013, enrollment in Medicaid expansion states has increased by 37.6 percent, with 13.9 million new enrollees in these states.[210] Because certain hospitals qualify based in part on their DSH percentage, which accounts for the number of the hospital's inpatients who are Medicaid and low-income Medicare patients, more hospitals have likely become eligible to participate in the 340B program over the past few years.[211]

In the wake of these expansions, the number of participating unique covered entities has grown from 3,200 in 2011, to 11,180 in February 2015, to 12,148 in October 2016, to 12,722 in October 2017.[212] Notably, the number of hospitals has grown significantly, from 591 in 2005, to 1,673 in 2011, to 2,479 as of October 2017.[213]

The number of child sites has also grown dramatically. In 2011, GAO reported that the number of child sites had nearly doubled over the previous decade, reaching just over 16,500 registered sites.[214] According to HRSA, that number has now reached 29,307.[215]

Part of the apparent growth in child sites can be attributed to a 2012 HRSA rule which changed how child sites must be registered. The rule provided that each hospital department administering 340B drugs must be registered as a child site, even if multiple separate

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[206] Section 7101, as amended by HCERA Sec. 2302, amended PHSA Sec. 340B.
[207] Julia Paradise et al., *Medicaid at 50: Low-Income Pregnant Women, Children, and Families, and Childless Adults*, THE HENRY J. KAISER FAMILY FOUNDATION (May 6, 2015), https://www.kff.org/report-section/medicaid-at-50-low-income-pregnant-women-children-and-families-and-childless-adults/.
[208] Medicaid and CHIP Payment and Access Commission, *Medicaid expansion to the new adult group* (last accessed Dec. 19, 2017), https://www.macpac.gov/subtopic/medicaid-expansion/.
[209] Medicaid and CHIP Payment and Access Commission, *Medicaid enrollment changes following the ACA* (last accessed Dec. 19, 2017), https://www.macpac.gov/subtopic/medicaid-enrollment-changes-following-the-aca/.
[210] *Id*.
[211] 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* (Spring 2016), *available at* http://340breform.org/userfiles/May%202016%20AIR340B%20Avalere%20Charity%20Care%20Study.pdf.
[212] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018, available at* https://www.hrsa.gov/about/budget/budgetjustification2018.pdf; U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).
[213] Email from U.S. Dep't of Health and Human Services Staff to Committee Staff (Dec. 21, 2017); U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).
[214] U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).
[215] Email from U.S. Dep't of Health and Human Services Staff to Committee Staff (Dec. 21, 2017).

departments are housed within one building.[216] Thus, part of the growth may be artificial because many hospitals began newly registering as child sites facilities that had previously been in operation. For example, Erlanger Health System noted in their letter to the committee, "[w]e would note again that you will see a dramatic increase in the number of child sites following our audit and HRSA's direction to register hospital departments as child sites."[217] Johns Hopkins Hospital (JHH) echoes Erlanger's statement:

> In accordance with new child site registration requirements (updated in April 2014), JHH has registered all individual outpatient departments and clinics (221). This does not reflect an effort by JHH to expand its 340B program by constructing or acquiring new clinics…. Most have been critical components of patients' care since the start of JHH's participation in the 340B program, well prior to the requirement to enroll each separately.[218]

This rule change alone, however, cannot account for the increase in child sites. After the rule was last updated in 2014, the number of child sites grew from 25,348 registered sites in October 2016,[219] and reached 29,307 sites by October 2017.[220]

In addition to an increase in child sites, the number of contract pharmacies has grown greatly since HRSA issued their 2010 guidance on contract pharmacies. In 2011, GAO reported that while HRSA did not track individual contract pharmacies in use, there were more than 7,000 contract pharmacy arrangements through the program.[221] In their 2018 Budget Justification, HRSA reported that 27 percent of covered entity sites have contract pharmacy arrangements, resulting in approximately 18,078 unique pharmacy locations.[222] GAO is currently examining the growth of contract pharmacy arrangements at the committee's request.

The amount that covered entities save on 340B drugs has also increased. In FY 2013,

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[216] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Hot Topics*, *available at* https://www.hrsa.gov/opa/updates/august-2014.html.
[217] Letter from Kevin M. Spiegel, FACHE, President & CEO Erlanger Health System, Assistant Professor University of Tennessee College of Medicine, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 20, 2017).
[218] Letter from Redonda G. Miller, MD, MBA, President, The Johns Hopkins Hospital, to the Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, and Hon. Diana DeGette, Ranking Member, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 14 (Sept. 29, 2017).
[219] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, *available at* https://www.hrsa.gov/about/budget/budgetjustification2018.pdf.
[220] Email from U.S. Dep't of Health and Human Services Staff to Committee Staff (Dec. 21, 2017).
[221] U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).
[222] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, *available at* https://www.hrsa.gov/about/budget/budgetjustification2018.pdf.

HRSA estimated that covered entities saved $3.8 billion on drug expenditures.[223] In FY 2014, that estimate rose to $4.5 billion in savings.[224] In CY 2015, covered entities saved approximately $6 billion.[225] According to the responses the committee received to its September 2017 letter to select covered entities, one covered entity saw its program savings increase by over 529 percent in three years.

Figure 4: Estimated 340B Program Savings: 2013 versus 2016*, **, ***

Covered Entity	2013	2016	% Increase
Erlanger Health System (TN)	$3,010,079	$18,938,111	529.1 %
Cedars-Sinai Medical Center (CA)	$21,100,000	$55,700,000	164 %
Johns Hopkins Hospital (MD)	$41,398,000	$109,100,000	164 %
UC San Francisco (CA)	$36,652,522	$82,931,835	126.3%
Mission Health System, Inc. (NC)	$18,014,353	$37,440,073	107.8 %
Cook Area Health Services (MN)	$100,409	$207,808	107 %
University of Washington Medical Center (WA)	$16,650,039	$31,091,454	86.8%
Intermountain Primary Children's Hospital (UT)	$3,376,012	$6,217,754	84.2 %
Grady Memorial Hospital (GA)	$28,139,538	$48,183,675	71.2%
Harborview Medical Center (WA)	$24,282,264	$41,219,791	69.8%
Hudson Headwaters Health Network (NY)	$4,876,405	$6,625,533	35.9 %
Northern Nevada HOPES (NV)	$1,413,969	$1,915,809	35.4 %
Emory University Hospital Midtown (GA)	$38,907,913	$44,072,375	13.3 %
Parkland Health and Hospital System (TX)	$147,325,149	$129,523,015	-12.1%****
Duke University Hospital (NC)	N/A	$103,674,873	N/A
NYU Langone Health (NY)	N/A	$66,894,274	N/A
Northside Hospital (GA)	N/A	$52,949,357	N/A

** Program savings for different covered entities cannot be compared in this chart as some of these covered entities calculated program savings using different methods.*
*** The estimated savings provided to the committee oftentimes included numerous disclaimers as to why they were only approximate estimates and therefore actual program savings, program revenue, and/or percent increase may be higher or lower than the amount of savings listed in the above table.*
**** Some covered entities reported by fiscal year and some reported by calendar year.*
***** Although Parkland Health and Hospital System's program savings are reflected as decreasing between 2013 and 2016 in this chart, Parkland explained to committee staff that, due to the way Parkland calculated program savings, years 2012-2015 are likely represented as higher than actual savings.*

Covered entities cited a variety of different factors for this increase in 340B program savings, including, but not limited to, an increase in insured patients, an increase in the cost and number of medicines prescribed, and an increase in pharmacy access for patients in areas that otherwise did not have access through expanded contract pharmacy arrangements. In addition, numerous third-party consultants offer services to covered entities to help maximize program savings.[226] For example, one wholesale distributor, McKesson, published an article on

[223] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2016, available at* https://www.hrsa.gov/about/budget/budgetjustification2016.pdf.
[224] *Id.*
[225] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).
[226] *See, e.g.*, McKesson, *340B Consulting* (last accessed Dec. 5, 2017), *available at* http://www.mckesson.com/pharmacies/growth-and-expansion/340b-consulting/; RxStrategies, Inc., *RxStrategies' Integrated 340B Solutions* (Mar. 3, 2017), http://rxstrategies.com/rxstrategies-integrated-340b-solutions/; Vizient,

December 4, 2017, entitled *How Hospital Pharmacies Can Maximize on 340B Drug Savings*.[227] In the article, McKesson describes "how carving Medicaid into 340B can save money on outpatient drug purchases, and the steps hospital pharmacies can take to maximize their 340B savings."[228] McKesson estimates that for "each Medicaid prescription charged through 340B, the hospital would save more than $7. For a large hospital or health system that bills for 500,000 Medicaid prescriptions a year, that's an annual savings of $3.6 million."[229]

The rapid growth of the 340B program shows no signs of stopping, and poses challenges to HRSA's ability to effectively oversee the program. HRSA's auditing has remained at or below 200 annual audits of covered entities since 2012, when HRSA's practice of auditing covered entities began. As mentioned above, in 2016, HRSA audited fewer than two percent all of covered entities.

Minimizing risk and maximizing opportunity for pharmacy operations and 340B programs (last accessed Dec. 5, 2017), https://www.vizientinc.com/Members/Case-studies/Minimizing-risk-and-maximizing-opportunity-for-pharmacy-operations-and-340B-programs.

[227] McKesson, *How Hospital Pharmacies Can Maximize on 340B Drug Savings* (Dec. 4, 2017), *available at* http://www.mckesson.com/blog/how-hospital-pharmacies-can-maximize-on-340b-drug-savings/.

[228] *Id*.

[229] *Id*.

VI. Covered Entity Use of the 340B Program

A. Congressional Intent of the 340B Program

Finding: Congress did not clearly identify its intent for the program and did not clearly identify the program's parameters, leaving the statute silent on many important program requirements. Moreover, given the vastly changed health care landscape and 340B program environment, it is unclear whether, and to what degree, the program's original structure is still relevant.

Congress established the Medicaid Drug Rebate Program through the Omnibus Budget Reconciliation Act of 1990 (OBRA 90). Before the Medicaid Drug Rebate Program was implemented in 1991, drug manufacturers often provided substantial discounts on their medicines to certain types of safety-net providers. Because the Medicaid Drug Rebate Program requires that pharmaceutical manufacturers provide Medicaid with the manufacturers' lowest or "best price" for outpatient drugs, some stakeholders were concerned that after the program was implemented, manufacturers might limit discounts to some of these safety-net providers.

Congress therefore established the 340B program through the Veterans Health Care Act of 1992.[230] According to the House Report accompanying the legislation, the program was established, in part, to respond to the increase in prescription drug prices for the Department of Veterans Affairs and some federally-funded clinics and public hospitals following the enactment of the 1990 Medicaid prescription drug rebate program.[231] The report indicated the legislation was intended to "stretch scarce Federal resources as far as possible:"

> Hard evidence on the effect of OBRA 90 on prescription drug prices is still being compiled. The testimony received by the subcommittee is not dispositive as to the impact of the OBRA 90 Medicaid rebate program. There is still uncertainty as to the extent to which manufacturers have raised prices to purchasers other than Medicaid, and the extent to which such increases were due to the provisions of OBRA 90. But two points seem clear. Prices paid for outpatient drugs by the [U.S. Department of Veterans Affairs] and some Federally-funded clinics and public hospitals, have increased substantially over the last two years. Those price increases have in turn reduced the level of services and the number of individuals that these hospitals and clinics are able to provide with the same level of resources.…
>
> In giving these "covered entities" access to price reductions the committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.[232]

Beyond these statements in the House Report, it is unclear exactly how Congress intended covered entities to use the 340B program. Congress remained silent in the statute on

[230] PL 102-585 (Nov. 4, 1992).
[231] H.R. Rep. 102-384, Pt. 2 (1992).
[232] *Id*.

many important questions regarding the structure and oversight of the program. During the committee's July 2017 hearing, HRSA responded the "statute is silent," or in a similar manner, over a dozen times when asked questions about program requirements.[233] Although covered entities significantly benefit from revenue that is generated through the program when a patient's insurer reimburses the product at a higher price than the covered entity paid for the prescription drug, the statute is silent on how covered entities must use these funds. Moreover, as HRSA testified at the July 2017 hearing, HRSA does not have any authority to track the amount of revenue covered entities generate through participation in the program or how they use the money:

> Q: There is a lack of clarity in how the intent of the program is, which you outlined in your testimony in your documents there. The absence of reporting requirements and specific mandates on how savings must be spent – can you elaborate a little bit more on what that impact is?
>
> A: So the statute is silent regarding how covered entities have to use their savings. Therefore, HRSA doesn't have authority to require what these entities are doing with their savings.[234]

Notably, there is no requirement that the discounted 340B price be passed on to uninsured patients who seek treatment at 340B covered entities. As a result, the covered entity may acquire the drug at a discounted price, but the uninsured patient may still pay the full list price for the drug at the pharmacy. In 2015, HRSA testified "the law does not…specify the status of any of the patients that could potentially benefit from the program."[235] Similarly, in 2017, HRSA testified "[s]o the amount that [covered entities] charge the patient after they receive that discount, again, is a decision made at the hospital. The price that they charge is outside of the 340B statute."[236]

The committee's investigation found that some covered entities pass 340B program savings on to uninsured or underinsured patients, while others do not. For example:

- One Community Health Center, Cook Area Health Services (CAHS), said "CAHS passes the full 340B savings directly to all uninsured and underinsured patients, who are charged only the 340B price for their drugs."[237]

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[233] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript* (Jul. 18, 2017).
[234] *Id.* at 41.
[235] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong., *Preliminary Transcript*, at 71 (Mar. 24, 2015).
[236] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 43 (Jul. 18, 2017).
[237] Letter from Cook Area Health Services, Inc. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

- One FQHC, ARcare, said "ARcare has a 340B 'Cash Card' that is provided to eligible patients who lack sufficient drug benefit coverage. The 'Cash Card' ensures that patients possessing the card are able to directly benefit from the 340B program by paying the discounted 340B cost of their medication."[238]

- One DSH hospital, NYU Langone Health (NYULH), said "NYULH does not have any specific policies to help ensure that uninsured and underinsured patients directly benefit from the Program by receiving discounts on 340B drugs, since this is not the way in which the Program is structured."[239]

In 2017, GAO testified that Congress should clarify the intent of the program to improve program integrity.

> Q: I wanted to ask Dr. Draper what are the most important actions out of GAO's recommendations to improve program integrity in 340B and how should Congress prioritize?
>
> A: Well, I think one of the key pieces is really clarifying the intent of the program. The intent was set up 25 years ago and, you know, there is a – I think there is a misperception [what] it does. It doesn't explicitly talk about uninsured or under insured patients being treated by the – by the – to receive benefits through the program. That is implied, depending on – you know, depending on the types of covered entities.[240]

Moreover, the intent and purpose of the program are even less clear given the changing landscape in the health care sector. According to GAO: "HRSA has undertaken efforts to improve oversight of the 340B program. However, there are a number of critical issues that remain unresolved including whether the intent of the program, which was established nearly 25 years ago, is still relevant today, given the vastly changed healthcare landscape and 340B program environment."[241]

Similarly, in its recent report entitled *Making Medicines Affordable*, the National Academies Press commented on how much the health care landscape has changed since the program's inception, especially in relation to hospitals:

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[238] Letter from Steven F. Collier, MD, FACHE, Chief Executive Officer, ARcare, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 21, 2017).
[239] Letter from Gilda Ventresca Ecroyd, Vice President, Office of Government and Community Affairs, NYU Langone Health, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).
[240] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 59-60 (Jul. 18, 2017).
[241] *Id*. at 39.

> However, in the years since the program's inception, the structure of hospitals in the United States has dramatically changed, with nonprofit hospitals increasingly displaying characteristics of for-profit hospitals … and standalone hospitals pursuing mergers and affiliations with other hospitals and hospital systems and outpatient provider groups.[242]

B. 340B Program Savings

Finding: Congress did not establish any mechanisms to monitor or calculate program savings or specify how they are used. As a result, covered entities use program savings in a variety of different ways. Some covered entities are restricted in the way they can use program funds due to other federal grant requirements.

The 340B program generates savings for covered entities by allowing them to purchase certain outpatient medications for less than they otherwise would pay—saving approximately 25 to 50 percent.[243] Moreover, because covered entities can purchase 340B drugs for all eligible patients regardless of their insurance status, including for patients enrolled in private insurance or the Medicare program, a covered entity can generate revenue if the reimbursements from payers exceeds the discounted price that the covered entity paid for the drug.[244]

i. Restrictions on the Use of Program Savings by Covered Entities

The 340B statute does not restrict how covered entities use 340B savings. It also does not provide HRSA any authority to require or even explain how covered entities use 340B program savings or track how covered entities use these savings. HRSA testified about the absence of reporting requirements and lack of requirements on how program savings must be used by covered entities at the committee's July 2017 hearing. HRSA noted that the statute is silent on these issues and HRSA therefore does not have authority to provide guidance or clarity on either issue. HRSA testified:

> Q: There is a lack of clarity in how the intent of the program is, which you outlined in your testimony in your documents there. The absence of reporting requirements and specific mandates on how savings must be spent – can you elaborate a little bit more on what that impact is?
>
> A: So the statute is silent regarding how covered entities use their savings. Therefore, HRSA doesn't have authority to require what these entities are doing with their savings.[245]

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[242] National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 6 (Nov. 2017).
[243] 340B Prime Vendor Program, *340B Price/Covered Outpatient Drugs* (last accessed Dec. 1, 2017), *available at* https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/.
[244] *See, e.g.*, Medicare Payment Advisory Commission, *Report to the Congress: Overview of the 340B Drug Pricing Program*, at viii (May 2015).
[245] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 41 (Jul. 18, 2017).

In the same hearing, HRSA reiterated this point and further stated that the agency does not have access to information about program savings or how savings are used by covered entities. HRSA testified:

> Q: Do we or do we not know or audit how the savings are spent? That seems to be one of the issues. We all believe that everybody is a good actor and the money is going to the people most in need, as well as savings. But I also am not clear that HRSA – that there is a clear definition of how the money should be spent or that we track the money. Is that correct?
>
> A: So the statute is silent as to how savings are used. Therefore, HRSA does not audit or have access to that information.
>
> * * *
>
> Q: Do we know if those savings get passed specifically back to people who need reduction in prices on the drugs?
>
> A: The statue is silent in that area. So HRSA does not have that information.
>
> Q: Okay. So we don't know that. And those savings, could the 340B hospitals take that money and use it for good things but not necessarily back to the same person that is buying the drugs?
>
> A: So that – because the statute is silent --[246]

In addition, both HHS OIG and GAO have raised concerns in testimony before the committee about the lack of transparency regarding the amount of program savings generated by participation in the 340B program and how covered entities use those savings. In 2015, HHS OIG testified, "I do believe we have concerns about program integrity that then compromise the ability of the program to achieve its goals. So more clarity around how the savings are used would allow us to understand the benefits of the program."[247] In 2017, GAO testified that there are no requirements regarding whether covered entities track their savings or how covered entities use their 340B program savings and, as a result, neither the federal government nor most covered entities have access to that information.[248] GAO indicated that it is possible that the discounts are not passed on to low-income patients and stated that, given the lack of transparency, there is oftentimes no way of knowing how much low-income patients pay for 340B drugs.[249] GAO's testimony echoed their 2011 report, *Manufacturer Discounts in the 340B*

[246] *Id.* at 52-53.
[247] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. On Health of the H. Comm. on Energy and* Commerce, 114th Cong., at 51 (Mar. 24, 2015).
[248] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 47 & 53 & 77 (Jul. 18, 2017).
[249] *Id.* at 53-54 & 63-64.

Program Offer Benefits, but Federal Oversight Needs Improvement.[250] GAO found that covered entities have generally reported using the 340B program to support or expand access to services, but that HRSA's oversight, which primarily relied on covered entities self-policing, was inadequate.[251]

ii. Calculation and Tracking of 340B Savings

Currently, there is no consistent methodology that covered entities use to estimate their program savings from participation in the 340B program. Some covered entities do not track this information at all. In the course of its investigation, the committee found numerous ways in which covered entities may track 340B program savings. Some entities reported to the committee an estimate most accurately characterized as program revenue (e.g. Cook Area Health Services, below) while others reported program savings (e.g. NYU Langone, below). For example:

- "ARcare tracks its 340B revenues by comparing its gross pharmaceutical reimbursements (reimbursement and copays less contracted pharmacy dispense fees and third-party administration fees) and 340B cost of goods sold (the amount ARcare paid for the medications dispensed or administered). With the assistance of its third-party administrator, ARcare receives and reviews reports that track the revenue. Those figures overstate 340B savings, but ARcare does not have access to the non-340B pricing data … that would allow it to compare the 340B cost of goods sold to what it might have paid for the drugs absent the 340B program."[252]

- "[Cook Area Health Services] only records the net between 340B program revenue less 340B acquisition cost and dispensing fees in its financial statements" and "[t]he organization receives semi-monthly statements from [their] 340B Drug Pricing program contract administrator Rx Strategies. These statements identify direct purchase costs as well as the amount of money the organization receives when the insured patients' insurance reimbursements exceed the total of the 340B price and dispensing fees."[253]

- "[Erlanger Health System (EHS)] calculates the amount of savings it generates through participation in the Program in three different ways. (a) Covered Entity Savings- derived by analyzing all 340B and [Wholesale Acquisition Cost (WAC)] purchases and comparing to GPO pricing. Savings is derived as the amount saved as opposed to making all purchases at GPO pricing (which would be the case without 340B in place). This is

[250] U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).
[251] *Id*. at 13.
[252] Letter from Steven F. Collier, MD, FACHE, Chief Executive Officer, ARcare, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 21, 2017).
[253] Letter from Cook Area Health Services, Inc. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

represented as 'net savings.'…(b) Erlanger Pharmacies Inc. (EPI) Savings- EPI is a wholly-owned subsidiary of ContinuCare Health Services, Inc. (A wholly-owned subsidiary of EHS) and a contracted pharmacy to the covered entities. This saving is calculated by analyzing all purchases at 340B compared to retail pricing (comparable to WAC). These savings are recognized on the EPI income statement and subsequently recognized in the EHS consolidated financials. (c) Contract Pharmacy savings- derived by analyzing the reimbursement less the dispensing fee, actual administrative fees and actual 340B replenishment purchases for each contract pharmacy."[254]

- "[Grady Health System] does not routinely calculate the amount of savings it generates each year through participation in the 340B Drug Pricing Program, though Grady does periodically (as needed for informational purposes) develop[] working estimates of its 340B savings … Tabulating 340B savings annually would require the establishment of separate and time intensive data capture and accounting processes to inventory and compare various drug prices (e.g., GPO, WAC, and 340B) and document cost differences. We are not set up to do this presently and would need to redirect scarce resources to do so."[255]

- NYU Langone's "savings from the 340B program are calculated by subtracting the 340B price from the GPO price for Gross Savings and further subtracting the cost of purchasing medications at WAC price due to 340B requirements and Program administration costs to arrive at Net Savings. We do not track the money received from insurer reimbursement due to the fact that payor reimbursement methodologies vary. For example, medication reimbursement may be grouped with other services and not itemized as a stand-alone; in other instances reimbursement mechanisms do not provide sufficient detail to infer specific medication payments. For contract pharmacies, we utilize the Sentry software platform to calculate savings using the formula of Reimbursement minus Cost of Medication minus Dispensing Fee."[256]

- "Hudson Headwaters purchases 340B drugs and dispenses them to patients through contract pharmacy arrangements. The calculation of the 340B program benefit can be shown as: (insurance payment + co-pay or other patient payment) – (340B drug cost + dispensing fees and admin expenses)."[257]

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[254] Letter from Kevin M. Spiegel, FACHE, President & CEO Erlanger Health System, Assistant Professor University of Tennessee College of Medicine, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 20, 2017).
[255] Letter from John Haupert, FACHE, Chief Executive Officer, Grady Health System, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).
[256] Letter from Gilda Ventresca Ecroyd, Vice President, Office of Government and Community Affairs, NYU Langone Health, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).
[257] Letter from Tucker Slingerland, M.D., Hudson Headwaters Health Network, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

During briefings with committee staff, many covered entities indicated that the committee's request that they calculate program savings caused them to calculate savings for the first time. For example, one covered entity told the committee that it generated over $72 million in savings from 340B program participation in 2016, and that, until the committee requested the information, they had never calculated their program savings nor had any entity requested information about their program savings.

In addition to calculating savings in various ways, covered entities also differ in how program savings are allocated within their budgets. For example, at the October 2017 hearing, witnesses provided the following answers regarding whether and how program savings are allocated in their budgets:[258]

Northside:	They aren't earmarked. They are tracked and monitored and then our growth is tracked and monitored. And we do ensure that our growth far exceeds the savings.
Johns Hopkins:	One way to think about it, perhaps, is that there is not really a check that comes back, if you will. This is a lower price paid. So there isn't a check that comes back that then you have the opportunity to say where it goes. This is a reflection of paying less for a drug than you otherwise would pay. So there is not really a budgeted amount that you could say that is what you are going to put in each of these buckets.
Mission Health:	To directly answer the question, there is not a dollar-for-dollar tracking no more than there would be an earmark for a tax dollar that I might pay in income tax. But on the other hand, we track very closely our savings. We know those savings and when we prepare our budget for each year, we include those dollars in the charity care allocations in all of these programs. So I would say that yes, they are targeted but not literally dollar-for-dollar.
ARCW:	In our budgeting process, we identify the savings that we anticipate in the coming year and we direct it to the pharmacy, health, and social services that I discussed in my testimony.
Carolina Health Centers:	I would have to echo my colleagues to some degree. It is not an exact line item transfer dollar-for-dollar from one cost center to another center, but at the beginning of the year, as part of both the budgeting and the strategic planning process, we estimate what we anticipate in those savings to be and then look at what programs they can fund, what otherwise unfunded programs they can fund. Then at the end of the year, we do an annual report to our Board of Directors linking those two together.

[258] *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., at 52-54 (Oct. 11, 2017).

iii. Requirements for HRSA Grantees

Covered entities benefit from program flexibility as it enables them to use the program savings in ways that are tailored to serve their specific community and patient population.[259] Each covered entity provides unique services, serves a unique population, and faces unique challenges in their community.[260]

While the 340B statute does not impose any requirements on recipients regarding how they use the program savings, federal grantees often have restrictions on their use of 340B program savings due to their grant requirements. Likewise, federal grantees, including FQHCs and Ryan White Grantees, are subject to additional HRSA oversight because of their status as a federal grantee. For example:

- At the October 2017 hearing, a FQHC, Carolina Health Centers, testified that their federal grant requirements mandate that FQHCs use 340B program savings "for purposes that advance their HRSA-approved scope of project."[261] The FQHC testified, "one of our grant conditions is that we are required to use all program incoming, including what is generated outside of the grant, for the purposes of advancing our HRSA scope projects."[262]

- At the October 2017 hearing, the Ryan White Program grantee, Aids Resource Center of Wisconsin, testified that the entity is limited on how it uses its 340B savings since, under its grant requirements and HRSA guidance, 340B savings are considered Ryan White HIV/AIDS program income and program income must be used for the purposes and under the conditions of the federal award.[263]

- Hudson Headwaters told the committee, "[a]s an FQHC, Hudson Headwaters is subject to intensive oversight by HRSA to ensure our on-going compliance with the 18 Program Requirements. This oversight takes many forms, including: site visits; mandatory annual reporting on budget, patient, and quality measures (Which are posted publicly on the HRSA website); frequent contact with our Project Officers; and regular re-competitions for grant funding. In addition, we are required by statute to reinvest all 340B savings into activities that are approved by HRSA and advance our mission of expanding access to quality care to medically underserved populations."[264]

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[259] *See, e.g., id.* at 84.
[260] The use of program funds by covered entities is discussed below in Section VI.B.
[261] *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, at 24 (Oct. 11, 2017).
[262] *Id*. at 83.
[263] *Id.* at 29.
[264] Letter from Tucker Slingerland, M.D., Hudson Headwaters Health Network, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

- ARcare, another FQHC, said it was "required by law to use any reimbursement or public funding for purposes that further the objective of the project."[265]

Numerous HRSA grantees such as FQHCs and Ryan White Grantees told the committee that they found the additional program requirements manageable.

C. Charity Care Provided by Covered Entities

Finding: The 340B statute does not require covered entities to report the level of charity care provided. As a result, there is a lack of data on how much charity care is provided by covered entities. Further, because there is no universally accepted definition of charity care, drawing a fair comparison of charity care provided across covered entities is difficult, if not impossible. Finally, while charity care spending often exceeds program savings, charity care levels have been on the decline at some hospitals, even as program savings increase.

As previously mentioned, Congress did not clearly identify the intent of the program when it stated that the program was intended to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[266] Because there is not a requirement that program savings be spent in a specific way, or that entities provide a certain level or type of charity care, covered entities use program savings in a variety of different ways. For example:

- Cedars-Sinai Medical Center, a DSH hospital, said that "in [FY] 2016, it spent "$695,634,000 on community benefit activities," which included "two mobile medical clinics staffed by bilingual nurse practitioners, registered nurses, social workers, and other healthcare professionals …. [that] provide a range of preventative services, including well-child and immunization clinics for children, treatment for minor illnesses, dental screenings, blood pressure screenings for adults, and linkages to additional health services at family homeless shelters, public housing developments, … [schools], and community based organizations," and a "Healthy Habits program [that] provides nutrition education and obesity prevention programs and elementary and middle schools."[267]

- Erlanger Health System, a DSH hospital, said its "uncompensated care costs exceed[ed] $100 million for [FY] 2017." Erlanger said the 340B savings in part fund a "free prescription home delivery service," "a clinical pharmacist at the FQHC child site [who] provides education and assistance to help patients gain a greater understanding of their medications and disease state," and allow Erlanger

[265] Letter from Steven F. Collier, MD, FACHE, Chief Executive Officer, ARcare, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 21, 2017).
[266] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program*, *available at* https://www.hrsa.gov/opa/.
[267] Letter from Thomas M. Priselac, President & Chief Executive Officer, Cedars-Sinai Medical Center, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 29, 2017).

to provide many generic prescriptions to patients for as low as four dollars at some contract pharmacies.[268]

- Mission Health, a DSH and Critical Access Hospital, said that "67 percent of Mission Health's hospitalized patients are uninsured or covered by Medicare and Medicaid. In 2016, Mission Health's total value of charity and unreimbursed care was nearly $105 million and total 2016 community investments were more than $183 million." Mission Health's community investment activities included "two … mobile oral care programs that provide free preventative and restorative oral care to school-aged children[,]" a Mountain Area Medical Airlift program with "two helicopters available 24 hours a day [that] provides air medical services [over] roughly 10,000 square miles … and has transported more than 21,000 patients," and Sexual Assault Nurse Examiners "that are specially trained, registered nurses who provide comprehensive care for victims of sexual assault, domestic violence, and child, elder, and dependent-adult abuse and neglect, and other violence crimes," among other community services.[269]

- Parkland, a DSH hospital, said that its "DSH percentage is 49.2 percent" and "payor mix is 38 percent charity, 28 percent Medicaid, 16 percent Medicare, 10 percent self-pay, and 8 percent commercial insurance." Parkland's "outreach to the community includes care in 12 Community Oriented Primary Care health centers, 12 Youth & Family centers, 10 women's health centers, acute response clinics, homeless outreach mobile units and nursing homes, [and] to inmates in the Dallas County Jail." Parkland further said that "[i]n FY 2016, [Parkland] provided $871 million in uncompensated care" and "97,200 unique patients received charity care."[270]

However, entities use different methodologies to calculate the amount of charity care that they provide to patients. As a result, it can be difficult to fairly and accurately compare charity care levels of various entities.

Indeed, the covered entities that received the committee's September 8, 2017 letter defined charity care in numerous ways. The three primary differences in how entities calculated charity care were whether to include bad debt,[271] whether to include community benefit

[268] Letter from Kevin M. Spiegel, FACHE, President & CEO Erlanger Health System, Assistant Professor University of Tennessee College of Medicine, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 1, 5-6 (Sept. 20, 2017).
[269] Letter from Ronald A. Paulus, M.D., President and Chief Executive Officer, Mission Health System, Inc., Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 2, 16-17 (Sept. 22, 2017).
[270] Letter from Fred Cerise, MD, MPH, President & CEO, Parkland Health & Hospital System, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 1, 3 (Sept. 22, 2017).
[271] The committee heard from several entities and advocacy groups that include bad debt in their measure of charity care. While bad debt may reflect an entity's services to low-income and vulnerable individuals and provide a fuller understanding of an entity's financial burden, it is crucial that—if bad debt is included in uncompensated and

activities, and how to calculate the percentage of health care services that are provided as charity care. Further, as Parkland Health and Hospital System noted, "[w]hile some organizations will report charity care as the amount of charges the institution generates for charity care, that representation overstates the actual costs. We are reporting actual costs to Parkland."[272]

Entities varied on what activities were considered appropriate to include in charity care estimates. Some entities included "community benefit activities," while others included only uncompensated care costs as a measure of charity care. For example, Johns Hopkins Hospital (JHH) stated in its response to the committee that "[c]ommunity benefit is a more appropriate indicator, than charity care alone, of JHH's overall commitment to its community and free or discounted care to vulnerable patients."[273] Using such a metric, JHH reported that its spending on community benefit activities for FY 2016 was nearly $200 million dollars, which the hospital described as including: "charity care or funding for free or discounted medically necessary care for patients, plus community health improvement programs and health screenings, accredited training of doctors, nurses and allied professionals, financial and in-kind contributions to community groups, and other community building activities."[274]

Further, when asked what percentage of total health care services provided by each organization is charity care, entities did not agree on what metric should be used to as an indicator of "total health care services." Covered entities provided that "total health care services" could be measured by examining hospital operating expenses,[275] net patient service revenue,[276] total patient care operating costs,[277] and operating revenues.[278] During the committee's October 2017 hearing, the committee asked covered entities what they thought was the best measure to estimate an entity's commitment to serving low-income and uninsured individuals:

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charity care estimates—the entity ensures that any amounts later collected through the collections process are not included in the entity's charity care calculations.

[272] Letter from Fred Cerise, MD, MPH, President & CEO, Parkland Health & Hospital System, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 3 (Sept. 22, 2017).

[273] Letter from Redonda G. Miller, MD, MBA, President, The Johns Hopkins Hospital, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, and Hon. Diana DeGette, Ranking Member, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 8 (Sept. 29, 2017).

[274] *Id*.

[275] Letter from Daniel S. Owens, Chief Executive Officer, Emory University Hospital Midtown, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 11 (Sept. 29, 2017).

[276] Letter from Steven F. Collier, MD, FACHE, Chief Executive Officer, ARcare, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 5 (Sept. 21, 2017).

[277] Letter from Thomas M. Priselac, President & Chief Executive Officer, Cedars-Sinai Medical Center, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 29, 2017).

[278] Letter from Kevin M. Spiegel, FACHE, President & CEO Erlanger Health System, Assistant Professor University of Tennessee College of Medicine, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 7 (Sept. 20, 2017).

Question: We have had a lot of different ways we have heard about how the money you get out of this program is tracked to do charity care….This makes it a little hard to do apples to apples comparison of whether covered entities are truly using 340B savings to improve patient care. So to each of you, what do you think is the best measure to estimate an entity's commitment to serving low-income and uninsured individuals? Do community benefit programs serve only low-income and uninsured patients or the entire community, including those with commercial insurance? Would a patient receive one element of care for free, at a reduced cost, be counted as one of those patients? I mean how do we track this?

* * *

Northside: I do think industry standard is not to reflect the provision of care to the vulnerable population of the percent of just operating expenses, which is what was done in the AJC article. I would say that is inaccurate or at least incomplete. When comparing to expenses, you are including things like overhead, and telephone, and depreciation on your buildings. So we would emphasize other more commonly quoted mechanisms, which would be the provision of charity and indigent in terms of total patient revenues or distinct patient served and those are the ways that we quoted in our submissions.

Mission Health: I would point you, perhaps, to the idea behind Schedule H for the IRS filing and the community benefit. I think there might be opportunities there to define and identify a specific reporting. I would think about total unreimbursed care because that is really what we are talking about here.

Carolina Health Centers: I think the term or concept of charity care is one that is not terribly familiar for community health centers or in the community health center world, not because we don't understand that concept, but because we operate under a set of statutory requirements that essentially mean we are on the hook for taking care of everyone, regardless of their ability to pay, and for providing a full range of services, regardless of their ability to pay, and have been for decades. So my health center, the $4.2 million that is listed as charity care really represents the cost of all care provided to patients for which we receive no compensation.… So the health centers do have a very concrete way of measuring that.[279]

[279] *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 60-62 (Oct. 11, 2017).

Further, because the 340B statute does not include any reporting requirements, HRSA is unable to provide any information on the level of charity care provided by covered entities. In July 2017, HRSA testified that they did not have the authority to request information about how covered entities used program savings:

> Q: Okay. But is there any data which would show the level of charity care they are providing? Anything that they are required to show you?
>
> A: They do not share anything with HRSA. They may report charity care information on their cost reports that is submitted to CMS.
>
> Q: And we don't know if that charity care money came from the 340B or came from something else?
>
> A: Yes, HRSA would not know that.
>
> Q: So as I understand it so far with the vague guidelines of eligibility for patients, the intent of the program, of course, to help the indigent population -- good. The idea that other people who may not fit that definition may still have the hospital or clinic purchasing at a discount and can use that money in any way, shape, or form and you have no way of finding out and they are not required to keep data and the books aren't kept in such a way that anybody could trace it if they wanted to?
>
> A: Yes. The statute, again, does not in any way mention what covered entities do with that savings or that they have to report it to HRSA.[280]

The committee analyzed data from Worksheet S-10 of the Medicare cost reports, as available in the CMS Healthcare Cost Report Information System (HCRIS), to identify how much charity care and unreimbursed care and uncompensated care was reported by DSH hospitals that received the committee's September 8, 2017 letter. The amount of charity care and unreimbursed and uncompensated care differed greatly across the covered entities:

[280] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 45-46 (Jul. 18, 2017).

Figure 5: Select Data for Select Hospitals from Medicare Cost Report Submissions for 2015[281]

	Total Operating Expenses*	Cost of Charity Care-Total**	Cost of Unreimbursed and Uncompensated Care***	Estimated Savings as Calculated by Entities****
Dallas County Hospital District	$1,530,686,240	$396,051,781	$454,708,458	$163,607,998
UCSF Medical Center (CA)	$3,100,587,242	$9,105,327	$297,028,036	$48,969,427
Grady Memorial Hospital (GA)	$894,292,825	$128,000,025	$174,022,464	$41,610,167
NYU Hospitals Center (NY)	$3,241,048,237	$30,798,905	$100,477,229	--
Duke University Hospital (NC)	$1,922,256,226	$88,631,398	$97,981,838	--
Cedars-Sinai Medical Center (CA)	$2,865,868,438	$34,321,412	$93,019,056	$42,100,000
Harborview Medical Center (WA)	$915,048,238	$22,149,698	$67,670,987	$33,913,794
Erlanger Medical Center (TN)	$743,398,577	$30,663,444	$51,376,071	--
Northside Hospital (GA)	$1,603,727,959	$13,278,505	$45,277,244	$51,811,078
Mission Health[282] (NC)	$1,205,110,197	$29,155,329	$43,817,407	$35,350,752
Emory University Hospital Midtown (GA)	$698,888,484	$16,840,662	$37,432,007	$39,618,918
The Johns Hopkins Hospital (MD)	$2,152,342,294	$14,462,788	$34,346,128	$69,749,000
University of Washington Medical Center (WA)	$1,126,648,993	$8,826,587	$21,954,392	$21,774,743
Intermountain Primary Children's Hospital (UT)	$433,768,433	$5,474,127	$11,060,789	$4,938,455

** Total Operating Expenses: Operating expenses incurred that arise during the ordinary course of operating the hospital complex less any deductions from operating expenses that the hospital specifies on the cost report.*
*** Cost of Charity Care-Total: Charity care costs for both insured and uninsured patients. This figure may be negative (-) if payments received from patients for amounts previously written off as charity care exceed the cost of patients approved for charity care and uninsured discounts.*
**** Cost of Unreimbursed and Uncompensated Care: Total unreimbursed costs of: 1) Medicaid, CHIP, state/local indigent care programs; 2) charity care; 3) non-Medicare and non-reimbursable Medicare bad debt.*
***** Program savings for different covered entities cannot be compared in this chart as some of these covered entities calculated program savings using different methods. The estimated savings included numerous disclaimers as to why they were only approximate estimates and therefore actual program savings, program revenue, and/or percent increase may be higher or lower than the amount of savings listed in the above table. See the covered entity's response in the October 2017 hearing record for information on how the covered entity calculated this estimate. Moreover, while the Medicare cost report data is for FY 2015, some covered entities submitted program savings by Calendar Year. The 2015 estimated savings for certain covered entities are not included in this chart either because the covered entity did not participate in the program at that time or the estimated savings were not provided to the committee in a format enabling it to be included.*

[281] Information in the table is from: U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, *Hospital 2552-10 Cost Report Data files* (last updated Nov. 4, 2014), https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospital-2010-form.html; U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, The Provider Reimbursement Manual - Part 2, Chapter 40-Hospital and Hospital Health Care Complex Report (last accessed Dec. 14, 2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html.

[282] The information for Mission Health includes the sum of Mission Hospital (NC), The McDowell Hospital (NC), Transylvania Community Hospital (NC), Angel Medical Center (NC), Highlands-Cashiers Hospital (NC), and Blue Ridge Regional Hospital (NC).

In addition to the vagueness surrounding how entities define and measure charity care, the recent report issued by the National Academies Press revealed that some 340B hospitals with the highest operating margins also provide the least amount of uncompensated care.

> Evidence about the impact of 340B revenue on safety net and community need engagement among qualifying hospitals is largely anecdotal….GAO conducted a cross-sectional comparison of 340-B qualified Medicare disproportionate share hospitals with non-340B hospitals in 2012 using publicly available data from Medicare hospital cost reports (GAO, 2015). The report found that 340B hospitals provided more uncompensated care than did non-340B hospitals and also had lower profit margins than non-340B hospitals, in part because they provided more uncompensated and charity care. A more recent report found that hospitals participating in 340B in 2014 exhibited widely varying financial stability and safety net care provision….Some 340B disproportionate share hospital (DSH) program participants operated at a substantial loss, but at least one-quarter of participants operated with a comfortable margin. Many of the hospitals with the highest operating margins were also those that provided the least uncompensated care, while the hospitals that provided the most uncompensated care had the lowest operating margins.[283]

Similarly, in March 2016, the Medicare Payment Advisory Commission (MedPAC) found that hospitals' "total (all-payer) profitability reached a 30-year high in 2014 and that total margins for hospitals increased to 7.3 percent.[284] Moreover, MedPAC determined that the 340B program is not "targeted to hospitals with high levels of uncompensated care or to hospitals with financial difficulties."[285] In the report, MedPAC stated:

> Currently, the 340B program is not well targeted to hospitals with high levels of uncompensated care or to hospitals with financial difficulties. We find that 40 percent of 340B hospitals provide less than the median level of uncompensated care (3.6 percent) as reported on Worksheet S-10 of the Medicare cost reports. While the median all-payer margin is 3.8 percent for 340B hospitals compared with 5.3 percent at non-340B hospitals, there is wide variation in profitability among 340B hospitals: 25 percent of 340B hospitals reported all-payer margins of over 8 percent in 2014. Because of variation in the uncompensated care provided by 340B hospitals and variation in the profit margins of 340B hospitals, we are suggesting that a portion of the 340B discounts be redirected toward the hospitals providing the most uncompensated care.[286]

Furthermore, information provided to the committee reveals that at some hospitals, charity care has been on the decline, even as 340B savings and other revenue grow at those

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[283] National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 106 (Nov. 2017).
[284] Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy – Chapter 3: Hospital inpatient and outpatient services* (March 2016).
[285] *Id*.
[286] *Id*.

hospitals.[287] Several entities pointed to the passage of the PPACA to explain the decrease in charity care. For example, Cedars Sinai Hospital reported that the number of patients that received charity care dropped from 150,672 in 2012 to 126,968 in 2016.[288] Cedars Sinai wrote "[p]lease note that the number of uninsured patients in California and the U.S. began dropping significantly starting in 2013 with the implementation of the Affordable Care Act."[289] Similarly, Johns Hopkins Hospital (JHH) reported to the committee that its charity care spending "decreased from FY2015 to FY2016 consistent with national trends in states that expanded Medicaid."[290] Specifically, JHH reported that its charity care spending in 2012 was $36,281,442, and had fallen to $28,302,449 in 2016.[291]

In the case of JHH, the decline in charity care may be offset by an increase in community benefit activities, which, as described above, JHH believes is a more appropriate measure.[292] JHH's "total net community benefit," which includes charity care, rose from $173,015,061, to $191,099,530 in that same time frame.[293] Media reports, however, have suggested that there has not been a consistent increase in community benefit spending as charity care declines and revenues rise:

> [I]n many cases, top hospitals' community benefit spending has remained flat or declined since the ACA took effect, too. For example, Massachusetts General Hospital in Boston, which has been ranked as the best hospital in the world, spent $53.8 million on community benefits in 2015, down from $62.1 million in 2013, even as its total annual revenue went up by more than $200 million.[294]

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[287] Hospitals that Politico reported had experienced increased revenues while decreasing their charity care between 2013 and 2015 included UCLA, UCSF, Massachusetts General, and Johns Hopkins, each of which are 340B covered entities and received the committee's September 8th letter. Dan Diamond, *How Hospitals got richer off Obamacare*, POLITICO (July 17, 2017) *available at* https://www.politico.com/interactives/2017/obamacare-non-profit-hospital-taxes/.

[288] Letter from Thomas M. Priselac, President & Chief Executive Officer, Cedars-Sinai Medical Center, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 29, 2017).

[289] *Id*.

[290] Letter from Redonda G. Miller, MD, MBA, President, The Johns Hopkins Hospital, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, and Hon. Diana DeGette, Ranking Member, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 29, 2017).

[291] *Id*.

[292] *Id*.

[293] *Id*.

[294] Dan Diamond, *How hospitals got richer off Obamacare*, POLITICO (Jul. 17, 2017), *available at* https://www.politico.com/interactives/2017/obamacare-non-profit-hospital-taxes/.

D. Medicare Part B and the 340B Program

Finding: There is a financial incentive for 340B hospitals to prescribe more, and/or more expensive drugs to Medicare Part B beneficiaries, and prescribing trends indicate that 340B hospitals do prescribe more and more expensive drugs to Medicare Part B beneficiaries as compared to non-340B hospitals.

Medicare Part B covers services and supplies considered medically necessary to treat a disease or condition, including a limited number of outpatient prescription drugs.[295] Medicare generally pays 106 percent of the Average Sales Price (ASP) for most Part B drugs, regardless of the amount the hospital paid to purchase the Part B drug from the pharmaceutical manufacturer.[296] Medicare therefore pays the same amount for Part B drugs to both 340B hospitals and non-340B hospitals even though 340B hospitals can purchase outpatient drugs at reduced prices through the 340B Program.

In November 2015, HHS OIG issued a report finding that Medicare Part B payments to covered entities for 340B-purchased drugs substantially exceeded the covered entities' costs to obtain the drugs.[297] OIG found that "[i]n the aggregate, Part B payment amounts were 58 percent more than the statutorily based 340B ceiling prices [in 2013], which allowed covered entities to retain approximately $1.3 billion."[298] The agency also noted that Medicare beneficiary cost-sharing obligations are not reduced to reflect the discounted 340B prices (Part B beneficiaries typically are responsible for 20 percent of the Part B payments in coinsurance), and Medicare Part B does not share in any of the 340B program savings realized by hospitals.[299]

Similarly in 2015, GAO issued a report finding that "per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals."[300] This indicated that on average, those patients were prescribed either more, or more expensive drugs by 340B hospitals than by other hospitals.[301] The trend could not be explained by patient or hospital characteristics.[302] According to GAO, this trend seemed to be driven by the fact that CMS pays hospitals for drugs according to a statutorily defined formula—a set rate—regardless of the cost at which the hospital acquired the drugs, and therefore, there is a financial incentive at 340B hospitals to prescribe more drugs or more expensive drugs to Medicare beneficiaries "in order to maximize the revenue generated by the difference between the cost of the drug and Medicare's reimbursement."[303] In other words, because hospitals were able to buy 340B drugs at discounted prices and still collect Medicare

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[295] CMS, *What Part B Covers*, Medicare.gov (last accessed Sept. 19, 2017), *available at* https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html.
[296] 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf.
[297] U.S. Dep't of Health and Human Services, *Office of Inspector General, Part B Payments for 340B-Purchased Drugs*, OEI-12-14-00030 (Nov. 2015).
[298] *Id*. at 8.
[299] *Id*. at 4.
[300] U.S. Gov't Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015).
[301] *Id*. at 21.
[302] *Id*. at 24-26.
[303] *Id*. at 29.

reimbursements at a set rate, prescribing more, or more expensive drugs to Medicare beneficiaries allowed hospitals to increase their 340B program savings. GAO noted in conclusion that this trend raises concerns about "the appropriateness of the health care provided to Medicare beneficiaries if it is overly influenced by financial incentives to prescribe outpatient drugs."[304]

E. Consolidation of Oncology Clinics

Finding: There has been a marked increase in consolidation of private oncology practices, which, in some instances, negatively impacts the quality of patient care and can result in increased patient cost.

The dramatic growth in 340B child sites can be attributed in part to the issue of consolidation, or the practice of 340B hospitals acquiring private practices and registering those practices as child sites. The committee explored this issue with particular focus on the acquisition of oncology practices. A 2016 report from the Community Oncology Alliance (COA) showed that there has been a 172 percent increase in the consolidation of community oncology practices into hospitals since 2008.[305] A 2017 report from COA showed that from 2008 to 2016, the percentage of Medicare Part B oncology drug reimbursements has more than tripled at 340B hospitals, while at private practices the percentage of reimbursements fell from 72 to 49 percent.[306] According to a GAO report issued in 2015, the average number of oncology patients grew for all hospitals between 2008 and 2012, but grew the most at 340B DSH hospitals.[307] For non-340B hospitals, the growth in oncology patients treated was one to two percent; for 340B hospitals, the growth in oncology patients treated was five percent.[308]

According to the 2017 report by the National Academies Press, this trend is driven by profit motive. Acquiring an oncology practice can be quite lucrative for a hospital. Oncology drugs are very expensive, so a 340B hospital that is able to purchase those drugs at a discount can realize a significant profit margin if it chooses not to pass those savings on to the patient. According to the National Academies Press report:

> For example, hospital-affiliated outpatient practices that qualify for 340B discounts can purchase drugs at reduced cost while still receiving full reimbursement for them in addition to their ability to charge facility fees. Conversely, community oncology practices that do not qualify for 340B discounts operate on lower per person-per treatment margins derived from the administration of the drugs they purchase, including the revenue generated off buy and bill reimbursements and the ability to

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[304] *Id*.
[305] Community Oncology Alliance (COA), *2016 Community Oncology Practice Impact Report: Tracking the Changing Landscape of Cancer Care* (Oct. 4, 2016), *available at* https://www.communityoncology.org/wp-content/uploads/2016/09/PracticeImpactReport-2016-Report.pdf.
[306] Berkeley Research Group, *The Oncology Drug Marketplace: Trends in Discounting and Site of Care* (Dec. 2017), *available at* https://www.communityoncology.org/wp-content/uploads/2017/12/BRG_COA-340B-Study_NOT_EMBARGOED.pdf.
[307] U.S. Gov't Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442, at 27 (June 2015).
[308] *Id*. at 28-29.

> charge facility fees (Polite et al., 2014). These disparities in revenue-generating incentives may act to encourage the consolidation of health care providers (Baker et al., 2014; Cutler and ScottMorgan, 2013). For example, there has been significant growth in 340B eligibility among outpatient clinics affiliated with 340B participating hospitals preceding and following [PPACA] implementation. As a result, GAO estimates that 340B discounts apply to 50 percent of cancer drugs sold and paid for by Medicare part B (GAO, 2015).[309]

A 2017 report from COA noted that the profit margin realized by 340B hospitals on oncology drugs after Medicare reimbursement was 49 percent in 2015, up from 39.5 percent in 2010.[310] The margin realized by non-340B hospitals in 2015 was 6 percent.[311]

Some hospitals explained to the committee that because the cost of oncology drugs is high, operating an oncology practice can be very expensive, and as a result, it is not uncommon for such a practice to approach a hospital for purchase in order to achieve financial stability. For example, in the committee's October 2017 hearing, one covered entity testified that they were approached by an oncology clinic that wanted to be acquired by the hospital:

> Q: …Northside did, however, acquire two oncology practices in 2013, did it not?
>
> A: Those discussions began in 2011 and completed in 2012.
>
> Q: Okay. So Ms. Banna, can you explain why Northside acquired these sites?
>
> A: Absolutely. We were approached by a large oncology practice that was seeking integration with the hospital system, as were several other hospital systems in the Atlanta area. We worked with them throughout 2011 and 2012 to determine the model that would provide the right kind of clinically-integrated care that both parties were looking for and completed that transaction in 2012.[312]

The committee was unable to determine the frequency of such solicitations.

Regardless of the motivation for such consolidation, these acquisitions often result in higher cost of care to patients due to additional costs imposed by the hospital, such as facility fees. Hospitals charge patients an average of 189 percent more than for infusions than what a

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[309] National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 113 (Nov. 2017).
[310] Berkeley Research Group, *The Oncology Drug Marketplace: Trends in Discounting and Site of Care* (Dec. 2017), *available at* https://www.communityoncology.org/wp-content/uploads/2017/12/BRG_COA-340B-Study_NOT_EMBARGOED.pdf.
[311] *Id*.
[312] *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, at 95-96 (Oct. 11, 2017).

private oncology practice would charge, according to a 2014 study by IMS Institute for Healthcare Informatics.[313] The National Academies Press noted that:

> For drugs dispensed or used by clinicians at a hospital-affiliated clinic or an outpatient infusion center affiliated with a hospital, these providers also charge payers facility fees, which may amount to 50 percent or more of the drug's acquisition cost. As the site of care for outpatient infusion services has increasingly shifted toward hospital-owned or affiliated practices in recent years, spending associated with this form of care has grown (MedPAC, 2017b).[314]

In the case of Northside specifically, the *Atlanta Journal-Constitution* reported that after Northside acquired Atlanta Cancer Care in 2013, the out of pocket cost of treatment for one patient rose from $20 to $212, a more than 1000 percent increase.[315] The cost to his insurer rose from $2,735 to $5,661, a more than 200 percent increase.[316] The *Journal* spoke with at least three other patients whose cost of care had increased, despite no change in the care they received.[317]

Not only do these acquisitions often result in higher cost of care for patients, GAO found that for Medicare Part B beneficiaries in particular, 340B DSH hospitals "prescribed more oncology drugs, or prescribed more expensive oncology drugs," than did non 340B hospitals treating Medicare Part B oncology patients.[318] As explained in an earlier section of this report, this reflects the financial incentive of 340B hospitals maximize revenue generated by Medicare reimbursements, and calls into question the appropriateness of care provided.[319]

In addition to increasing a patient's out of pocket costs, consolidation can result in a decline in quality of care. The committee had confidential conversations with several physicians and administrators with experience treating oncology patients before, during, and after such an acquisition by a hospital.

- One doctor who spoke to the committee detailed a troubling decline in patient care after the doctor's private oncology practice was acquired by a large hospital. The doctor also noted that while the treatment regime patients received did not change, costs rose "markedly." The doctor noted one patient in particular who shared his bills for a bone marrow biopsy showing the increase in cost of care over a three-year period. Two years before the practice was acquired, the patient's biopsy cost $1,000 when performed at the

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[313] Roni Caryn Rabin, *Chemo Costs in U.S. Driven Higher By Shift to Hospital Outpatient Facilities*, KAISER HEALTH NEWS (May 6, 2014), *available at* https://khn.org/news/chemo-costs-in-u-s-driven-higher-by-shift-to-hospital-outpatient-facilities/.
[314] National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 113 (Nov. 2017).
[315] Carrie Teegardin, *When doctors sell out, hospitals cash in*, THE ATLANTA JOURNAL-CONSTITUTION (Jul. 6, 2013), *available at* http://www.myajc.com/news/when-doctors-sell-out-hospitals-cash/AtShGSUuv3kmN6sBKL2nvM/.
[316] *Id*.
[317] *Id*.
[318] U.S. Gov't Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442, at 28 (June 2015).
[319] *Id*. at 29.

private practice. A year later, one year before the practice was acquired, the practice could no longer afford to perform the biopsy, and referred the patient to the hospital that would eventually acquire the practice. When the same procedure was performed by the hospital, the patient was bill $7,000. The next year, after the practice was acquired by the hospital, the patient was billed $14,000 for the procedure that had cost him only $1,000 two years prior. The doctor further stated that the kit needed for the procedure cost the practice $125. The practice first referred the patient to the hospital because the reimbursement for the kit had dropped to $100, and the practice could no longer afford to perform the procedure. The doctor stated that despite the higher costs, no services were added that improved patient experience, and in fact qualify of care and patient satisfaction declined.

The doctor stated that prior to the acquisition, overall patient support was superior. The practice employed registered nurses (RNs) and there were eight staff members devoted to optimizing the quality of patient care. Within roughly a month of the acquisition, the hospital removed the RNs from the practice and replaced them with licensed practical nurses (LPNs). According to the doctor, an LPN's salary is about half of that of an RN, and the hospital explained to the oncology practice that it needed to cut costs wherever it could. LPNs, however, have less experience than RNs, and are unable to provide the same services. The doctor noted that RNs are able to keep patients out of the emergency room by providing symptom management by phone, whereas calls with LPNs often resulted in patients being referred to the emergency room. Emergency room visits can be very expensive, so not only does this lead to increased cost for patients, but it also leads to higher income for the hospital. Similarly, the hospital also decided to discontinue the practice's research project, because the project was not lucrative.

Finally, the doctor stated that immediately following the acquisition, the hospital asked if the doctor could change the patients' infusion regime such that after a certain drug was administered at the physician clinic, the patient would then be moved to the hospital to receive a subsequent drug. The doctor noted that this would require patients to be moved during a period in which the patient would be experiencing severe nausea. The doctor noted that this was medically unnecessary, as both drugs had previously been provided in one location, and the doctor could identify no other reason for the shift than profit incentive. The hospital did not ultimately require that the doctor change the infusion regime.

- An administrator of a community oncology center that was acquired by a 340B hospital stated that although the treatment regime did not change at all after the acquisition, patient prices rose by as much as 530 percent for some services after the acquisition. The administrator noted that several patients contemplated leaving the practice, but the administrator was unsure if any patients ultimately left, noting that in that area, there were not many alternative treatment centers available. The administrator also stated that patient satisfaction decreased after the acquisition, particularly because of a different software and additional forms used by the hospital that slowed down treatment and which the administrator found to be inefficient.

- More troubling, one doctor told the committee that the doctor had seen 16 patients put on a waiting list for patients without insurance. The doctor noted that the wait list was not a capacity issue, but a decision by the hospital to cap the number of uninsured patients that it will treat within a set period of time. Due to the nature of the cancer with which those patients had been diagnosed, several of those patients' conditions worsened during the time they waited for treatment.

- Finally, one doctor told the committee that after a local hospital began acquiring oncology clinics, private clinics could no longer compete, because the hospital refused to refer patients to those clinics, even if it would have been in the best interest of the patient. The doctor explained that the hospital was short staffed on oncology doctors, but refused to hire more doctors or refer patients to other treatment centers that were not within that hospital's 340B system, even though such a referral would mean the patient got treatment sooner. The doctor also noted that the treatment regime and procedures performed in the hospital were the same as they would be in a private clinic, but the hospital charged higher prices for those services. Finally, the doctor stated that the hospital refused to treat uninsured patients outside of an emergent setting. If such a patient came to the emergency room, the hospital would stabilize the patient, and refuse further treatment because the patient could not pay.

The committee has been unable to determine at this time how frequent or widespread such dynamics may be. However, the sincere concerns expressed by numerous health care providers who have witnessed these challenges suggest there may be at least some negative consequences of market dynamics associated with the 340B program. Given the widespread agreement between all covered entities that the aim of the 340B program is to assist these entities in providing care to patients, first-person reports of negative patient impacts or patient harm should be concerning to everyone focused on improving patient care.

F. Disproportionate Share Hospital Metric and Covered Entity Eligibility

Finding: The current metric used to determine hospital eligibility for the 340B program does not necessarily reflect the amount of charity care offered by the hospital or the outpatient population for the hospital. Hospitals have a financial incentive to open child sites in areas that do not reflect the DSH percentage of the parent entity, thus enabling the hospital to gain access to a higher number of commercially insured patients.

As shown in Figure 1, one of the requirements for hospitals to qualify as covered entities and participate in the 340B program is that they must be a DSH hospital and have a minimum disproportionate share adjustment percentage to qualify for program participation. The requirement that certain hospitals have a disproportionate share adjustment percentage above 11.75 percent (or greater than or equal to 8 percent for some hospitals) to qualify as a covered entity is a statutory requirement.[320] Congress referred to Section 1886 of the Social Security Act for the definition of a disproportionate share hospital for purposes of the 340B program, which only addresses Medicare payment for hospital inpatient services.[321] According to Section 1886

[320] PHSA § 340B(a)(4)(L)(ii).
[321] *See id*.

of the Act, there are two ways that a hospital can qualify for the Medicare DSH adjustment: (1) the primary method; and (2) the alternate special exemption method.[322] Under the primary method, the DSH patient percentage is determined by calculating 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 patients eligible for Medicaid but not Medicare Part A.[323] The alternate special exemption is for large urban hospitals that can show that more than 30 percent of their total net inpatient care revenues are from state and local governments for indigent care.[324]

Therefore, although the 340B program is an outpatient program, hospital eligibility for the 340B program is calculated by analyzing inpatient care. The only requirement for an outpatient facility to be eligible as a child site of a 340B hospital is that the facility be listed on the hospital's Medicare cost report; the child site need not be independently eligible for program participation.[325] This raises concerns about whether the patient population served by a child site is reflective of the patient population served by the parent entity. If a DSH hospital were to open a child site in an affluent area in which a large percentage of the patient population has commercial health insurance, it is possible the hospital could profit significantly from prescribing discounted 340B drugs to patients that are charged the full price for those drugs and for which the hospital receives a larger payment than it would from a Medicaid/Medicare patient. Because covered entities are not required to track or report program savings, and many choose not to, there is currently no available data on which child sites generate the most savings and revenue for covered entities. Many covered entities told committee staff that they track drug purchases and savings in the aggregate and are unable to identify program savings generated by each child site.

While this practice is not prohibited, it does not seem to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[326] Although the program's specific purpose may be unclear, as previously discussed, the DSH eligibility requirement makes clear that hospitals are eligible based on serving vulnerable and underserved populations. Given the changing health care landscape, especially regarding consolidation and the growth in child sites, it is unclear whether Congress intended for this outcome. In 2015, when asked about the use of the DSH metric, GAO testified that because the health care landscape has changed so dramatically, it is especially important for Congress to clearly define the intent of the program. GAO testified:

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[322] U.S. Dep't of Health and Human Services, Centers for Medicare & Medicaid Services, *Disproportionate Share Hospital (DSH)* (last modified Sept. 29, 2017), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html.

[323] U.S. Dep't of Health and Human Services, Centers for Medicare & Medicaid Services, *Disproportionate Share Hospital (DSH)* (last modified Sept. 29, 2017), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html.

[324] *Id*.

[325] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 98 (Jul. 18, 2017).

[326] Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program, available at* https://www.hrsa.gov/opa/.

Q: In your report, you noted that using the DSH adjustment percentage as part of the 340B eligibility criteria for hospitals has the effect of making eligibility for 340B expand as more people become insured due to broader Medicaid coverage. Since your report was written, we have seen the uninsured rates decline at hospitals in states that have expanded Medicaid. The question is, do you think it makes sense for hospitals in those states to gain full access to 340B just as their charity care burden is decreasing due to patients gaining Medicaid or do you think there might be another metric for 340B eligibility that could work better than the DSH metric to help ensure the program reaches the hospitals that are truly serving a disproportionate share of uninsured and vulnerable patients?

A: Well, it is probably best if I first explain what DSH is. It is actually an inpatient indicator. The 340B Program is an outpatient program. DSH is actually the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and Supplemental Security Income and the percentage of total inpatient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A. So it is really an inpatient indicator and it is sometimes used as a proxy for uncompensated care or the amount of low-income clients a particular facility serves. So the question is an interesting one. And part of the issue is that it is a difficult question to answer because much has changed in the healthcare landscape over the last several years since the 340B Program was created in 1992. One of the big things, of course, is the healthcare reform that was recently enacted which provided coverage for more people than originally was the case when the program was initially established. However, I think the bigger question is, what is the intent of the 340B Program. And there is a lot of uncertainty or lack of clarity around what is this program intended to do. In our prior work when we issued our 2011 report, there was a lot of varying interpretations of what the 340B Program was. HRSA talks about the program. And the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more patients and provide more comprehensive services…. Others believe that this is a program to assist low-income individuals in need of medications. And while it does that, there is no criteria in terms of patient eligibility, no criteria related to level of income. So it could benefit anyone, any level of income as long as they meet the other criteria for an eligible patient. And I can just tell you that when we conducted our work in 2011, we found a range of payer mixes in the hospitals that we interviewed. We asked them about their Medicaid and uninsured payer mix and it ranged anywhere from 15 percent to 85 percent. So it is really all over the board, and I think it is just really being able to add more clarity. It is important to add more clarity and more specificity to what is the intent of the program, what is it intended to do.[327]

[327] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and* Commerce, 114th Cong., at 47-48 (Mar. 24, 2015).

Moreover, it is unclear whether the DSH metric ensures that the program is available for hospitals that are truly serving a disproportionate share of uninsured and vulnerable patients. According to the recent report issued by the National Academies Press, there is "little correlation between county-level uninsured rates and the adjusted DSH patient percentage" of a hospital.[328]

> Evidence about the impact of 340B revenue on safety net and community need engagement among qualifying hospitals is largely anecdotal…. GAO conducted a cross-sectional comparison of 340B-qualified Medicare disproportionate share hospitals with non-340B hospitals in 2012 using publicly available data from Medicare hospital cost reports…. The report found that 340B hospitals provided more uncompensated care than did non-340B hospitals and also had lower profit margins than non-340B hospitals, in part because they provided more uncompensated and charity care. A more recent report found that hospitals participating in 340B in 2015 exhibited widely varying financial stability and safety net care provision….Some 340B disproportionate share hospital (DSH) program participants operated at a substantial loss, but at least one-quarter of participants operated with a comfortable margin. Many of the hospitals with the highest operating margins were also those that provided the least uncompensated care, while the hospitals that provided the most uncompensated care had the lowest operating margins. Furthermore, there was little correlation between county-level uninsured rates and the adjusted DSH patient percentage.[329]

On the other hand, in its response to the Questions for the Record following the October 2017 hearing, Mission Health recently defended the use of the DSH metric to determine 340B eligibility by arguing that the DSH metric provides direct insight into the culture of the hospital and its commitment to caring for vulnerable, uninsured, and underinsured patients:

> Even though the metric measures inpatient care, the Disproportionate Share Hospital (DSH) metric is appropriate for use in the 340B program, especially with respect to urban DSH and safety net hospitals.
>
> The DSH metric identifies hospitals that provide inpatient services to a larger number of Medicaid and low-income Medicare/SSI patients than other hospitals (as opposed, for example, to hospitals that more routinely provide stabilizing treatment and then transfer or refer those patients to other medical centers for acute care). In other words, the DSH metric percentage identifies hospitals that provide a disproportionate share of inpatient care that is reimbursed below the actual cost of providing that care and correspondingly, identifies those hospitals that consistently serve a larger number of the most vulnerable patients in the community.
>
> These vulnerable patients are often in need of complex care, require more resources, and are almost universally unable to afford the care that they need. The DSH metric, while imperfect, provides direct insight into the culture of the hospital

[328] National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 106 (Nov. 2017).
[329] *Id*.

> and its commitment to caring for vulnerable, uninsured, and underinsured patients; that culture and philosophy of caring is unlikely to differ between inpatient and outpatient services. Importantly, those unique outpatient settings that are similarly dedicated to providing care to the most vulnerable (e.g., Rural Health Centers) separately qualify for the program.
>
> There is no perfect metric, and perfect is often the enemy of the good. The DSH metric effectively identifies those hospitals providing higher amounts of care to inherently vulnerable populations, as is consistent with the goals of the 340B Program. The data used to support the calculation is readily available to the Health Resources and Services Administration (HRSA) and results in a reliable and clear metric for determining access to the 340B Program.[330]

In recent years, there have been fewer uninsured patients and charity care has declined. At the same time, because Medicaid enrollment has increased and the DSH metric measures Medicare and Medicaid inpatient stays, an increased number of entities are eligible to participate in the program. In 2017, GAO testified that another weakness with the DSH metric is that it is based on patients with health care coverage:

> Q: This metric for qualifying DSH hospitals is an inpatient measure yet 340B is for outpatient drugs. So does it make sense for us to use an inpatient metric for an outpatient program?
>
> A: Well, we do believe that that is a – that is one of the weaknesses of the DSH measure. The other is that it really – the formula is based on covered patients and that would be those covered by Medicare and Medicaid. So, you know, there are weaknesses inherent in that measure.[331]

[330] Letter from Ronald A. Paulus, M.D., President and Chief Executive Officer, Mission Health System, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, *Additional Questions for the Record* (Nov. 21, 2017).

[331] *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 114 (Jul. 18, 2017).

VII. Conclusion

The 340B program is a vital lifeline to health care providers that allows them to purchase certain outpatient medications at reduced rates. For some covered entities, the 340B program and related savings are critical to the entity's financial viability and their ability to keep their doors open. For others, the program allows them to invest more dollars to extend care to underserved populations, to create programs that serve specific community needs, and to provide life-saving drugs at discounted prices to the populations that need them the most.

In recent years, however, concerns have been raised about how some entities use the program and how HRSA administers and oversees the program. Over the past two years, the committee has examined the 340B program by holding three hearings, meeting with more than 50 shareholder and advocacy groups, and reviewing documents from both HRSA and covered entities about how the 340B program is used. The committee's investigation has uncovered several weaknesses in program administration and oversight.

Program participation has more than quadrupled over the past 10 years, yet HRSA has remained largely the same size. This explosion in program growth has raised concerns about HRSA's ability to effectively oversee the program with their limited resources. Per a 2014 federal court ruling, HRSA's authority to oversee the program and enforce program requirements is limited. HRSA needs more regulatory authority to promote compliance, clarify requirements, and ensure program integrity.

Further, the intent and parameters of the program are unclear. Covered entities are not required to use program savings in any specific way, which has led to concerns about whether the money is truly devoted to improving patient care. Clarifying the intent of the program will better enable HRSA to oversee the program in a way that is consistent with that intent, as well as provide further guidance to participating covered entities on how best to utilize the program to improve patient care.

Finally, a lack of reporting requirements has resulted in a lack of reliable data. The little data that are available are self-reported by entities that measure savings, charity care, and program value in differing ways. There are dueling claims among program participants and stakeholders about whether the program is working to best serve indigent and vulnerable patients and whether, given program growth, the lack of clear Congressional purpose, and the changing health care landscape, the program's original structure is still appropriate. Reforming the program to promote transparency and accountability will allow for an accurate accounting of the full scope of the program's use and will help promote program integrity and oversight.

The 340B program is an important piece of our nation's health care system. Reforming the 340B statute is an important step toward providing quality health care to our most vulnerable populations. As the program continues to expand, additional program examination is likely to be warranted.

VIII. Recommendations

- HRSA should soon finalize and begin enforcing regulations in each of the three areas in which it currently has regulatory authority, including the 340B Alternative Dispute Resolution process, the imposition of civil monetary penalties against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug, and the calculation of ceiling prices.

- Congress should give HRSA sufficient regulatory authority to adequately administer and oversee the 340B program, including the ability to improve program integrity, clarify program requirements, monitor and track program use, and ensure that low-income and uninsured patients directly benefit from the 340B program.

- Congress should require certain covered entities to conduct independent audits of program compliance, and should determine what such audits should assess and evaluate.

- All covered entities should perform independent audits of their contract pharmacies at regular intervals to ensure 340B program compliance.

- Congress should equip HRSA with more resources and staff to conduct more rigorous oversight and more effective management of the 340B program.

- Congress (and HHS to the degree possible) should take steps to identify and reduce duplicate discounts for drugs paid for under Medicaid managed care.

- Congress should evaluate whether the permissible scope of HRSA's audits should be expanded to cover other features of the program.

- HRSA should work toward ensuring that it audits covered entities and manufacturers at the same rate.

- Congress should clarify the intent of the 340B program to ensure that HRSA administers and oversees the 340B program in a way that is consistent with that intent. In doing so, Congress also should evaluate how developments in the health care landscape over the past 25 years have affected, if at all, the structure and goals of the 340B program.

- Congress (or HRSA where HRSA already has authority to make such changes) should promote transparency in the 340B program, including ensuring that covered entities and other relevant stakeholders have access to ceiling prices and requiring covered entities to disclose information about annual 340B program savings and/or revenue.

- Congress should establish a mechanism to monitor the level of charity care provided by covered entities. This should include a clear definition of charity care such that the data can be used to fairly compare care provided across entities.

- Congress should reassess whether DSH is an appropriate measure for program eligibility, or whether a metric based on outpatient population would be more appropriate.

IX. Appendix

Year	Legislative Changes	Program Change Summary
1992	Veterans Health Care Act of 1992 (VHCA, P.L. 102-585); § 602	340B program authorizing legislation
1993	National Institutes of Health Revitalization Act of 1993 (NIHRA, P.L. 103-43), § 2008	NIHRA made a technical change to the directory language of VHCA.
2003	The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173), § 101, § 103, § 303, § 1002	MMA amended the Social Security Act (SSA) by changing the Disproportionate Patient Percentage (DPP) hospitals needed to qualify as Disproportionate Share Hospitals (DSHs). As a result, approximately 800 new small urban and rural hospitals became eligible for the 340B program.
2006	Deficit Reduction Act of 2005 (DRA, P.L. 109-171), § 6001, § 6004	DRA revised the Medicaid definition of Average Manufacturer Price (AMP) and made other technical changes. As a result of the AMP definition change, drug manufacturers were reluctant to extend 340B program prices to university health clinics and certain health center lookalikes, because under the new AMP definition, drug manufacturers were required to consider sales to university clinics and lookalikes as being included in the calculation of each covered drug's AMP. If the university clinic and lookalike sales were included in AMP, those transactions would increase drug manufacturer rebates. Prior to the AMP definition change in DRA, sales to university health clinics and lookalikes were considered sales at nominal price and as a result were excluded from the AMP calculation. DRA also amended the SSA to include children's hospitals as 340B covered entities. Covered entities under the 340B program are identified in the Public Health Service Act (PHSA) [PHSA §§ 340B (a)(4)(A)-(N), Covered Entity, Defined], and not the SSA. As a result, there may have been some uncertainty about whether children's hospitals were eligible for the 340B program. HRSA published children's hospital participation guidance in 2007, but final guidance was not issued until September 2009. Some children's hospitals enrolled in the 340B program in 2009, but most enrolled after the ACA amended the PHSA [PHSA § 340(a)(4)(M)] by adding children's and other hospital types to the list of covered entities eligible to participate in the 340B program.
2009	Omnibus Appropriations Act, 2009, (OAA, P.L. 111-8) §§ 221(a)-(b)	OAA amended the SSA [SSA § 1927(c)(1)(D), Limitation on Sales at Nominal Price] to specify that covered drug sales to certain 340B program covered entity types – lookalikes and university health clinics were to be considered sales at nominal price and would therefore drug manufacturers could exclude the amount of those sales from the calculation of AMP for each affected drug. The 340B covered entity sales that were to be considered nominal price sales were to nonprofit entities that have the same functions as federal PHS grantees, but don't receive grants and entities based at institutions of higher learning whose primary purpose was to provide health services to students of the institution.

Year	Legislative Changes	Program Change Summary
2010	Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) §§ 7101-7103, § 2501 and Health Care and Education Reconciliation Act of 2010 (HCERA, P.L. 111-152), § 2302	ACA added four new hospital covered entities that were eligible to participate in the 340B program (1) critical access hospitals, (2) freestanding cancer hospitals, (3) sole community hospitals, and (4) rural referral centers. ACA also clarified that children's hospitals were eligible to participate in the 340B program. ACA extended 340B program discounted ceiling prices to inpatient drugs, but the inpatient drug extension was repealed [HCERA § 2302]. ACA required the Secretary to establish an administrative dispute resolution process and to promulgate regulations implementing civil monetary penalties on manufacturers and covered entities. ACA required drug manufacturers to have non-discrimination policy when there are drug shortages so that 340B covered entities have the same access to drugs at ceiling prices as do non-340B drug purchasers. ACA required drug manufacturers to report ceiling prices to the Secretary [PHSA § 340B(a)(1)]. ACA increased Medicaid rebates from 17.1% on single source drugs to 23.1% and on multiple source drugs from 11% to 13%. For Medicaid, the federal government received the entire amount of the rebate increase. The ACA Medicaid rebate increase resulted in increased discounts (lower ceiling prices) for 340B covered entities (increases of 17.1% to 23.1% for single source drugs and 11% to 13% for multiple source drugs. The amount of the ACA increased drug discount was available to 340B program covered entities. ACA limited the total rebate (Medicaid)/discount (340B) to a maximum of 100% of AMP. ACA required the Government Accounting Office (GAO) to conduct a study and issue a report on the 340B drug pricing program. ACA/HCERA stipulated that for the new hospital covered entities added by ACA, including children's hospitals, orphan drugs (as defined in the Food Drug and Cosmetic Act, § 526, for the treatment of a rare disease or condition) were not included in definition of covered outpatient drugs. The hospital covered entities that were not entitled to the 340B ceiling price discount were children's hospitals, critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals. DSHs were entitled to the 340B ceiling prices for orphan drugs.
2010	Medicare and Medicaid Extenders Act of 2010 (MMEA, P.L. 111-309), § 204	MMEA amended the PHSA to exempt children's hospitals from the requirement that orphan drugs were not subject to the 340B ceiling price discounts for the newly added ACA hospital covered entities (critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals). Other covered entities, including DSHs and children's hospitals are entitled to the 340B ceiling price discount on orphan drugs.

Source: Review of Public Laws, legislation, and guidance.

Exhibit K

HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable

Your 340B Report for Thursday July 9, 2020

Tom Mirga
Jul 9, 2020

A note from Publisher and CEO Ted Slafsky: Attention 340B covered entities! I am honored and excited to be speaking on a virtual panel July 15 hosted by 340B Report sponsor PSG on the latest 340B developments. I am speaking with a great group of experts including my long-time colleague Bill von Oehsen of Powers Law (also a 340B Report sponsor) and Dustin Ottemiller, Vice President of Finance and Population Health at Jefferson Health. I hope you can join us for this timely and candid conversation. More details about the event and how to register can be found in PSG's sponsored content article, which is immediately after our lead story below.

HRSA says that although its 2010 contract pharmacy guidelines remain in effect, "guidance is not legally enforceable." The agency says it "strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements." | Source: Shutterstock

HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable

In what some perceive as a break with a position dating back to 1996, the U.S. Health Resources and Services Administration (HRSA) said late yesterday that although its 2010 contract pharmacy guidance remains in effect, it is not legally enforceable. HRSA was responding to questions from 340B Report about drug manufacturer Eli Lilly's July 1 decision to stop providing 340B discounts on its erectile dysfunction drug Cialis when it is dispensed by contract pharmacies.

Asked if Lilly is obligated to provide 340B-priced product to contract pharmacies, HRSA told us:

> Contract pharmacies are a mode for dispensing 340B drugs and serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Manufacturers that refuse to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point of access for obtaining their prescriptions. HRSA strongly encourages all

> manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.

We asked HRSA if it would take action against Lilly for not providing 340B-priced drugs to contract pharmacies. It said:

> As previously stated, HRSA strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.

We also asked HRSA if it still stands by its 2010 contract pharmacy guidelines. HRSA answered:

> The 2010 guidance is still in effect. However, guidance is not legally enforceable. Regarding the 340B Program's guidance documents, HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.

When 340B Report broke the news two days ago of Lilly's decision to stop providing 340B discounts on Cialis shipped to contract pharmacies, attorneys for health care providers interpreted the company's move as an invitation to the U.S. Health and Human Services (HHS) Department either to sue Lilly or initiate administrative proceedings against it in defense of HRSA's 340B contract pharmacy guidelines. It appears now that HHS and HRSA have concluded that Lilly cannot be compelled to provide 340B discounts on drugs dispensed by contract pharmacies. One attorney for providers said HRSA appears to be breaking with the position it has held on that subject for 24 years.

An attorney for drug manufacturers, however, agreed with Lilly's position that the 340B statute imposes no obligation on manufacturers to sell to contract pharmacies at the 340B price. The government would likely fail if it tried to enforce HRSA's non-binding contract pharmacy guidance, the attorney said.

Attorneys for providers also say HRSA's statement to 340B Report that program guidelines are legally unenforceable could encourage other drug manufacturers to follow Lilly's lead and declare that they, too, will stop providing 340B discounts on drugs dispensed by contract pharmacies. Depending on how many manufacturers did so, that could significantly reduce

provider revenues on 340B drugs—with harmful effects, providers say, on patient care. It also could boost drug manufacturer profits.

More broadly, HRSA's statement that 340B guidance in general cannot be enforced raises questions about the viability of many 340B program requirements—not just those for manufacturers, but for covered entities, too.

According to Stephen Kuperberg, Counsel with Powers Law, a 340B Report sponsor, when HRSA issued guidance in 1996 setting parameters for covered entities to contract with a single outside pharmacy, it "did not believe that its guidance established any new right or obligation. Rather, it interpreted the obligations established by the 340B statute in light of existing common law contract and agency law."

"Congress certainly intended for the 340B statute to be enforceable," Kuperberg continued. "That the agency has now decided it cannot act to enforce what it has maintained for over two decades was a clear and enforceable right under the statute is puzzling and disquieting, and certainly could be seen among other manufacturers as an invitation to follow suit."

Richard Church, Partner at K&L Gates, noted that when a South Carolina community health center sued HRSA in federal court in 2018 over its termination from 340B over an adverse audit finding, HRSA similarly backed down.

"Their options were similar here to either challenge Eli Lilly and risk litigation or simply encourage compliance with their guidance," Church said. "It appears they have chosen the latter path. Each of these incidents suggests that much of their guidance may not be enforceable, particularly if HRSA is unwilling to risk another litigation loss on this front."

Andrew Ruskin, also Partner at K&L Gates, added that "covered entities may opt to explore where they believe they have similar flexibilities in interpreting HRSA's guidance. That is, unless and until HRSA does get rulemaking authority from Congress."

Todd Nova, a Shareholder in Hall Render, said, "Much like with the 340B mega-guidance that was withdrawn, it seems HRSA OPA [Office of Pharmacy Affairs] is acknowledging that they do not have direct statutory guidance conferring authority to establish regulations governing contract pharmacy arrangements. Still, it is common for agencies across the HHS spectrum including OPA to publish sub-regulatory guidance that provides insight into their interpretation of existing statutory authority. Though it's somewhat subjective, at some point that guidance becomes 'longstanding' and can be afforded the force of law by a court. The 2010

contract pharmacy guidance has been in place for quite some time now, so I do not think HRSA OPA is suggesting it is unenforceable but rather is acknowledging it is sub-regulatory rather than an authorized regulation."

Jason Reddish, Partner at Feldesman Tucker, said, "HRSA clearly continues to believe in the contract pharmacy model and rightly supports that covered entities have the well-settled ability to contract with a pharmacy to dispense the 340B drugs that they have a right to purchase. The contract pharmacy guidance is simply that—guidance for entities that choose to use a contract pharmacy so they can do so in a manner that prevents diversion and fee-for-service Medicaid duplicate discounts."

John Shakow, a Partner at King & Spalding who represents drug manufacturers, said, "The law doesn't impose any obligation on manufacturers to sell to contract pharmacies at the 340B price, so in that respect Lilly is well within its rights. Manufacturers also aren't obliged to cause product purchased by a covered entity to be shipped to anyone other than the covered entity itself (with certain exceptions). Because there is no legal obligation on manufacturers to honor contract pharmacy arrangements in this way, any attempt by the government to enforce HRSA's non-binding guidance would likely fail."

Exhibit L

United States Government Accountability Office

Report to Congressional Requesters

December 2020

DRUG PRICING PROGRAM

HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements

GAO-21-107

GAO Highlights

Highlights of GAO-21-107, a report to congressional requesters

December 2020

DRUG PRICING PROGRAM

HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements

Why GAO Did This Study

Covered entities can realize substantial savings through 340B Program price discounts, enabling them to stretch federal resources to reach more eligible patients and provide more comprehensive services.

GAO was asked to provide information on HRSA's efforts to oversee covered entities' compliance with 340B Program requirements. This report describes (1) the audit findings that HRSA issued to address covered entity noncompliance with 340B Program requirements; and (2) other efforts HRSA uses to help ensure that covered entities comply with 340B Program requirements.

GAO reviewed documentation, including relevant federal laws and regulations and HRSA's policies, procedures, and guidance, related to 340B Program oversight. GAO also reviewed HRSA data on the number and type of audit findings made from audits finalized during fiscal years 2012 through 2019 as of September 2020—the latest data available at the time of the audit. GAO also interviewed officials from HRSA, agency contractors, and 340B Program stakeholders.

GAO provided a draft of this report to HHS for review. The agency provided written and technical comments on the draft, both of which were incorporated as appropriate.

View GAO-21-107. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

The 340B Drug Pricing Program (340B Program) requires drug manufacturers to sell outpatient drugs at a discount to covered entities—eligible hospitals and other entities participating in the program—in order for their drugs to be covered by Medicaid. Participation in the 340B Program has grown from nearly 9,700 covered entities in 2010 to 12,700 in 2020. The Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) administers the program and oversees covered entities' compliance with 340B Program requirements through annual audits, among other efforts. If audits identify noncompliance with program requirements, HRSA issues findings to covered entities and requires them to take corrective action to continue participating in the 340B Program (see table).

Audit Findings Issued to Covered Entities by the Health Resources and Services Administration (HRSA) for Fiscal Years 2012-2019, as of September 2020

340B Program findings of noncompliance	Number
Eligibility of covered entities. Failure to maintain eligibility-related requirements (e.g., covered entities' oversight of their contract pharmacies).	561
Diversion of 340B drugs to ineligible patients. 340B drugs distributed to individuals who are not eligible patients of a covered entity (e.g., patients' health records are not maintained by the covered entity).	546
Duplicate discounts. Prescribed drugs that may have been subject to both the 340B price and a Medicaid rebate.	429
Total	**1,536**

Source: GAO analysis of information received from HRSA. | GAO-21-107

HRSA officials told GAO that, beginning in fall 2019, the agency started issuing findings only when audit information presents a clear and direct violation of the requirements outlined in the 340B Program statute. HRSA officials explained that guidance, which is used to interpret provisions of the 340B statute for the purposes of promoting program compliance among covered entities, does not provide the agency with appropriate enforcement capability. For example, HRSA officials reported that there were instances among fiscal year 2019 audits in which the agency did not issue findings for a failure to comply with guidance related to contract pharmacies in part because the 340B statute does not address contract pharmacy use and, therefore, there may not have been a clear statutory violation.

In addition to audits, HRSA provides education to covered entities about 340B Program requirements and has implemented other efforts to identify noncompliance. For example, HRSA

- requires all covered entities to recertify their eligibility to participate in the 340B Program annually (e.g., self-attesting to compliance); and
- uses a self-disclosure process through which covered entities can disclose and correct self-identified instances of noncompliance.

Contents

Abbreviations

340B OPAIS	340B Office of Pharmacy Affairs Information System
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

December 14, 2020

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Michael C. Burgess
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Brett Guthrie
Republican Leader
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The 340B Drug Pricing Program (340B Program), named for the statutory provision authorizing it in the Public Health Service Act, requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities—certain hospitals and recipients of federal grants—in order for their drugs to be covered by Medicaid.[1] Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the cost of the drugs, according to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B Program. These savings allow covered entities to generate revenue under the program when purchasing 340B drugs for eligible patients whose insurance reimbursement exceeds the 340B price paid for the drugs. According to HRSA, the purpose of the 340B Program

[1]42 U.S.C. § 256b. Medicaid is a joint federal-state program that finances health care, including prescription drugs, for certain low-income and medically needy populations.

is to enable covered entities to use these gains to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.[2]

Entities eligible to participate in the 340B Program include certain types of federal grantees and nonprofit hospitals that provide care to the medically underserved and meet other criteria, such as being owned by a unit of state or local government.[3] Participation in the 340B Program has grown from nearly 9,700 covered entities in 2010 to 12,700 covered entities in 2020. According to HRSA, about 80 percent of covered entities are grantees (e.g., a family planning clinic), and 20 percent are hospitals. However, a covered entity may have multiple sites of operation, and about three-quarters of the approximately 37,500 covered entity sites participating in the program are affiliated with hospitals.

Since the establishment of the 340B Program, participation of these covered entities has been contingent on compliance with statutory program requirements; HRSA has issued interpretive guidance and statements of policy to assist covered entities in complying. For example, covered entities must maintain compliance with the statutory definitions pertaining to eligibility to continue participating in the program.[4] Covered entities are also prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the covered entities.[5] Finally, covered entities cannot subject manufacturers to duplicate discounts in which drugs prescribed to Medicaid beneficiaries

[2]The Public Health Service Act does not explicitly state the purpose of the 340B program; thus, HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became the statute. See H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act). See also Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act).

[3]See 42 U.S.C. § 256b(a)(4)(L)(i) (incorporated by reference into 42 U.S.C. §§ 256b(a)(4)(M)-(O)).

[4]See 42 U.S.C. § 256b(a)(4). For an example of relevant guidance, see *Statutory Prohibition on Group Purchasing Organization Participation* (Feb. 7, 2013).

[5]42 U.S.C. § 256b(a)(5)(B). For an example of relevant guidance, see Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

For our prior work on this topic, see GAO, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement,* GAO-20-212 (Washington, D.C.: Jan. 21, 2020).

are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.[6]

To oversee covered entities' continued compliance with these requirements, HRSA implemented in fiscal year 2012 a systematic approach for auditing covered entities. HRSA issues findings for noncompliance with 340B Program requirements based on information gathered through its audit process. Covered entities must address findings to avoid termination from the program. As of September 2020, HRSA finalized over 1,240 audits conducted from fiscal years 2012 through 2019, and almost 900 of them resulted in at least one finding.

In prior reports, we raised concerns about the oversight of the 340B Program and made recommendations to strengthen HRSA's audit process and guidance to covered entities regarding compliance with 340B Program requirements. (Appendix I provides information on the status of these recommendations.) You asked us to review HRSA's efforts to oversee covered entity compliance with 340B Program requirements. This report describes (1) the audit findings HRSA issued to address covered entity noncompliance with 340B Program requirements, and (2) other efforts HRSA has undertaken to help ensure that covered entities comply with 340B Program requirements.

To describe the audit findings HRSA issued to address covered entity noncompliance with 340B Program requirements, we reviewed relevant federal laws and regulations, as well as HRSA's policies, procedures, and guidance related to 340B Program audits. We also reviewed HRSA-provided information on the number and type of audit findings finalized from fiscal years 2012 through 2019.[7] At the time of our review in September 2020, HRSA had finalized 199 of 200 fiscal year 2019 audits. Additionally, we interviewed HRSA officials about the audit process and findings issued since fiscal year 2012 and reviewed related

[6]42 U.S.C. § 256b(a)(5)(A). The Medicaid Drug Rebate Program, established under the Omnibus Budget Reconciliation Act of 1990, requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8). For an example of relevant guidance, see *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

[7]We did not include audit findings from fiscal year 2020 because the vast majority of audits conducted in that year were not finalized at the time of our review. For updated information about audit findings issued by HRSA, see Health Resources and Services Administration, *Program Integrity*, accessed September 24, 2020, www.hrsa.gov/opa/program-integrity/index.html.

documentation. Finally we spoke with the contractor that has conducted audits on HRSA's behalf since fiscal year 2017.[8]

To describe other efforts HRSA has undertaken to help ensure that covered entities comply with 340B Program requirements, we reviewed relevant HRSA policies and procedures related to 340B Program oversight. We also reviewed HRSA-provided information on the number of covered entities that were found through efforts other than audits to be noncompliant from fiscal year 2012 through June 2020. We interviewed officials from HRSA, the 340B Prime Vendor, trade organizations that represent covered entities, and other stakeholders that provide covered entities with 340B compliance assistance such as organizations that conduct independent audits of covered entities' 340B Programs.[9]

We conducted this performance audit from January 2020 to December 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B Program requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities. Entities eligible to participate in the program must submit an application to and be approved by HRSA. Once registered for the program, covered entities must maintain compliance with program requirements related to eligibility, diversion, and duplicate discounts. As of September 2020, there were nearly 12,700 covered entities participating in the program.

Entities Eligible for the 340B Program

Entities eligible to participate in the 340B Program include federal grantees that receive one of 10 types of federal grants, as specified in statute.[10] These include federally qualified health centers (which provide

[8]Beginning in fiscal year 2017, HRSA has contracted with The Bizzell Group to perform 340B Program audits.

[9]The 340B Prime Vendor's role includes supporting the distribution of covered outpatient drugs through the 340B Program and serving as a resource to covered entities and other 340B stakeholders. Apexus, a pharmacy solutions provider, began serving as the 340B Prime Vendor in 2004.

[10]See 42 U.S.C. §§ 256b(a)(4)(A)-(K). All such grant programs are administered by agencies within HHS.

comprehensive community-based primary and preventive care services to medically underserved populations), as well as family planning clinics and Ryan White HIV/AIDS program grantees (see fig. 1).[11] Other entities eligible to participate include six types of hospitals that generally perform a government function to provide care to low-income, medically underserved individuals. These types of hospitals include critical access hospitals (small, rural hospitals with no more than 25 inpatient beds) and disproportionate share hospitals (general acute care hospitals that serve a disproportionate number of low-income patients).[12] In addition, eligible hospitals fall under one of three classifications: (1) hospitals owned or operated by a unit of state or local government; (2) nonprofit corporations that have been formally granted state or local governmental powers; or (3) private, nonprofit hospitals (referred to as nongovernmental hospitals) that have contracts with state or local governments to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare.[13] Proprietary, for-profit hospitals are not eligible to participate in the program.

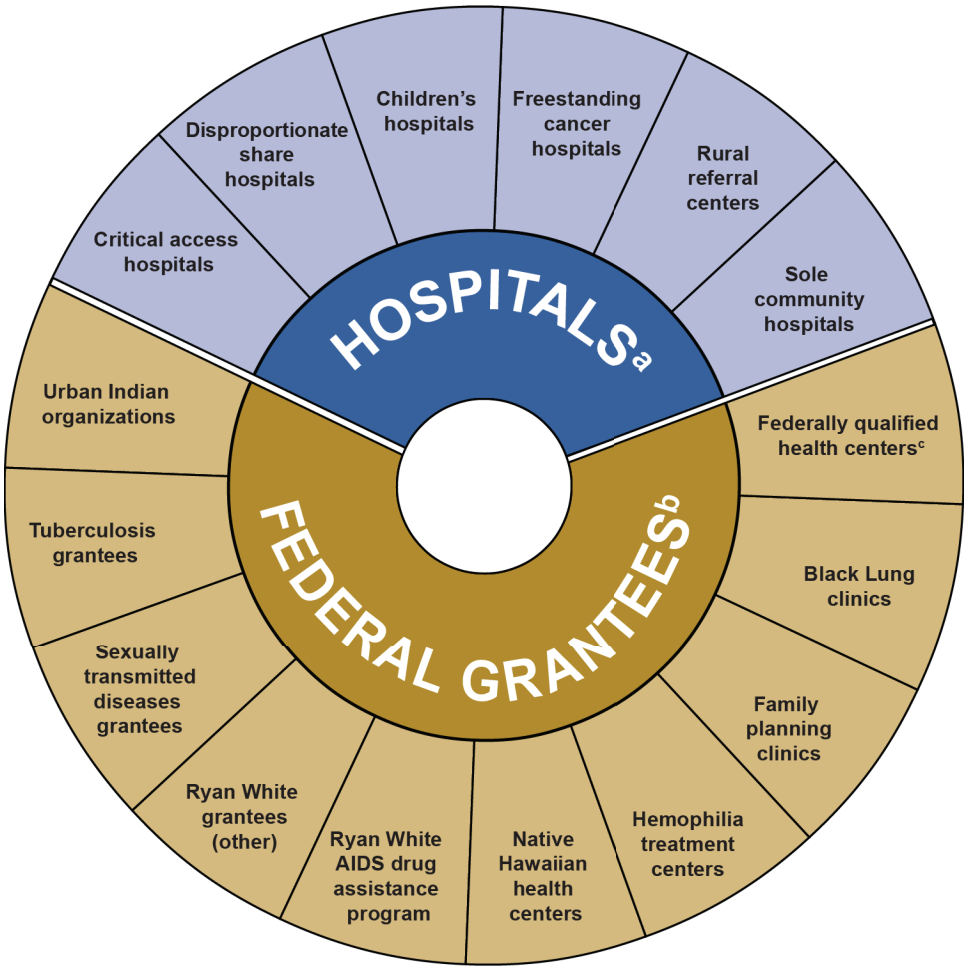
[11]Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the federally qualified health center program, but do not receive federal grants are referred to as federally qualified health center look-alikes and a relatively small number of them participate in the 340B program.

[12]See 42 U.S.C. §§ 256b(a)(4)(L)-(O).

[13]See 42 U.S.C. § 256b(a)(4)(L)(i) (incorporated by reference into 42 U.S.C. §§ 256b(a)(4)(M)-(O)). Medicare is the federal program that provides coverage of health care services for individuals age 65 and older, certain individuals with disabilities, and individuals with end-stage renal disease.

For our prior work on this topic, see GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements,* GAO-20-108 (Washington, D.C.: Dec. 11, 2019).

Figure 1: Types of Entities Eligible to Participate in the 340B Program



Source: GAO analysis of section 340B of the Public Health Service Act. | GAO-21-107

[a]Eligible hospitals are (1) owned or operated by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare. Medicaid is the joint federal-state program that finances health care for certain low-income and medically needy populations. Medicare is the federal health care program for the elderly, disabled, and individuals with end-stage renal disease. With the exception of critical access hospitals, 340B hospitals are required to meet specified disproportionate share adjustment percentages by treating a disproportionate number of low-income Medicare and Medicaid patients.

[b]Eligible grantees are typically eligible for the program because they receive some type of federal support, such as a federal grant.

[c]Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the federally qualified health center program, but do not receive federal grants, are referred to as federally qualified health center look-alikes, and a relatively small number of them participate in the 340B Program.

Some entities, typically federally qualified health centers and hospitals, have a main site and one or more associated sites, which can include satellite clinics, off-site outpatient facilities, hospital departments, and other facilities. According to HRSA officials, to participate in the 340B Program and be considered part of the covered entity, the associated sites must also be registered and maintain compliance with program requirements.

340B Program Registration

To register for the 340B Program as covered entities, eligible entities must first submit an application through an online database, the 340B Office of Pharmacy Affairs Information System (340B OPAIS). Entities must provide specific information about themselves, their associated sites, and their affiliated pharmacies. Entities may also be asked to provide other supporting documentation when completing their registration. For example, federal grantees must provide information about the grant that makes them eligible for program participation.

Once approved by HRSA and registered for the program, covered entities can begin purchasing drugs from manufacturers at 340B discounted prices. Covered entities may provide 340B drugs to patients through one or more dispensing methods. Specifically, covered entities may dispense these drugs through pharmacies—either through in-house pharmacies they own; through the use of contract pharmacy arrangements, in which they contract with outside retail pharmacies (contract pharmacies) and pay them to dispense drugs on their behalf; or both. A covered entity may register an unlimited number of contract pharmacy arrangements with HRSA.[14]

340B Program Requirements

Covered entities must maintain compliance with 340B Program statutory requirements in three areas to continue participating in the program. HRSA historically has issued interpretive guidance and statements of policy (such as the definition of a patient eligible to receive 340B Program drugs, which is not defined in statute) to assist covered entity compliance.

Eligibility of covered entities. Covered entities must ensure that they have contracts in place for all contract pharmacy locations and maintain

[14]See Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).

For our prior work on this topic, see GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* GAO-18-480 (Washington, D.C.: June 21, 2018).

auditable records. Covered entities must ensure that contact and eligibility-related information for themselves, their associated sites, and their contract pharmacies in 340B OPAIS is accurate and kept up to date. Generally, hospitals must meet specified disproportionate share hospital adjustment percentages by treating a disproportionate number of low-income Medicare and Medicaid patients.[15] Certain types of hospitals that participate in the 340B Program are also prohibited from procuring outpatient drugs through a group purchasing organization.[16]

Diversion of 340B Program drugs to ineligible patients. Covered entities cannot divert any drugs purchased at the 340B price to an individual who is not eligible to receive them. The 340B statute does not define an eligible patient of a covered entity. In the absence of a statutory definition, HRSA guidance states that diversion occurs when 340B drugs are given to individuals who are not "patients" of the covered entity. It generally defines such patients as individuals whose health care records are not maintained by the covered entity, for whom the covered entity does not maintain responsibility for care, or who are receiving services that are not consistent with the type of services for which the covered entity qualified for 340B eligibility.[17] In order to comply with this requirement, covered entities must, among other actions, have adequate controls in place to ensure that 340B drugs are only distributed to eligible patients with outpatient status. These controls include ensuring that any

[15]A hospital's disproportionate share hospital adjustment percentage is generally based on its disproportionate share hospital patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicaid and Medicare patients. To be eligible for the 340B program, disproportionate share hospitals, free-standing cancer centers, and children's hospitals must maintain a disproportionate share hospital adjustment percentage of greater than 11.75 percent. Sole community hospitals and rural referral centers must maintain a disproportionate share hospital adjustment percentage greater than or equal to 8 percent. Critical access hospitals are eligible without a disproportionate share hospital adjustment percentage. See 42 U.S.C. § 256b(a)(4)(L)(ii) (incorporated by reference into 42 U.S.C. §§ 256b(a)(4)(M)), 42 U.S.C. § 256b(a)(4)(O).

[16]Hospitals buy drugs at prices negotiated directly with manufacturers or at prices negotiated by buying intermediaries, known as group purchasing organizations, which pool the purchasing power of multiple providers to bargain for lower prices from manufacturers. Disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals participating in the 340B Program may not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. See 42 U.S.C. §§ 256b(a)(4)(L)(iii) (incorporated by reference into 42 U.S.C. § 256b(a)(4)(M)).

[17]See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

software used by the covered entity to determine the eligibility of patients is effective and that oversight of the entity's 340B drug inventory guarantees that drugs are properly distributed and replenished.

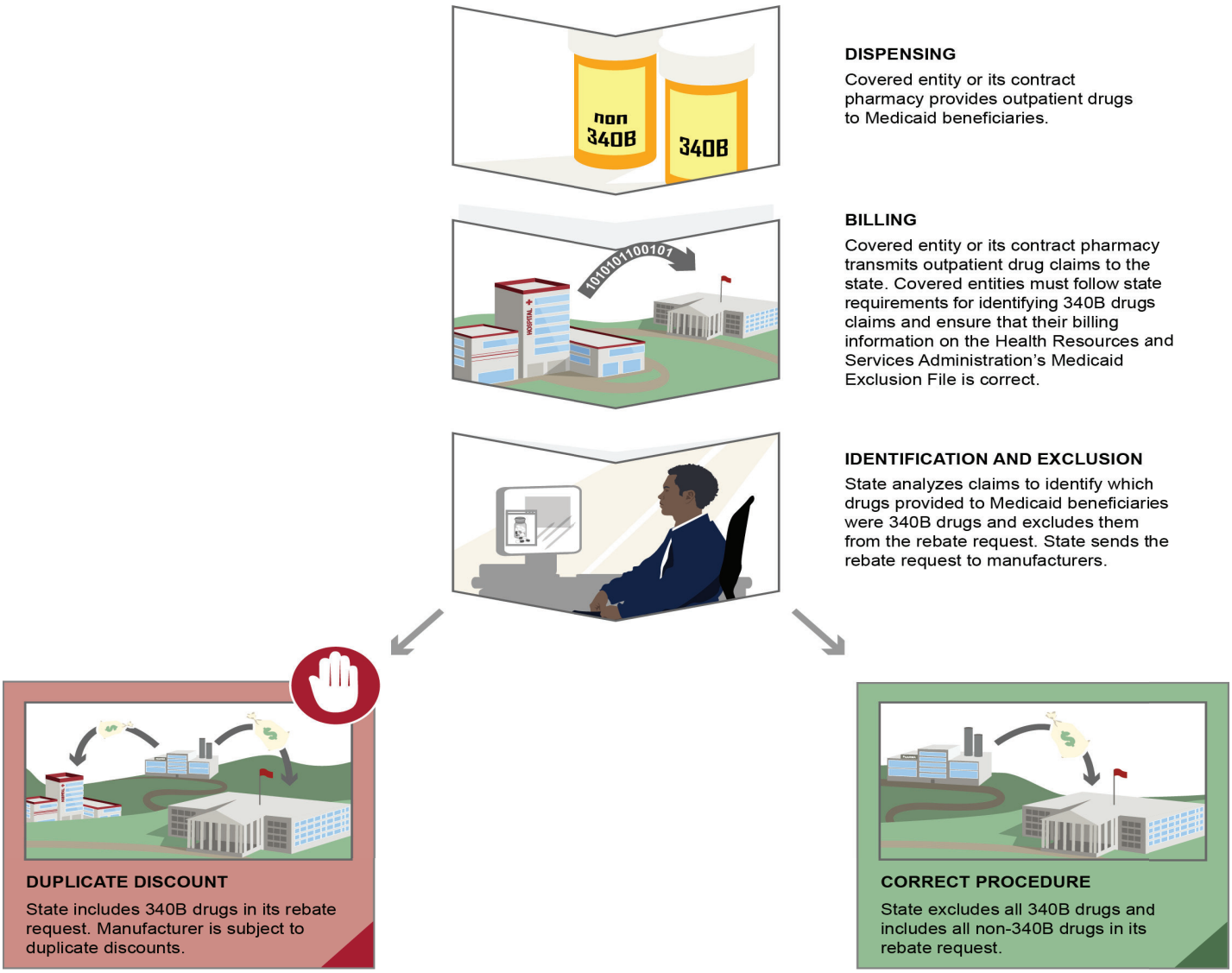
Duplicate discounts. Covered entities cannot subject drug manufacturers to duplicate discounts, which may occur when drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. States need to know whether covered entities provided 340B drugs to Medicaid fee-for-service and managed care beneficiaries in order to exclude those drugs from the rebate requests they submit to manufacturers.[18] There are several different procedures used to identify and exclude 340B drugs from Medicaid rebate requests. For example, covered entities and their contract pharmacies may be required by states to use codes on drug claims (claim identifiers) to indicate drugs that were purchased at the 340B discounted price. Covered entities that purchase and dispense 340B drugs for Medicaid fee-for-service patients are required by HRSA to ensure that their billing information is correctly listed on HRSA's Medicaid Exclusion File, which is used by certain states to determine which covered entities' claims should be excluded from rebate requests to manufacturers.[19] If a state is not aware that a covered entity provided 340B drugs to Medicaid fee-for-service beneficiaries, it would not know to exclude those drugs claims from its rebate requests, which could lead to duplicate discounts (see fig. 2).

[18]States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, states reimburse providers directly for each service delivered. Under a capitated managed care model, states typically contract with managed care organizations to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pay each organization a set amount per beneficiary per month to provide or arrange those services.

[19]In 1993, HRSA established the Medicaid Exclusion File by issuing guidance for the prevention of duplicate discounts in Medicaid fee-for-service, specifying that HHS provide covered entity Medicaid provider numbers to the state Medicaid agencies on a regular basis. See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (Jun. 23, 1993).

When the Medicaid Exclusion File was created, Medicaid drug rebates were provided only under fee-for-service. According to HRSA, the Medicaid Exclusion File is not to be used for Medicaid managed care. HRSA has not created a mechanism for covered entities to use to identify 340B drugs provided to Medicaid managed care beneficiaries, but encourages covered entities to work with states to develop strategies to prevent duplicate discounts for drugs reimbursed through managed care. See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

Figure 2: Example of How Covered Entities Prevent Duplicate Discounts for 340B Program Drugs in Medicaid Fee-for-Service



Source: GAO. | GAO-21-107

Note: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, states reimburse providers directly for each service delivered. Under a capitated managed care model, states typically contract with managed care organizations to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pay each organization a set amount per beneficiary per month to provide or arrange those services. This graphic does not reflect the role of managed care organizations in preventing duplicate discounts in Medicaid managed care.

When the Medicaid Exclusion File was created in 1993, Medicaid drug rebates were provided only under fee-for-service. According to HRSA, the Medicaid Exclusion File is not to be used for Medicaid

managed care. HRSA has not created a mechanism for covered entities to use to identify 340B drugs provided to Medicaid managed care beneficiaries. See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

HRSA is responsible for overseeing the 340B Program, including covered entities' compliance with the statutory requirements applicable to eligibility, diversion, and duplicate discounts. A federal district court ruled in 2014 that HRSA had limited rulemaking authority to carry out the 340B Program, and agency rulemaking authority was limited to specified purposes, such as the establishment of an administrative process to resolve claims by covered entities and manufacturers.[20] That court has also acknowledged the agency's authority to interpret the 340B statute and to issue guidance documents interpreting statutory provisions.[21] According to HRSA, such authority does not provide it with appropriate enforcement capability. Beginning with fiscal year 2017, HRSA has requested the provision of general authority to issue regulations in each of its annual budget requests. According to HRSA, this authority would allow it to set clear, enforceable standards of participation on all aspects of the 340B Program and help ensure compliance with 340B Program requirements.

HRSA's Audit Process

HRSA has increased the number of covered entities audited since fiscal year 2012, and in fiscal year 2015 began its current practice of auditing 200 entities per year.[22] Beginning in fiscal year 2017, HRSA contracted with an outside organization to perform audits on its behalf. These audits include reviews of each covered entity's policies and procedures, an assessment of overall compliance with respect to 340B Program

[20]Other specific agency rulemaking authority includes defining standards of methodology to calculate 340B ceiling prices for covered outpatient drugs and imposition of civil monetary penalties for manufacturers that knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug. *See Pharm. Research & Mfrs. of Am. v. United States HHS*, 43 F. Supp. 3d 28, 39-45 (D.D.C. May 23, 2014).

[21]*See Pharm. Research & Mfrs. of Am. v. United States HHS*, No. 14-1685, p. 12 (D. D.C. Oct., 14, 2015).

[22]HRSA conducted 51 audits in fiscal year 2012, 94 audits in fiscal year 2013, and 99 audits in fiscal year 2014.

HRSA's audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year) and those that are targeted based on information from stakeholders such as drug manufacturers about potential noncompliance (10 percent of the audits conducted). The criteria for risk-based audits include a covered entity's volume of 340B drug purchases, number of contract pharmacies, time in the 340B Program, and complexity of its program.

requirements, and reviews of a sample of prescriptions filled during a 6-month period to identify any instances of noncompliance (such as diverting 340B drugs to ineligible patients or failing to prevent duplicate discounts by not applying state-required claim identifiers).

Once the audit is completed, HRSA's contractor provides the agency with the results. HRSA officials then determine whether the covered entity should receive any findings of noncompliance with program requirements in the areas of eligibility, diversion, and duplicate discounts, which must be addressed by the entity using a corrective action plan.[23] Since the agency began conducting audits in fiscal year 2012, HRSA officials have also determined whether to recommend areas for improvement based on a failure to follow best practices that may reflect applicable guidance but not statutory requirements. These do not require a corrective action plan by the entity, but they encourage the entity to follow best practices related to compliance with 340B Program requirements.

After HRSA issues a final letter to the covered entity indicating the agency's decision to issue any findings of noncompliance and areas for improvement, covered entities may submit a disagreement letter to dispute the agency's decision. Based on HRSA's review of the disagreement letter, which may be accompanied by evidence provided by the entity, HRSA issues a second final letter that either reverses or upholds the findings being disputed and the audit is considered final.[24] Findings of noncompliance from all finalized audits are permanently made public on HRSA's website; areas for improvement are not made public. To avoid termination from the 340B Program, covered entities must address and correct all audit findings through corrective action plans. HRSA closes out the audit once the entity attests that the corrective action plan has been fully implemented and any necessary repayments have been made to affected manufacturers.

[23]The audits review covered entities' policies and practices to see if the potential for duplicate discounts exists. However, in order to determine whether duplicate discounts have actually occurred, a covered entity must then check with its state Medicaid agency to see if it has received rebates for the same drugs for which the entity received a discounted price.

[24]From fiscal year 2012 through February 2020, covered entities disagreed with 672 findings, and based on their disagreements, HRSA reversed 192 of these (29 percent).

As of September 2020, HRSA Had Issued Over 1,500 Findings of Noncompliance in Finalized Audits of Covered Entities since Fiscal Year 2012

HRSA reported that the agency issued a total of 1,536 findings to address covered entity noncompliance found in the 1,242 finalized audits conducted from fiscal years 2012 through 2019 as of September 2020.[25] These findings, which address violations of statutory requirements and a failure to follow guidance that HRSA developed to clarify these requirements, were in the areas of eligibility (561), diversion (546), and duplicate discounts (429) (see table 1).

[25]HRSA conducted one audit in fiscal year 2019 that we did not include because it had not been finalized at the time of our review in September 2020.

Table 1: Eligibility, Diversion, and Duplicate Discount Findings of Noncompliance Issued by the Health Resources and Services Administration (HRSA) for 340B Program Audits Conducted from Fiscal Years 2012–2019, as of September 2020

Audit findings in three areas of 340B Program requirements	Number issued
Eligibility of covered entities	
Incorrect record in HRSA's 340B Office of Pharmacy Affairs Information System	457
Obtaining covered outpatient drugs through a group purchasing organization[a]	54
Failure to oversee 340B Program compliance at contract pharmacies	40
Other eligibility-related violations (e.g., maintaining auditable records)	10
Total eligibility-related findings	**561**
Diversion of 340B Program drugs to ineligible patients	
Dispensing 340B drugs to ineligible individuals (e.g., individuals prescribed drugs at an ineligible site, individuals who did not meet eligibility definition set in HRSA guidance)[b]	463
Failure to ensure proper inventory management of 340B drugs	76
Systematic errors in the software used to determine 340B eligibility[c]	7
Total diversion-related findings	**546**
Duplicate discounts	
Inaccurate information on the Medicaid Exclusion File[d]	264
Billing contrary to information on the Medicaid Exclusion File[d]	108
Failure to follow state Medicaid requirements (e.g., omitting codes on drug claims known as claim identifiers to indicate drugs purchased at the 340B discounted price)	34
Duplicate discount-related errors at contract pharmacies	23
Total duplicate discount-related findings	**429**
Total	**1,536**

Source: GAO analysis of information received from HRSA. | GAO-21-107

Note: The table shows findings for the 1,242 audits that HRSA has conducted and finalized since it began conducting audits in fiscal year 2012, as of September 2020. This includes findings for the 199 audits finalized for fiscal year 2019 (out of 200 conducted). These findings address both violations of statutory requirements and a failure to follow guidance that HRSA developed to clarify these requirements. Covered entities must maintain compliance with 340B Program requirements in the three areas shown in this table to continue participating in the program. See 42 U.S.C. §§ 256b(a)(4), (5)(A),(B).

[a]Hospitals buy drugs at prices negotiated directly with manufacturers or at prices negotiated by buying intermediaries, known as group purchasing organizations. Disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals participating in the 340B Program may not obtain covered outpatient drugs through a group purchasing organization. See 42 U.S.C. §§ 256b(a)(4)(L)(iii)(incorporated by reference into 42 U.S.C. § 256b(a)(4))(M)).

[b]According to HRSA guidance, in general, an eligible patient is an individual who (1) has health records that are maintained by the covered entity, (2) 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 such that responsibility for the care remains with the covered entity, and (3) receives services consistent with the range of services for which grant funding or federally qualified health center look-alike status has been provided. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

[c]This finding could be issued if HRSA found that the covered entity failed to ensure that the patient eligibility verification systems used by the entity or its contract pharmacies accurately screened for

patient eligibility by, for example, not affording an accurate evaluation of the prescribing provider when determining 340B eligibility.

[d]In 1993, HRSA issued final guidance for the prevention of duplicate discounts in Medicaid fee-for-service, establishing that the Department of Health and Human Services will provide covered entity Medicaid provider numbers to the state Medicaid agencies on a regular basis through a mechanism known as the Medicaid Exclusion File. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (Jun. 23, 1993). According to HRSA, the Medicaid Exclusion File does not apply to the prevention of duplicate discounts under Medicaid managed care. See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

HRSA officials told us that, beginning in fall 2019, the agency started issuing findings, which require covered entities to take corrective action, only when audit information presents a clear and direct violation of the requirements outlined in the 340B Program statute. HRSA officials explained that 340B Program guidance, which is used to interpret provisions of the 340B statute for the purposes of promoting program compliance among covered entities, does not provide the agency with appropriate enforcement capability. Following a covered entity's 2019 legal challenge to HRSA's authority to enforce audit findings, HRSA evaluated its ability to require and enforce corrective action, and it concluded that in the absence of binding and enforceable regulations, the agency would no longer issue findings based solely on noncompliance with guidance.[26] For example, HRSA officials reported that there were instances among fiscal year 2019 audits in which the agency:

- did not issue diversion findings for dispensing 340B drugs to ineligible individuals as defined by HRSA guidance because the 340B statute does not provide criteria for determining patient eligibility;[27] and
- did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other

[26]See Genesis Health Care v. Azar, No. 19-cv-01531 (D.S.C. Dec. 18, 2019) (granting defendant's motion to dismiss). Genesis contended that, absent judicial review, HRSA would continue to incorporate its allegedly unlawful and narrower definition of "patient" into its audit standards, so Genesis, as well as other covered entities, would continue to be subject to the same standards. However, the court indicated that the proper time to challenge this allegedly narrower definition of "patient" is when the definition is used in an audit that marks the completion of the agency's decision-making process and affects the legal rights of the relevant actors and has appreciable legal consequences.

[27]For the statutory requirements related to diversion of 340B drugs, see, for example, 42 U.S.C. § 256b(a)(5)(B). For relevant guidance, see 59 Fed. Reg. 47884 (Sep.19, 1994) and 61 Fed. Reg. 55156 (Oct. 24, 1996).

measures as set forth in guidance because the 340B statute does not address contract pharmacy use.[28]

HRSA officials also said that there were instances among fiscal year 2019 audits in which the agency also did not issue duplicate discount findings for a failure to follow a state's Medicaid requirements, including billing the state Medicaid office for a 340B drug without using a claim identifier to indicate a drug purchased at the 340B discounted price. HRSA officials said that these findings were not issued because the agency does not have statutory authority to enforce state Medicaid requirements.[29]

While HRSA issued 164 findings to covered entities for the 199 fiscal year 2019 audits that were finalized as of September 2020, there were 36 instances in which the information gathered in these audits did not result in a finding, but would have resulted in one in the past, according to HRSA officials. HRSA officials noted that, in certain instances in which an audit reveals that a covered entity failed to follow program guidance or best practices, the agency may issue an area for improvement, which does not require corrective action. However, HRSA officials noted that the full extent to which audits will be affected by the agency's increased focus on clear and direct violations of statute is not yet certain.

HRSA Has Undertaken Multiple Efforts to Prevent and Correct Noncompliance

In addition to the audits, HRSA uses several educational resources to promote covered entities' compliance with 340B Program requirements. HRSA also implemented program integrity checks on hospitals and contract pharmacies, an annual recertification process, and a self-disclosure process to identify noncompliance.

Education on 340B Program requirements. HRSA and the 340B Prime Vendor, Apexus, provide covered entities with educational resources to promote compliance with 340B Program requirements. HRSA's website features 340B Program guidance, peer-to-peer webinars on complying with program requirements, and a frequently asked questions section that addresses topics such as 340B OPAIS database management and proper Medicaid Exclusion File use. Since fiscal year 2004, HRSA has entered into an agreement with Apexus to provide covered entities with

[28]For the statutory requirements related to 340B Program eligibility, see 42 U.S.C. § 256b(a)(4). For relevant guidance, see, for example, 75 Fed. Reg. 10272 (Mar. 5, 2010).

[29]For the statutory requirements related to duplicate discounts, see 42 U.S.C. § 256b(a)(5)(A). HRSA officials noted that they share information related to a covered entity's failure to follow a state's Medicaid requirements with the Centers for Medicare & Medicaid Services, which oversees the Medicaid Drug Rebate Program.

educational opportunities. Specifically, Apexus maintains a website with educational resources and answers to frequently asked questions about program compliance. It also administers courses on 340B Program compliance, which trained nearly 11,000 participants in fiscal year 2019, according to Apexus officials. Additionally, Apexus officials said their national call center, which received 27,800 inquiries in fiscal year 2019, serves as an information resource for covered entities. Officials from Apexus and HRSA told us that they plan to implement a new, proactive approach for working with covered entities that will include emailing compliance-boosting tips beginning in December 2020.

Program integrity checks of 340B hospitals to assess eligibility. HRSA conducts program integrity checks of specific requirements of hospitals, both during registration and on a quarterly basis, to assess their eligibility to participate in the 340B Program. Specifically:

- **Hospital Medicare cost report checks during registration.** In calendar year 2017, HRSA began conducting Medicare cost report checks for a random sample of 10 percent of hospitals registering for the 340B Program.[30] The agency uses the documentation to verify that the data provided to HRSA during registration are consistent with the information in the latest Medicare cost report. Specifically, HRSA officials said that they use this information to confirm that the hospital can demonstrate that it recorded outpatient charges as the 340B Program only applies to outpatient drugs. According to HRSA, from calendar years 2017 through 2019, 750 hospitals attempted to register for the 340B Program, and three of the 75 hospitals that HRSA randomly selected for its review had their registration denied because the information in their Medicare cost reports indicated that they were ineligible to participate in the program.
- **Nongovernmental hospital contract reviews during registration.** In calendar year 2017, HRSA began conducting contract integrity checks for a random sample of 20 percent of nongovernmental hospitals during registration. To participate in the 340B Program, these private, nonprofit hospitals must have contracts with state or local governments to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare. For the selected hospitals, HRSA requests a copy of the contract, which the

[30]Hospitals—and other institutional providers—that render services to Medicare beneficiaries are required to submit Medicare cost reports to the Centers for Medicare & Medicaid Services annually. Among other things, these reports contain information on facility characteristics, utilization data, and financial statement data.

agency reviews to verify that it is signed by both hospital and government officials, is in effect, and does not expire before program participation would begin. According to HRSA, from calendar years 2017 through 2019, 610 nongovernmental hospitals attempted to register for the 340B Program, and three of the 122 hospitals HRSA selected for review had their registration denied because they did not have a contract in place prior to attempting to register for the 340B Program.

HRSA officials told us that they recently made changes to this review. Specifically, in January 2020, HRSA began to include all nongovernmental hospitals registering for the program, as opposed to reviewing contracts from a sample of hospitals. Additionally, in July 2020, HRSA officials implemented an additional analysis of the contracts to determine whether they provided for the provision of health care services to low-income individuals not eligible for Medicare or Medicaid as required for 340B Program eligibility.

- **Quarterly disproportionate share hospital adjustment percentage checks.** In fiscal year 2015, HRSA began conducting quarterly checks of the Medicare cost reports of all hospitals for which 340B Program eligibility is dependent on maintaining a disproportionate share hospital adjustment percentage that does not fall below the statutory thresholds defining program eligibility.[31] From fiscal years 2015 through 2019, HRSA officials told us that they conducted this check more than 25,000 times and identified 86 hospitals that appeared not to have met the requirement. Nearly one-third (27) of those 86 hospitals were not able to provide documentation supporting their eligibility, thus were terminated from the 340B Program.
- **Quarterly hospital classification reviews.** In fiscal year 2019, HRSA began conducting quarterly checks of Medicare cost report data for all hospitals participating in the program to identify those that list themselves as proprietary for further review, as this designation could identify for-profit hospitals that are not eligible for the 340B program. Hospitals that listed themselves as proprietary on their most recent Medicare cost report may be required to submit documentation confirming their nonprofit status. HRSA conducted this check in fiscal year 2019, and of the 2,521 hospitals reviewed, 14 were identified as

[31]This integrity check applies to enrolled disproportionate share hospitals, free standing cancer centers, children's hospitals, sole community hospitals, and rural referral centers based on their particular disproportionate share hospital adjustment percentage. Critical access hospitals are eligible without a disproportionate share hospital adjustment percentage.

ineligible for program participation based on being listed as proprietary. According to HRSA, all 14 hospitals subsequently provided official documentation supporting their eligibility, thus were not terminated from the program.

Quarterly program integrity checks of contract pharmacy arrangements. Beginning in fiscal year 2017, HRSA began conducting quarterly checks of a randomly selected 5 percent of new contract pharmacy arrangements, which covered entities are required to register with HRSA. HRSA verifies that each contract is in effect, signed by officials from the covered entity and the pharmacy, lists all entity sites and pharmacy locations, and corresponds with the information in 340B OPAIS. If the covered entity fails to produce a contract, HRSA will terminate the contract pharmacy from the 340B Program and review the entity's other contract pharmacy arrangements. According to HRSA, from fiscal years 2017 through 2019, less than 2 percent of the 589 contract pharmacy arrangements that HRSA reviewed were terminated.

Annual recertification of eligibility. Covered entities are statutorily required to complete an annual recertification process to continue participating in the 340B Program.[32] Prior to the beginning of the recertification period, HRSA alerts covered entity officials of the upcoming requirement and disseminates daily notifications until the covered entity completes the process. To recertify, covered entities must ensure that their basic information—including contact information for entity officials and contract pharmacy addresses—is updated and accurate in 340B OPAIS and self-attest to being in compliance with all 340B Program requirements. HRSA officials told us that the agency may request supporting documentation if a covered entity makes changes to statutorily required data or other key elements of its records during recertification. Failure to recertify will result in a covered entity being terminated from the 340B Program. From fiscal years 2012 through 2019, nearly 2,000 covered entities have been terminated through the recertification process due to loss of a qualifying grant, a disproportionate share hospital adjustment percentage falling below the statutory threshold, or failing to recertify, among other reasons.

Self-disclosure to identify noncompliance. Following the implementation of HRSA's audit process in fiscal year 2012, officials said that the agency began a self-disclosure initiative to allow covered entities

[32]42 U.S.C. § 256b(a)(7)(E)).

to report and correct self-identified instances of noncompliance with 340B Program requirements. As of June 2020, covered entities made 521 self-disclosures to HRSA, with nearly half (232) of these being related to diversion. For example, in fiscal year 2019, one disproportionate share hospital reported that it mistakenly purchased outpatient covered drugs through a group purchasing organization, violating the group purchasing organization prohibition. In fiscal year 2020, another disproportionate share hospital reported its ineligibility for the 340B Program based on its disproportionate share hospital adjustment percentage falling below the statutory threshold.

According to HRSA, covered entities that self-disclose compliance breaches have to prepare and submit corrective action plans, which must include a description of the breach and the entity's plan to remedy the cause of the issue, disclose the breach to manufacturers, and make any necessary repayments. Corrective action plans are expected to be completed within 6 months of approval.

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report, which are reproduced in app. II, and technical comments, both of which we have incorporated as appropriate. In its written comments, HHS responded to our characterization of its implementation efforts in app. I of this report, which includes a table with the status of our previous recommendations related to HRSA oversight of the 340B Program. Specifically, HRSA addressed the implementation of two recommendations made in our 2019 report on nongovernmental hospitals participating in the 340B Program.[33]

First, we previously recommended that HRSA should "provide more specific guidance for 340B Program auditors on how to determine if nongovernmental hospitals' contracts with state and local governments require the provision of health care services to low-income individuals not eligible for Medicaid or Medicare." HHS concurred with this recommendation, and in June 2020, the agency indicated that HRSA had updated its audit guidance to specify that auditors should contact HRSA if any required contract elements, including this provision, are not easily identified.

However, this updated guidance does not describe how auditors are to identify whether contracts actually require these services. Rather, it cautions them not to "dive too [deeply]" to identify such information.

[33]GAO-20-108.

Reliance on the initiative of individual auditors to contact HRSA with questions does not ensure uniform or adequate application of this statutory eligibility requirement. Therefore, we remain concerned that HRSA lacks reasonable assurance that the audits are appropriately identifying nongovernmental hospitals that may be participating in the 340B Program based on contracts that are inconsistent with program requirements or HRSA's guidance. Thus, we consider this recommendation open.

Second, we previously recommended that HRSA should "require nongovernmental hospitals participating in the 340B Program to demonstrate that they have contracts with state or local governments in effect prior to the beginning of their audits' periods of review and should apply consistent and appropriate consequences for hospitals that are unable to do so." As noted in the 2019 report, HRSA updated its draft audit procedures for fiscal year 2020 audits in September 2019 to specify that auditors should look for effective dates that cover the entire audit period.

While this is an important step, HRSA must also demonstrate that it has ceased accepting retroactive contract documentation and applies consistent and appropriate consequences when auditors find that nongovernmental hospitals did not have contracts in effect prior to the beginning of their audit periods. In its written comments, HHS indicated that HRSA had not taken these actions. We continue to believe that allowing hospitals that fail to demonstrate that they meet the statutory requirement of having contracts in place that cover the audit's period of review to continue to participate in the 340B Program without consequences undermines the effectiveness of HRSA's audit process and increases the risk that ineligible hospitals will receive discounts under the program. Thus, we consider this recommendation open.

We are sending copies of this report to the appropriate congressional committees, the Secretary of HHS, the Administrator of HRSA, and other interested parties. In addition, the report will be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at DraperD@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix III.

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Director, Health Care

Appendix I: Prior GAO Recommendations Related to Oversight of the 340B Program

The 340B Program requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities. The Health Resources and Services Administration (HRSA) is the agency within the Department of Health and Human Services (HHS) that is responsible for administering and overseeing the 340B Program. Since 2011, we have reported on HRSA's oversight of the program and made a number of recommendations. See table 2 for our previous recommendations and the status of their implementation.

Table 2: Status of Prior GAO Recommendations Related to the Health Resources and Services Administration's (HRSA) Oversight of the 340B Program, as of July 2020

Recommendations from: *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* (GAO-11-836) Published: Sept. 23, 2011	**Concur (Y/N)**	**Status**
Recommendation 1: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of Health and Human Services (HHS) should instruct the administrator of HRSA to conduct selective audits of 340B covered entities to deter potential diversion.	Y	This recommendation has been implemented.
Recommendation 2: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS should instruct the administrator of HRSA to finalize new, more specific guidance on the definition of a 340B patient.	Y	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
Recommendation 3: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS should instruct the administrator of HRSA to further specify its 340B nondiscrimination guidance for cases in which distribution of drugs is restricted.	Y	This recommendation has been implemented.
Recommendation 4: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS should instruct the administrator of HRSA to issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.	Y	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.

Recommendation 5: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS should instruct the administrator of HRSA to require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices.	Y	This recommendation has been implemented.
Recommendations from: *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (GAO-18-480) Published: June 21, 2018	**Concur (Y/N)**	**Status**
Recommendation 1: The Administrator of HRSA should require covered entities to register contract pharmacies for each site of the entity for which a contract exists.	N	As of July 2020, HRSA did not plan to take any actions to implement this recommendation.
Recommendation 2: The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with the Centers for Medicare & Medicaid Services as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs.[a]	Y	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
Recommendation 3: The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities.[a]	Y	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
Recommendation 4: The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit.	Y	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
Recommendation 5: The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance.	N	As of July 2020, HRSA did not plan to take any actions to implement this recommendation.
Recommendation 6: The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit.	N	As of July 2020, HRSA did not plan to take any actions to implement this recommendation.

Recommendation 7: The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.	Y	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
Recommendations from: *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* (GAO-20-108) Published: Dec. 11, 2019	**Concur (Y/N)**	**Status**
Recommendation 1: The Administrator of HRSA should ensure that the information it uses to verify nonprofit status for all nongovernmental hospitals that participate in the 340B Program is reliable—for example, by requiring and reviewing the submission of official documentation hospitals must already maintain or by ensuring the reliability of the data the agency uses.	Y	In June 2020, HHS reiterated that HRSA believes that the information it uses to determine nonprofit status is reliable, and HRSA is not taking steps to implement this recommendation at this time.
Recommendation 2: The Administrator of HRSA should implement a process to verify that every nongovernmental hospital that participates in the 340B Program has a contract with a state or local government as required by statute.	N	As of June 2020, HRSA did not plan to take any actions to implement this recommendation.
Recommendation 3: The Administrator of HRSA should amend its contract integrity check procedures for the 340B Program to include a review of whether hospitals' contracts with state and local governments require the provision of health care services to low-income individuals not eligible for Medicaid or Medicare as required by statute, and procedures should provide guidance for staff to conduct these reviews.	Y	This recommendation has been implemented.
Recommendation 4: The Administrator of HRSA should provide more specific guidance for 340B Program auditors on how to determine if nongovernmental hospitals' contracts with state and local governments require the provision of health care services to low-income individuals not eligible for Medicaid or Medicare.	Y	In June 2020, HHS indicated that HRSA had updated its audit guidance and procedures to more clearly specify that contracts must contain requirements for the provision of health care services to low-income individuals. However, these documents do not contain any specific guidance on how auditors are to evaluate whether contracts require these services. Without more specific guidance, HRSA lacks reasonable assurance that the audits are appropriately identifying deficiencies in nongovernmental hospitals' contracts with state or local governments.
Recommendation 5: The Administrator of HRSA should revise its 340B Program audit procedures to require auditors to document their assessments of whether nongovernmental hospitals' contracts with state and local governments are appropriately signed, cover the time periods under review, and require hospitals to serve low-income individuals not eligible for Medicaid or Medicare, such as by requiring auditors to separately affirm and record their review of each of these elements.	Y	This recommendation has been implemented.

Recommendation 6: The Administrator of HRSA should require nongovernmental hospitals participating in the 340B Program to demonstrate that they have contracts with state or local governments in effect prior to the beginning of their audits' periods of review and should apply consistent and appropriate consequences for hospitals that are unable to do so.	Y	In June 2020, HHS indicated that HRSA has taken certain steps to address this recommendation. However, HRSA still must show that it has ceased accepting retroactive contract documentation, and it has applied consistent and appropriate consequences when auditors find that nongovernmental hospitals did not have contracts in effect prior to the beginning of their audit periods. Allowing hospitals that are unable to demonstrate that they have contracts in place that cover their audits' periods of review to continue to participate without consequences undermines the effectiveness of HRSA's audit process, and it increases the risk that ineligible hospitals will receive discounts under the program.
Recommendations from: *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (GAO-20-212) Published: Jan. 21, 2020	**Concur (Y/N)**	**Status**
Recommendation 2: The Administrator of HRSA should incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures regarding the use and identification of 340B drugs into its audit process, working with Centers for Medicare & Medicaid Services as needed to obtain states' policies and procedures.	N	As of July 2020, HRSA did not plan to take any actions to implement this recommendation.
Recommendation 3: The Administrator of HRSA should require covered entities to work with affected drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care.[b]	N	As of July 2020, HRSA did not plan to take any actions to implement this recommendation.

Source: GAO analysis of information received from HRSA. | GAO-21-107

[a]This is a priority recommendation, which are those that GAO believes warrant priority attention from heads of key departments or agencies. They are highlighted because, upon implementation, they may significantly improve government operation—for example, by realizing large dollar savings; eliminating mismanagement, fraud, and abuse; or making progress toward addressing a high-risk or duplication issue.

[b]This report included one recommendation (Recommendation 1) to the Centers for Medicare & Medicaid Services and two recommendations to HRSA.

Appendix II: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

November 16, 2020

Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"340B DRUG PRICING PROGRAM: HRSA Uses Multiple Mechanisms to Help Ensure Compliance with Program Requirements"* (Job code 104047/GAO-21-107).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah C. Arbes -S
Digitally signed by Sarah C. Arbes -S
Date: 2020.11.16 14:04:47 -05'00'

Sarah C. Arbes
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, 340B DRUG PRICING PROGRAM: HRSA USES MULTIPLE MECHANISMS TO HELP ENSURE COMPLIANCE WITH PROGRAM REQUIREMENTS (GAO-21-107)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

HHS places the highest priority on the integrity of the 340B Drug Pricing Program (340B Program) and continually works to strengthen oversight of the Program. In this report, the GAO sought to review the Health Resources and Services Administration's (HRSA) efforts to oversee covered entity compliance with 340B Program requirements by examining (1) audit findings that HRSA issued to address covered entity noncompliance with 340B Program requirements and (2) other efforts HRSA uses to help ensure that covered entities comply with 340B Program requirements. The GAO had no recommendations in this report.

HHS appreciates the GAO's work in this area as it informs HHS' program integrity efforts. During the course of the study, HRSA took the opportunity to make improvements to the program and has worked to enhance some of its program integrity efforts.

The GAO report includes specific statements related to HRSA's issuance of audit findings only when information obtained from a covered entity during an audit presents a clear and direct violation of the 340B statute, as guidance does not provide appropriate enforcement capability. On the page titled "GAO Highlights," the GAO characterizes HRSA officials stating that there were instances in FY 2019 when HRSA did not issue audit findings for failure to comply with guidance related to contract pharmacies because the 340B statute does not address contract pharmacies. HRSA would like to clarify the following statement to ensure accuracy:

"…HRSA officials reported that**, *in the absence of a clear statutory violation*,** there were instances among fiscal year 2019 audits in which the Agency did not issue findings for failure to comply with guidance related to contract pharmacies***, in part,*** because the 340B statute does not address contract pharmacy use."

Guidance does not provide HRSA appropriate enforcement capability, and HRSA has requested regulatory authority in the President's Budget each year since fiscal year (FY) 2017. Binding and enforceable regulations for all aspects of the 340B Program would provide HRSA the ability to more clearly define and enforce policy and would significantly strengthen HRSA's oversight of the Program.

In addition, Appendix I of the Draft Report includes a table listing recommendations from previous GAO reports on the 340B Program since 2011. The table also includes the status of each recommendation. For the report titled "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements," HRSA would like to clarify the explanation provided by GAO regarding the implementation efforts for recommendations four and six.

Recommendation four states "…HRSA should provide more specific guidance for 340B Program auditors on how to determine if nongovernmental hospitals' contracts with state and

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, 340B DRUG PRICING PROGRAM: HRSA USES MULTIPLE MECHANISMS TO HELP ENSURE COMPLIANCE WITH PROGRAM REQUIREMENTS (GAO-21-107)

local governments require the provision of health care services to low-income individuals not eligible for Medicaid or Medicare." In Appendix I of the Draft Report, the GAO asserts that HRSA has not provided specific guidance on how auditors are to evaluate whether contracts require these services and that HRSA lacks reasonable assurance that the audits are appropriately identifying deficiencies in nongovernmental hospitals' contracts with state or local governments.

In June 2020, HRSA provided GAO with additional information to indicate that HRSA considered recommendation four to be implemented. Specifically, HRSA provided documentation to the GAO, including updated audit documents that detail that auditors are required to contact HRSA if there are any concerns with the contract or if there are elements that are not easily identified or questionable in nature. Such elements include whether the contract has a statement that the hospital is to provide health care services to low income individuals who are not entitled to benefits under Medicare or eligible for assistance under Medicaid.

As part of its response to recommendation four in June 2020, HRSA also stated that the 340B statute does not specify what constitutes the type or amount of service that must be provided to low-income individuals who are not eligible for Medicare and Medicaid. Without additional rulemaking authority from Congress, HRSA cannot issue legally binding regulations that would interpret existing statutory provisions. Therefore, absent this additional rulemaking authority, HRSA believes that it has implemented this provision by updating its guidance documents. HRSA continues to request that the GAO close the recommendation.

Similarly, recommendation six in the same report states "…HRSA should require nongovernmental hospitals participating in the 340B Program to demonstrate that they have contracts with state or local governments in effect prior to the beginning of their audits' periods of review and should apply consistent and appropriate consequences for hospitals that are unable to do so." In the June 2020 response, HRSA stated that as part of the proposed process of collecting contracts at registration, HRSA implemented this recommendation prospectively for newly registering hospitals. Through this process, HRSA reviews the contracts for hospitals to ensure that they include the name of the hospital, the name of the government agency, the dates to ensure that the contract is active, and signatures from both the covered entity and the government official. While this collection of contracts only applies to newly registering hospitals, HRSA continues to collect contract documentation for hospitals that change their eligibility classification during the annual recertification process. Additionally, HRSA also updated its audit procedures to include specific elements that the HRSA auditor must confirm, including that there is a contract in place and that it includes effective dates that cover the entire audit period.

HRSA's ability to impose consistent and appropriate consequences for hospitals that are unable to provide a contract that covers a certain period of time depends on the facts and circumstances of a particular case. While HRSA has authority to require that a contract exists, the 340B statute does not specify the details related to what those contracts must entail. As previously mentioned in this document, HRSA cannot issue legally binding regulations interpreting the existing

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, 340B DRUG PRICING PROGRAM: HRSA USES MULTIPLE MECHANISMS TO HELP ENSURE COMPLIANCE WITH PROGRAM REQUIREMENTS (GAO-21-107)

statutory provisions without additional rulemaking authority from Congress. HRSA has requested regulatory authority in every President's Budget since FY 2017 and has again requested this in the FY 2021 President's Budget. Therefore, enforcement related to this recommendation is challenging and will require evaluation on a case-by-case basis.

Based on the updated audit procedures as detailed and the implementation of this recommendation for new hospitals, HRSA believes that this recommendation is implemented. HRSA continues to request that the GAO close this recommendation.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A Draper (202) 512-7114 or DraperD@gao.gov

Acknowledgments

In addition to the contact named above, Hernán Bozzolo (Assistant Director), Amanda Cherrin (Analyst-in-Charge), and Michael Alleyne made key contributions to this report. Also contributing were George Bogart, Vikki Porter, and Caitlin Scoville.

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Exhibit M

William B. Schultz
PARTNER
Zuckerman Spaeder LLP
wschultz@zuckerman.com
202-778-1820

January 7, 2021

VIA EMAIL

Doug Langa
President
Novo Nordisk Inc.
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Jamie Haney
Corporate Vice President, Legal & General Counsel
Novo Nordisk Inc.
800 Scudders Mill Road
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haneyj@novonordisk.com

Dear Mr. Langa and Ms. Haney:

We represent the American Hospital Association, 340B Health, the Association of American Medical Colleges, America's Essential Hospitals, National Association of Children's Hospitals d/b/a the Children's Hospital Association, American Society of Health-System Pharmacists, Avera St. Mary's Hospital, Riverside Hospital, Inc., d/b/a Riverside Regional Medical Center, and Dignity Health d/b/a St. Mary's Medical Center in a lawsuit filed in the Northern District of California against Secretary Alex Azar and the Department of Health and Human Services (HHS) challenging the Department's failure to enforce the statutory requirement that Novo Nordisk, Inc. (Novo Nordisk) and five other drugs companies provide 340B covered entities covered outpatient drugs at or below the 340B ceiling price when 340B drugs are dispensed from a contract pharmacy. *American Hospital Association et al v. Department of Health & Human Services et al.*, No. 3:20-cv-08806-YGR.

After the lawsuit was filed, the General Counsel of HHS issued an advisory opinion on December 30, 2020, in which the Department agrees with us that the 340B statute requires drug companies to provide 340B entities covered outpatient drugs at or below the 340B ceiling price when those covered entities use contract pharmacies to dispense the drugs. *See* Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program. Accordingly, Novo Nordisk's policy of (with limited exceptions) not providing 340B discounts to 340B hospitals when Novo Nordisk's

drugs are dispensed through contract pharmacies is in clear violation of the statute, and Novo Nordisk should immediately discontinue its illegal practice. In addition, Novo Nordisk should reimburse 340B entities for the damages they have incurred due to Novo Nordisk's policy.

If Novo Nordisk continues its illegal practice, we will continue to seek to require that HHS enforce the 340B statute, covered entities are reimbursed for damages caused by the illegal policy, and the matter is referred to the HHS Inspector General for the imposition of civil money penalties.

We look forward to your response.

Sincerely,

William B. Schultz

William B. Schultz
Margaret M. Dotzel