



**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 contract 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.<sup>1</sup> 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 comports 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).<sup>2</sup>

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<sup>1</sup> 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”).

<sup>2</sup> 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,<sup>3</sup> 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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<sup>3</sup> *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.<sup>4</sup>

### **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.<sup>5</sup>

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<sup>4</sup> 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”).

<sup>5</sup> 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).<sup>6</sup>

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

<sup>6</sup> 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 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*,<sup>7</sup> 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).<sup>8</sup>

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.pfizerxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways\\_IPAP\\_Factsheet%202019.pdf](https://www.pfizerxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways_IPAP_Factsheet%202019.pdf) (last visited Dec. 21, 2020).

<sup>7</sup> “[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).

<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup> 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  
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<sup>9</sup> 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).

<sup>10</sup> 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).