No. 22-1676

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff–Appellee,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Delaware (No. 21-27)

OPENING BRIEF FOR THE FEDERAL DEFENDANTS

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

DAVID C. WEISS
United States Attorney

ALISA B. KLEIN
DANIEL AGUILAR
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-5432

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The issues presented in this appeal overlap substantially with the issues presented in the consolidated appeals pending before this Court in *Sanofi Aventis U.S., LLC v. U.S. Department of Health and Human Services*, Nos. 21-3167, 21-3379 and *Novo Nordisk Inc. v. U.S. Department of Health and Human Services*, Nos. 21-3168, 21-3380. Pursuant to the Court's order in this case, we have endeavored to avoid repetition and incorporate by reference relevant portions of the principal and answering brief that we filed in those appeals (Defendants' Principal Brief). *See* Order (3d. Cir. April 28, 2022) (citing Fed. R. App. P. 28(i)).

STATEMENT OF JURISDICTION

Plaintiff invoked the district court's jurisdiction under 28 U.S.C. § 1331. JA78. On February 16, 2022, the district court issued an order vacating the agency's action and remanding to the agency. JA51. On March 11, 2022, the district court issued an order and final judgment granting in part and denying in part plaintiff's motion for summary judgment. JA52-53. Defendants filed a notice of appeal on April 12, 2022, which is within 60 days of both orders. JA1; *see* Fed. R. App. P. 4(a)(1)(B). This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

Under Section 340B of the Public Health Service Act, as amended by the Affordable Care Act, drug manufacturers that participate in Medicaid and Medicare Part B shall "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). The questions presented are:

1. Whether the statute permits drug manufacturers to refuse to offer this price discount to a covered entity that uses contract pharmacies to dispense drugs purchased by the covered entity.

2. Whether the district court erred in vacating and remanding the agency's enforcement letters.

STATEMENT OF RELATED CASES

This case has not previously been before this Court. As noted above, there are appeals pending before this Court that raise substantially the same issues as the appeals in this case: *Sanofi Aventis U.S., LLC v. U.S. Department of Health and Human Services* and *Novo Nordisk Inc. v. U.S. Department of Health and Human Services*, Nos. 21-3167, 21-3168, 21-3379, 21-3380 (3d Cir.).

Substantially the same issues are also presented in the following cases pending before or within other federal courts: *Novartis Pharmaceuticals*

Corp. v. Johnson and *United Therapeutics Corp. v. Johnson*, Nos. 21-5299, 21-5304 (D.C. Cir.); *Eli Lilly and Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.); and *Boehringer Ingelheim Pharmaceuticals, Inc. v. Becerra*, No. 21-cv-2826 (D.D.C.).

STATEMENT OF THE CASE

I. Background

We incorporate by reference the statutory and factual background discussed in the Defendants' Principal Brief in the *Novo Nordisk* and *Sanofi* appeals. Like the drug manufacturers in those related cases, plaintiff AstraZeneca adopted a policy in 2020 that limited the circumstances in which plaintiff would offer the discounted 340B drug price to covered entities. AstraZeneca announced that it "only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy." JA245. To implement that policy, AstraZeneca "stop[ped] processing 340B" pricing for all "Contract Pharmacy arrangements" for all covered entities—the covered entities must then "contact AstraZeneca to arrange for" a single contract pharmacy "to be eligible to receive 340B pricing." *Id.*

As a result of AstraZeneca's new policy, covered entities reported to the U.S. Department of Health and Human Services (HHS) that they could

no longer receive many medications at the 340B discounted price, including asthma inhalers, JA159, blood thinners, JA160, medications for diabetes and lung cancer, JA164, and more. *See e.g.*, JA164-67, 170, 175, 180-83, 187-88, 192-93, 197-98, 202, 206-07, 209, 211-14, 221-24, 230-33, 237, 241. *See also* JA246-51 (identifying dozens of different medications affected by AstraZeneca's new policy).

Covered entities informed HHS that AstraZeneca's new policies have harmed their operations and their patients' access to necessary medications. For instance, Erie Family Health Center, Inc., serves 80,000 patients a year throughout the Chicago area. JA252-53. "Almost all of Erie's patients are low income" and over a quarter are uninsured. JA253. Erie explained that its participation in the 340B program "allows us to help our" uninsured and underinsured patients "afford their medications." *Id.* Without the statutory discounted prices, "critical medications—including, among many others, insulin, asthma inhalers, blood pressure medications, Pre-Exposure Prophylaxis (PrEP) for HIV, Suboxone and Narcan to treat opioid use disorder—would be unaffordable and inaccessible for these patients." *Id.* Savings from the discounted prices are either passed on to the patients or reinvested "into expanding access for our underserved patients" by covering other costs, investing in telemedicine, and operating

opioid treatment programs. *Id.* Erie's patients had previously filled thousands of their prescriptions at contract pharmacies and benefited from the 340B discounted price—but under the new policies, "these medications are inaccessible for an Erie patient paying out-of-pocket." JA256. Thus, contract pharmacies allowed Erie's patients to receive 1,860 annual prescription fills for drugs manufactured by plaintiff AstraZeneca. *Id.*

After AstraZeneca announced its new policy, Erie attempted to negotiate with AstraZeneca to designate a single contract pharmacy for dispensing its medications, but explained that such a limitation would be "unworkable * * * for our patients." JA256-57. Patients at Erie's Waukegan clinic "would need to travel nearly three hours one-way on public transportation to arrive at our one remaining contract pharmacy" in Chicago. JA257. Erie lacks the resources to create its own in-house pharmacies, which would be "a lengthy and expensive endeavor. Our patients cannot wait, they need access to affordable medications now." *Id.*

AstraZeneca's new policy caused an immediate and significant decline in its 340B discounted drug sales. The month before its policy took effect, AstraZeneca sold approximately 2,720,000 units of 340B medications—two months later, that number dropped over 90% to only 240,000 units. JA264. Covered entities also lost almost all of their price savings from the

statutory discount. Before the new policy, covered entities saved $53.5 million from wholesale pricing by purchasing AstraZeneca's drugs through the 340B program—two months later, those savings had dropped over 85% to $7.2 million. JA266.

In May 2021, HHS sent AstraZeneca a letter explaining that its policy was "in direct violation of the 340B statute" because the statute does not "grant[] 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." JA157. The letter directed AstraZeneca to cease its policy immediately and "refund all covered entities for overcharges that have resulted from" the policy, or risk the imposition of civil monetary penalties under 42 U.S.C. § 256(d)(1)(B). JA158.

II. District Court Proceedings

AstraZeneca brought this action in district court, challenging HHS's enforcement letter and an earlier-issued advisory opinion from the HHS General Counsel (which the agency has since withdrawn). JA35-38 & n.4. In denying HHS's motion to dismiss the complaint, the district court reasoned that the 340B statute was "ambiguous with respect to" whether drug manufacturers can impose limitations on a covered entity's use of contract pharmacies to dispense 340B drugs at the discounted price. JA21.

The court concluded that "HHS's current interpretation of the statute is permissible" but not required. JA25.

On cross-motions for summary judgment, the district court reiterated that reasoning and ruled that HHS could not premise an enforcement action on the "statutory text." JA41. In vacating HHS's enforcement letter, the court also declared that HHS had been inconsistent in its interpretation of the statute. JA44-45. The court noted that agency guidance issued in 1996 stated that covered entities could use only one contract pharmacy to distribute drugs purchased at the 340B price, whereas agency guidance issued in 2010 stated that covered entities could use multiple contract pharmacies. *Id.*

SUMMARY OF ARGUMENT

This appeal presents a question of law: whether the 340B statute allows a drug manufacturer to refuse to offer the 340B price to a covered entity that relies on multiple contract pharmacies to dispense the drugs purchased. The district court vacated HHS's enforcement letter because the court concluded that the statute is "ambiguous" and that HHS had been inconsistent in its interpretation of the statute.

The district court's mode of analysis was fundamentally mistaken. The ambiguity of a statutory provision and the consistency of an agency's

interpretation are relevant when an agency claims that its interpretation is entitled to *Chevron* deference. HHS has made no such claim here. On the contrary, as the district court in the related cases recognized, HHS does not claim and is not entitled to *Chevron* deference with respect to the question of statutory interpretation presented here. Nor does HHS have authority to restrict, through legislative rulemaking, the number of contract pharmacies that a covered entity may use. Accordingly, HHS previously addressed that issue through nonbinding guidance only.

If this Court regards the statutory text as ambiguous, the Court should resolve the ambiguity by using the familiar tools of statutory interpretation, which include consideration of the statutory structure, context, history, and purpose. For the reasons set forth in our brief in the related cases, these interpretive tools show that the statute does not allow drug manufacturers to "unilaterally create and establish policies" that "dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, --- F. Supp. 3d ---, 2021 WL 5150464, at *43 (D.N.J. 2021). Therefore, HHS properly premised its enforcement letter on plaintiff's violation of the statute, and the judgment of the district court should be reversed.

STANDARD OF REVIEW

This Court reviews the district court's summary judgment ruling de novo. *Bruni v. City of Pittsburgh*, 941 F.3d 73, 82 (3d Cir. 2019). Agency action is reviewed to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

ARGUMENT

For the reasons set forth in the Defendants' Principal Brief in the *Novo Nordisk* and *Sanofi* appeals, the 340B statute does not allow drug manufacturers to "unilaterally create and establish policies—whatever the underlying rationale—wherein they dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, --- F. Supp. 3d ---, 2021 WL 5150464, at *43 (D.N.J. 2021).

The district court in this case vacated HHS's enforcement letter because the court concluded that the relevant statutory text was ambiguous and that HHS had been inconsistent in its understanding of the statute. That ruling rests on a basic misunderstanding of administrative-law principles. The ambiguity of a statutory provision and the consistency of an agency's interpretation bear on the question whether the agency's interpretation is due *Chevron* deference. But there is no claim of *Chevron*

deference on the issue presented here. As the district court in the related cases recognized, HHS is not entitled to *Chevron* deference on matters pertaining to contract pharmacies and "HHS does not contend otherwise." *Sanofi*, --- F. Supp. 3d ---, 2021 WL 5150464, at *34.

Accordingly, if the district court perceived an ambiguity, it was the court's responsibility to resolve that ambiguity by employing all available tools of statutory interpretation, by "carefully consider[ing] the text, structure, history, and purpose of" the statutory scheme. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (quotation marks omitted); *see also King v. Burwell*, 576 U.S. 473, 486 (2015) (explaining the Court's "duty * * * is 'to construe statutes, not isolated provisions'"). And as the Defendants' Principal Brief explained, those tools of interpretation show that drug manufacturers may not refuse to offer the 340B price to covered entities that rely on multiple covered pharmacies to dispense the drugs that the covered entities purchase. The enforcement letter at issue here properly rested on AstraZeneca's violation of the statute.

Because HHS does not have rulemaking authority to restrict the number of contract pharmacies that a covered entity may use, HHS has consistently stated that its guidance on the issue was nonbinding. *See, e.g.*, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) (explaining that "these

guidelines create no new law and create no new rights or duties"). HHS explained that nonbinding nature when it advised covered entities to use a single contract pharmacy to dispense medications, *id*. at 43550, 43555, and when HHS later advised that covered entities could use multiple contract pharmacies to do so, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010) (explaining that "[t]his guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities").

In any event, HHS's guidance consistently interpreted the statute as prohibiting drug manufacturers from creating extra-textual barriers to a covered entity's ability to obtain drugs at the 340B price. For example, as early as 1993, shortly after Congress enacted Section 340B, HHS explained that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." 58 Fed. Reg. 68922, 68925 (Dec. 29, 1993). HHS thus explained that manufacturers "may not" require covered entities to demonstrate program eligibility, use drugs only for authorized services, keep drug pricing confidential, or "submit[] information related to drug acquisition, purchase, and inventory systems." *Id.*; *see also, e.g.*, 59 Fed. Reg. 25110, 25111-12 (May 13, 1994) ("Manufacturers may not single out covered

entities from their other customers for restrictive conditions that would undermine the statutory objective.").

Nor was the evolution of HHS's guidance regarding the number of contract pharmacies left unexplained. On the contrary, HHS explained that its guidance had evolved in light of its experience with a pilot program for using multiple contract pharmacies, its evaluation of the corresponding data, and its response to comments it received on the new proposal. 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007); 75 Fed. Reg. at 10272-79. Thus, even if that guidance had established binding rules (which it did not), HHS articulated a "satisfactory explanation for its action," consistent with the requirements of the Administrative Procedure Act. *Delaware Riverkeeper Network v. U.S. Army Corps of Engineers*, 869 F.3d 148, 154-55 (3d Cir. 2017).

CONCLUSION

The district court's judgment should be reversed.

Respectfully submitted,

SARAH E. HARRINGTON
Deputy Assistant Attorney General

DAVID C. WEISS
United States Attorney

ALISA B. KLEIN
/s/ Daniel Aguilar
DANIEL AGUILAR
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-5432
Daniel.J.Aguilar@usdoj.gov

June 2022

COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.

2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 2,347 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Georgia 14-point font, a proportionally spaced typeface.

3. On June 21, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system.

4. The text of the electronic version of this document is identical to the text of the hard copies that will be provided.

5. This document was scanned for viruses using Symantec Endpoint Protection version 14, and no virus was detected.

/s/ Daniel Aguilar
Daniel Aguilar

ADDENDUM

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42 U.S.C. § 256b. Limitation on prices of drugs purchased by covered entities.

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and 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.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to--

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that--

(i) 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 subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) Prohibiting resale of drugs

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.

(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[1] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[1] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions--

(1) In general

In this section, the terms “average manufacturer price”, “covered outpatient drug”, and “manufacturer” have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) Covered drug

In this section, the term “covered drug”--

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub.L. 111-152, Title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which--

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which--

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered

entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[2] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall--

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the

interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term “covered outpatient drug” shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.