

24-2092

Boehringer Ingelheim Pharms., Inc. v. Dep't of Health & Hum. Servs.

In the
United States Court of Appeals
For the Second Circuit

August Term, 2024
No. 24-2092

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN
SERVICES, ROBERT F. KENNEDY, JR., in his official capacity as Secretary
of Health and Human Services, CENTERS FOR MEDICARE AND
MEDICAID SERVICES, MEHMET OZ, in his official capacity as
Administrator of Centers for Medicare and Medicaid Services,
*Defendants-Appellees.**

On Appeal from a Judgment of the United States District Court for
the District of Connecticut.

ARGUED: APRIL 3, 2025
DECIDED: AUGUST 7, 2025

Before: LEVAL, BIANCO, and NARDINI, *Circuit Judges.*

* The Clerk of Court is respectfully directed to amend the official caption
as set forth above.

The Inflation Reduction Act of 2022 (the “IRA”) authorized the creation of the Medicare Drug Price Negotiation Program (the “Negotiation Program”) to limit the federal government’s spending on prescription drugs under Medicare. Under the statute, the Centers for Medicare and Medicaid Services (“CMS”) must select a certain number of the highest-expenditure drugs for participation in the program each year. For the initial 2026 pricing period, CMS selected ten drugs, including Jardiance, which is produced by Plaintiff-Appellant Boehringer Ingelheim Pharmaceuticals, Inc. (“Boehringer”).

Boehringer signed an agreement with CMS to participate in the Negotiation Program, but it did so “under protest” and at the same time commenced this lawsuit against the government. Boehringer raised five constitutional claims, alleging that the Negotiation Program (1) violates its Fifth Amendment right to procedural due process, (2) effects a *per se* physical taking of its Jardiance product in violation of the Fifth Amendment, (3) compels speech in violation of the First Amendment, (4) violates the Excessive Fines Clause of the Eighth Amendment, and (5) unconstitutionally conditions its participation in Medicare and Medicaid on the relinquishment of its constitutional rights. The company also alleged that CMS violated the Administrative Procedure Act (the “APA”) and the Medicare Act by issuing the standard agreement for the Negotiation Program without following notice-and-comment procedures. The district

court (Michael P. Shea, *Chief Judge*) granted summary judgment to the defendants on all claims.

Boehringer appeals the district court's dismissal of its claims under the First and Fifth Amendments and the APA. We agree with the district court's principal conclusions that: (1) *Boehringer's* direct constitutional claims fail because, under *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), participation in the Negotiation Program is voluntary and thus does not entail an unlawful deprivation of rights; (2) the program does not impose unconstitutional conditions on *Boehringer's* ability to participate in Medicare and Medicaid because the program is designed to promote the legitimate government purpose of controlling Medicare spending and does not regulate the company's conduct in the private market; and (3) the IRA expressly authorized CMS to implement the program during its first three years without following the APA's notice-and-comment requirement.

Accordingly, the judgment of the district court is AFFIRMED.

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WILLIAM J. NARDINI, *Circuit Judge*:

Reversing a nearly twenty-year policy that prevented the Centers for Medicare & Medicaid Services (“CMS”), which administers the Medicare program, from negotiating the prices of drugs purchased for the Medicare program, the Inflation Reduction Act of 2022 (the “IRA”) authorized the creation of the Medicare Drug Price Negotiation Program (the “Negotiation Program”) to limit the federal government’s spending on prescription drugs under Medicare. CMS is required to pick a certain number of the highest-expenditure drugs—subject to other criteria, including a lack of generic competitors—for participation in the program each year, beginning with 2026. The IRA sets price ceilings for the selected drugs—ranging from 40 to 75 percent of the average price paid by wholesalers in the private market—and requires CMS and the drug

manufacturers to agree to a statutorily defined “maximum fair price,” which must reflect factors such as the research and development costs of the drug. For the initial 2026 pricing period, CMS chose ten drugs, including Jardiance, which is produced by Plaintiff-Appellant Boehringer Ingelheim Pharmaceuticals, Inc.

Boehringer signed an agreement with CMS to participate in the Negotiation Program, but it did so “under protest” and at the same time brought this lawsuit against CMS; the U.S. Department of Health and Human Services, of which CMS is a constituent agency; and the leaders of both agencies. Boehringer raised five constitutional claims, alleging that the Negotiation Program (1) violates its Fifth Amendment right to procedural due process, (2) effects a *per se* physical taking of its Jardiance product in violation of the Fifth Amendment, (3) compels speech in violation of the First Amendment, (4) violates the Excessive Fines Clause of the Eighth Amendment, and (5) unconstitutionally conditions its participation in Medicare and Medicaid on the relinquishment of its constitutional rights. The company also alleged that CMS violated the Administrative Procedure Act (the “APA”) and the Medicare Act by issuing the standard agreement for the Negotiation Program without following notice-and-comment procedures. In a careful and comprehensive opinion, the district court (Michael P. Shea, *Chief Judge*) granted summary judgment to the defendants on all claims.

Boehringer appeals the district court’s dismissal of its claims under the First and Fifth Amendments and the APA. We agree with the district court’s principal conclusions that: (1) Boehringer’s direct

constitutional claims fail because, under *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), participation in the Negotiation Program is voluntary and thus does not entail an unlawful deprivation of rights; (2) the program does not impose unconstitutional conditions on Boehringer’s ability to participate in Medicare and Medicaid because the program is designed to promote the legitimate government purpose of controlling Medicare spending and does not regulate the company’s conduct in the private market; and (3) the IRA expressly authorized CMS to implement the program during its first three years without following the APA’s notice-and-comment requirement. Accordingly, the judgment of the district court is AFFIRMED.

I. Background

A. The Medicare Drug Price Negotiation Program

Medicare is a federal medical insurance program for people aged sixty-five and older and for certain younger people with disabilities. *See* 42 U.S.C. § 1395 *et seq.* The program is administered by CMS, a constituent agency of the U.S. Department of Health and Human Services (“HHS”). The Medicare statute is divided into five “Parts,” lettered A through E, which establish the terms of benefits provided under the program. As relevant here, Part B is a voluntary supplemental insurance program that covers outpatient care, including certain prescription drugs that are typically administered by a physician, and Part D is a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums. *See* 42 C.F.R. §§ 410.28,

423.120. Part D “operates as a public-private partnership between [CMS] and . . . private insurance companies called ‘Sponsors’ that administer prescription drug plans.” *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017). Under Part D, insurers negotiate drug prices with manufacturers, and then CMS pays the insurers fixed amounts based on their anticipated drug spending.

When Congress enacted Medicare Part D in 2003, it barred CMS from negotiating, or otherwise attempting to influence, the price of drugs covered by the program. Specifically, Congress provided that CMS “may not interfere with the negotiations between drug manufacturers and pharmacies and . . . sponsors,” and “may not . . . institute a price structure for the reimbursement of covered part D drugs.” 42 U.S.C. § 1395w-111(i)(1), (3) (2003). Nearly two decades later, Congress created an exception to that non-interference provision via the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (codified in pertinent part at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D), which authorized the Secretary of Health and Human Services to establish a Negotiation Program to limit the cost of certain drugs under Medicare Parts B and D.¹

¹ The Secretary delegated authority to administer the Negotiation Program to CMS. We therefore refer to CMS when discussing the program.

1. The Drug Selection Phase

The Negotiation Program operates in annual drug-pricing cycles in which CMS selects participating drugs and negotiates prices for a given calendar year (“pricing period”), beginning with 2026. 42 U.S.C. § 1320f(b). During each cycle, CMS first must identify negotiation-eligible drugs, which must have no generic or biosimilar competitors; must have been approved or licensed for at least seven years; and must rank among the fifty drugs with the highest total expenditures under either Medicare Part B or Part D over a recent twelve-month period. *See* 42 U.S.C. § 1320f-1(d), (e).² Next, CMS must select and publish a list of the negotiation-eligible drugs with the highest expenditures that will be subject to negotiation for that drug-pricing cycle. *Id.* § 1320f-1(a), (b)(1)(B). The statute requires the selection of ten drugs for the 2026 pricing period, fifteen drugs for 2027 and 2028, and twenty drugs for 2029 and all subsequent pricing periods. *Id.* § 1320f-1(a).

2. The Manufacturer Agreement

After completing the drug selection phase of a drug-pricing cycle, CMS has to engage with the manufacturers of the selected drugs to determine whether they intend to participate in the program. CMS must “enter into agreements,” by specified deadlines, with the

² The Negotiation Program applies only to drugs covered by Medicare Part D for the 2026 and 2027 pricing periods. 42 U.S.C. § 1320f-1(a)(1)–(2), (d)(1). Beginning with the 2028 pricing period, the program will also apply to drugs covered by Medicare Part B. *Id.* § 1320f-1(a)(3)–(4), (d)(1).

manufacturers that are willing to participate in negotiations. *Id.* §§ 1320f(a)(2), 1320f-2. Pursuant to this directive, CMS set out to create a standard agreement that could be used for negotiations with the manufacturer of each selected drug. On March 15, 2023, CMS issued initial guidance describing the possible contents of the prospective agreement and “voluntarily solicit[ed] comments” on the “[t]erms and conditions” that the agreement should contain. CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum* (Mar. 15, 2023), <https://perma.cc/54JU-BQDP>. In response to the comments received on the initial guidance, CMS issued revised guidance on June 30, 2023, which included the material terms of the negotiation agreement. *See* Joint App’x 97–294. Finally, on July 3, 2023, CMS issued a template of the Medicare Drug Price Negotiation Agreement (the “Manufacturer Agreement”). Although CMS solicited comments from the public in its March 15, 2023, guidance memorandum, the agency did not conduct a formal notice-and-comment process before issuing the agreement template.

Several provisions of the Manufacturer Agreement are relevant here. For one, the agreement provides that “CMS and the Manufacturer shall negotiate to determine . . . a maximum fair price for the Selected Drug.” Joint App’x 297. The manufacturer agrees to make that price available to “maximum fair price eligible individuals,” hospitals, health care providers, pharmacies, and other entities described in the IRA. *Id.*; *see also* 42 U.S.C. § 1320f(c)(2) (defining “maximum fair price eligible individual”). Additionally, the manufacturer must provide certain information to CMS about the

drug, including the average price paid by wholesalers to the manufacturer in the private market (the “private market price”) and any other information that CMS requires for the negotiation process. Joint App’x 297–98; *see also* 42 U.S.C. § 1320f-2(a)(4) (statutory provision stating that the Manufacturer Agreement must require the manufacturer to provide this information).³ Any information submitted by the manufacturer that CMS deems “proprietary information” can be used only for the Negotiation Program. 42 U.S.C. § 1320f-2(c). The agreement also provides that the manufacturer, by entering into the agreement, does not endorse CMS’s views or adopt the statutory definitions of terms such as “maximum fair price” for purposes other than carrying out the agreement. *See* Joint App’x 299. Specifically, the disclaimer states:

In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS’ views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term “maximum fair price” and other statutory terms throughout this Agreement reflects the parties’ intention that such terms be given the meaning specified in the statute and does not reflect any party’s views regarding the colloquial meaning of those terms.

Id.

³ The deadline to submit that data during the initial negotiation period was October 2, 2023. 42 U.S.C. § 1320f(d)(5)(A).

3. The Negotiation Phase

Once CMS and the manufacturer of a selected drug execute the Manufacturer Agreement, the negotiation phase begins. The IRA directs CMS to negotiate a statutorily defined “maximum fair price[]” for each selected drug. 42 U.S.C. § 1320f(a)(3). As an initial matter, the manufacturer must provide CMS with the required data about the selected drug. *Id.* §§ 1320f-3(b)(2)(A), 1320f(d)(5)(A). The negotiation then proceeds in a familiar pattern: offer, acceptance or counteroffer, response, and so on. But unlike typical negotiations, these have strict parameters for pricing, and they end with CMS effectively getting the final word.

CMS must make an initial offer as to the “maximum fair price” that it will pay for the drug. The IRA establishes a price ceiling on the maximum fair price based on the private market price of the selected drug. *See id.* § 1320f-3(c). In general, CMS may not offer or agree to a price that exceeds 75 percent of the private market price for any selected drug. *Id.* Lower price ceilings apply to drugs that have been approved or licensed for longer periods: 65 percent for drugs that have been approved or licensed for at least 12 years, and 40 percent for those that have been approved or licensed for at least 16 years. *Id.* To determine the maximum fair price, CMS must consider several factors, including the costs of researching, developing, manufacturing, and distributing the drug; whether alternative treatments are available; and the comparative effectiveness of any such alternatives. *Id.* § 1320f-3(e). Save for an exception not relevant here, there is no floor on the maximum fair price. *Id.* § 1320f-3(d).

Within thirty days of receiving CMS's initial offer, the manufacturer must either accept that offer or make a written counteroffer, which must be "justified based on the factors [specified in the statute]." *Id.* § 1320f-3(b)(2)(C)(i)–(ii). If the manufacturer makes a counteroffer, CMS must respond to it in writing. *Id.* § 1320f-3(b)(2)(D). CMS guidance provides that if CMS declines the counteroffer, the agency and the manufacturer may schedule "[u]p to three possible negotiation meetings" to "negotiate [the maximum fair price] for the selected drug." Joint App'x 187–88. During the initial negotiation period, CMS was required to make its final maximum fair price offer to the manufacturer by July 15, 2024, which the manufacturer was required to respond to by July 31, 2024; negotiations were to conclude by August 1, 2024.

The Manufacturer Agreement provides that if CMS and the manufacturer agree to a maximum fair price, that price is incorporated into the agreement through an addendum signed by the manufacturer. Joint App'x 302 (addendum providing that "the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug," and "the Manufacturer and CMS now agree to a price for the Selected Drug"). If the manufacturer does not agree to a maximum fair price by the deadline, it may incur "potential excise tax liability," as discussed below. *Id.* at 252; 26 U.S.C. § 5000D(b)(2). Once the maximum fair price is set, that price will take effect at the beginning of the first applicable pricing period and will continue to apply during subsequent pricing periods until the selected drug is no

longer eligible for the Negotiation Program or the price is renegotiated. *Id.* §§ 1320f(b)(1)–(2), 1320f-1(c), and 1320f-3(f).

4. Civil Monetary Penalties and the Excise Tax

Under the IRA, manufacturers that sign the Manufacturing Agreement but later violate certain statutory requirements are subject to civil monetary penalties. For every unit of a selected drug that a manufacturer sells at a price exceeding the maximum fair price, the manufacturer must pay a penalty equal to ten times the difference between the higher price and the maximum fair price. 42 U.S.C. § 1320f-6(a). Additionally, any manufacturer that fails to submit required information to CMS or otherwise fails to comply with the Negotiation Program’s requirements must pay a penalty of \$1,000,000 for each day of the violation. *Id.* §§ 1320f-6(c), 1320f-2(a)(4)–(5).

The IRA also authorizes an excise tax on sales of selected drugs by manufacturers that do not sign the Manufacturer Agreement or that fail to agree to a maximum fair price during negotiations with CMS. 26 U.S.C. § 5000D(a)–(b). The tax is assessed for each day of the “noncompliance periods,” which begin when the deadline to sign the Manufacturer Agreement or to agree to a maximum fair price has passed and generally end when the manufacturer reaches an agreement with CMS. *Id.* § 5000D(b). The excise tax is imposed “on the sale by the manufacturer . . . of any designated drug,” *id.* § 5000D(a), which the statute defines as “any negotiation-eligible drug . . . included on the list [of drugs selected under 42 U.S.C. § 1320f-1(a) for the Negotiation Program] which is manufactured or

produced in the United States or entered into the United States for consumption, use, or warehousing,” *id.* § 5000D(e)(1).

5. Alternatives to the Penalties and Excise Tax

A manufacturer that does not wish to participate in the Negotiation Program can avoid the excise tax by transferring ownership of the selected drug to another entity, or withdrawing all its products from Medicare and Medicaid. If, after signing the Manufacturer Agreement, a manufacturer decides to transfer ownership of the drug to another entity, it must notify CMS at least thirty days before the transfer becomes effective, per CMS guidance. Once the transfer becomes effective, any excise tax liability could be imposed on the new owner. If the manufacturer instead chooses to maintain ownership of the selected drug and withdraw all its products from Medicare and Medicaid, the excise tax will be “suspend[ed]” provided that (1) the manufacturer provides CMS with notice of termination of certain Medicare and Medicaid agreements, 26 U.S.C. § 5000D(c)(1)(A)(i), (c)(2)(B); and (2) none of the manufacturer’s drugs are covered by the Medicare Coverage Gap Discount Program Agreement or the Medicare Part D Manufacturer Discount Program Agreement, 26 U.S.C. § 5000D(c)(1)(A)(ii).

A manufacturer may terminate its agreements under the Medicare Coverage Gap Discount Program or the Medicare Part D Manufacturer Discount Program “for any reason,” but the termination will not become effective for eleven to twenty-three months after CMS receives the termination notice. 42 U.S.C.

§§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). Following the enactment of the IRA, some manufacturers, citing the long period before termination of those agreements can become effective, petitioned CMS to permit immediate termination of the agreements so that manufacturers could avoid the excise tax that they would otherwise need to pay during the statutory pre-termination period. To address this concern, CMS issued guidance establishing a process for manufacturers “to expedite [their] termination” from the Medicare programs. Joint App’x 99. By statute, CMS “may provide for termination” of Medicare Coverage Gap Discount Program agreements, and “shall provide for termination” of Manufacturer Discount Program agreements, after just 30 days “for a knowing and willful violation of the requirements of the agreement or other good cause shown.” 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). The CMS guidance permits the manufacturer to submit a notice to CMS stating its intent not to participate in the Negotiation Program and requesting termination of its agreements under Medicare and Medicaid. Upon receipt of such notice, “CMS will find good cause to terminate the [manufacturer’s] agreement(s) under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program . . . pursuant to [42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i)].” Joint App’x 217; *see also id.* (“CMS has determined . . . that it will automatically grant such termination requests upon receipt, and that it will expedite the effective date [of the termination so that it occurs thirty days after the manufacturer gives notice].”). Thus, under this process, a

manufacturer could withdraw from Medicare and Medicaid in as few as thirty days after providing notice to CMS.

6. Preclusion of Judicial and Administrative Review

The IRA precludes HHS and the federal courts from reviewing CMS's decisions regarding the selection and pricing of drugs for the Negotiation Program. Specifically, the statute provides that “[t]here shall be no administrative or judicial review” of (1) the determination of which drugs are negotiation-eligible, (2) the selection of drugs for the Negotiation Program, or (3) the final maximum fair price. 42 U.S.C. § 1320f-7(2)–(3).

B. Selection of Jardiance for the Negotiation Program

Pursuant to the IRA, CMS selected ten drugs for the initial 2026 pricing period, including Boehringer's Jardiance product. 42 U.S.C. § 1320f-1(a)(1); HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), <https://perma.cc/A36P-Z88Z>. The deadlines for CMS and the manufacturers of the selected drugs to enter into Manufacturer Agreements and for the manufacturers to submit the required data for the selected drugs were October 1 and 2, 2023, respectively. See 42 U.S.C. § 1320f(d)(4)–(5), 1320f-2(a), and 1320f-3(b)(2)(A). On October 3, 2023, CMS announced that each of the manufacturers, including Boehringer, had “chosen to participate in the Negotiation Program” and had signed the Manufacturer Agreement. CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability*

Year 2026 (Oct. 3, 2023), <https://perma.cc/3222-VPEE>. In August 2024, CMS announced that negotiations with Boehringer resulted in an agreement on a maximum fair price for Jardiance equal to 34 percent of its 2023 private market price. That price is scheduled to take effect on January 1, 2026.

C. District Court Proceedings

On August 18, 2023, Boehringer commenced this suit against HHS; Xavier Becerra, then-Secretary of Health and Human Services; CMS; and Chiquita Brooks-Lasure, then-Administrator of CMS.⁴ Boehringer raised five constitutional claims, alleging that the Negotiation Program (1) violates its Fifth Amendment right to procedural due process, (2) effects a *per se* physical taking of its Jardiance product in violation of the Fifth Amendment, (3) compels speech in violation of the First Amendment, (4) violates the Excessive Fines Clause of the Eighth Amendment, and (5) unconstitutionally conditions its participation in Medicare and Medicaid on the relinquishment of its constitutional rights. Boehringer also alleged that CMS violated the Administrative Procedure Act and the Medicare statute by issuing legislative rules without notice and comment. The parties subsequently cross-moved for summary judgment.

⁴ Pursuant to Federal Rule of Appellate Procedure 43(c)(2), Secretary of Health and Human Services Robert F. Kennedy, Jr., and CMS Administrator Mehmet Oz are automatically substituted for their predecessors as defendants.

In an order entered on July 3, 2024, the district court granted summary judgment to the defendants. The court first concluded that Boehringer's Fifth Amendment takings and due process claims fail because participation in the Negotiation Program is voluntary, and thus Boehringer has not been illegally deprived of any property interests. Next, the court dismissed Boehringer's First Amendment compelled speech claim, reasoning that because participation in the Negotiation Program is voluntary, the Manufacturer Agreement "did not 'compel' [Boehringer] to do anything." *Boehringer Ingelheim Pharms., Inc. v. United States Dep't of Health & Hum. Servs.*, No. 23-CV-01103 (MPS), 2024 WL 3292657, at *16 (D. Conn. July 3, 2024). The court also dismissed Boehringer's unconstitutional conditions claim, largely for the reasons it set forth with respect to the direct constitutional claims, and for the additional reason that "the condition the government has imposed—that [Boehringer] sell the drug for the maximum fair price—is closely related to the government's goal of controlling spending in the Medicare program." *Id.* at *19. Finally (as relevant here), the court dismissed Boehringer's APA claim, concluding that the IRA expressly permitted CMS "to implement the [Negotiation] Program through guidance for the first three negotiation cycles" and forgo the notice-and-comment requirement that otherwise would have applied.⁵ *Id.* at *21.

⁵ In the district court, Boehringer also alleged that CMS violated the Medicare Act's notice-and-comment requirement (in addition to the APA's) and that the IRA's excise tax violated the Excessive Fines Clause of the Eighth Amendment. The district court also dismissed those claims, but Boehringer does not raise them on appeal.

II. Discussion

Boehringer raises six principal arguments on appeal. First, the company argues that the Negotiation Program effects a *per se* taking of its Jardiance products (that is, the physical doses of the drug) by giving Medicare beneficiaries access to Jardiance on terms dictated by the government, in violation of the Takings Clause of the Fifth Amendment. Second, the company argues that the program violates the Due Process Clause of the Fifth Amendment because, among other reasons, the IRA bars administrative and judicial review of CMS's price-setting decisions. Third, the company argues that the program violates its First Amendment right to free speech by compelling the company to endorse the government's characterization of the program, including that the CMS-determined price is the "maximum fair price." Fourth, in connection with the foregoing arguments, Boehringer contends that the district court erroneously dismissed the company's three direct constitutional claims based on the incorrect conclusion that participation in the Negotiation Program is voluntary. Fifth, Boehringer argues that even if participation in the program were voluntary, the program would violate the unconstitutional conditions doctrine because Congress conditioned Boehringer's ability to market *any* products through Medicare and Medicaid on the company's participation in the program and relinquishment of its First and Fifth Amendment rights. Finally, Boehringer argues that CMS violated the Administrative Procedure Act by issuing the Manufacturer Agreement without following notice-and-comment procedures.

“We review a district court’s grant of summary judgment de novo, construing the evidence in the light most favorable to the nonmoving party and drawing all reasonable inferences in that party’s favor.” *Kuebel v. Black & Decker Inc.*, 643 F.3d 352, 358 (2d Cir. 2011). “Summary judgment is appropriate only if ‘there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.’” *Id.* (quoting Fed. R. Civ. P. 56(a)).

The district court correctly granted summary judgment to the government on all claims. Applying our holding in *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), we conclude that participation in the Negotiation Program is voluntary because there is no legal compulsion to offer products or services through the program. We therefore reject Boehringer’s argument that the Negotiation Program directly violates the company’s rights under the First and Fifth Amendments. Further, we conclude that the program does not *indirectly* violate Boehringer’s constitutional rights under the unconstitutional conditions doctrine because the requirements to which Boehringer objects fall within Congress’s broad power to set the terms of federally funded programs and have no bearing on the company’s activity outside the contours of Medicare and Medicaid. Lastly, we conclude that Boehringer’s APA claim fails because CMS’s issuance of the Manufacturer Agreement fell within the IRA’s exemption from the APA’s notice-and-comment requirement.

A. Whether Participation in the Negotiation Program Is Voluntary

The threshold question underlying Boehringer's direct constitutional claims is whether participation in the Negotiation Program is voluntary. Under *Garelick*, the answer is yes.

In that case, a group of New York hospital-based anesthesiologists challenged a federal law that limited the amount they could charge under Medicare Part B to set percentages of the Medicare-defined "reasonable" charge for their services. The anesthesiologists argued that they were required to treat Medicare patients under New York law and thus had no choice but to submit to the Medicare price regulations. This regulatory scheme, they argued, gave rise to a regulatory taking of their property interests in their licenses and medical practices without just compensation, in violation of the Fifth Amendment.⁶

We affirmed the dismissal of the anesthesiologists' takings claim on the ground that their participation in Medicare was in fact

⁶ "A regulatory taking . . . occurs where even absent a direct physical appropriation, governmental regulation of private property 'goes too far' and is 'tantamount to a direct appropriation or ouster.'" *1256 Hertel Ave. Assocs., LLC v. Calloway*, 761 F.3d 252, 263 (2d Cir. 2014) (quoting *Lingle v. Chevron USA Inc.*, 544 U.S. 528, 537 (2005)). In contrast, "[a] physical taking occurs when there is either a condemnation or a physical appropriation of property." *Id.*

The anesthesiologists in *Garelick* also raised a second takings theory that has no bearing on this case, so we need not address it here. *See Garelick*, 987 F.2d at 916.

voluntary.⁷ We explained that “[a] property owner must be legally compelled to engage in price-regulated activity for regulations to give rise to a taking.” *Garelick*, 987 F.2d at 916 (citing *Bowles v. Willingham*, 321 U.S. 503, 517–18 (1944)). “By contrast,” we continued, “where a service provider voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no taking.” *Id.* Applying these principles, we determined that the anesthesiologists had no viable takings claim because the challenged statute “d[id] not require anesthesiologists, or

⁷ Other circuits have recognized in various contexts that participation in Medicare and Medicaid is voluntary. See, e.g., *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1279–80 (11th Cir. 2014) (explaining that participation in Medicare is voluntary); *Franklin Mem’l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009) (provider participation in Medicaid is voluntary); *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) (“participation in the Medicare program is a voluntary undertaking”); *Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) (“Despite the strong financial inducement to participate in Medicaid, a nursing home’s decision to do so is nonetheless voluntary.”); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (“provider participation [in Medicare] is voluntary”); see also *Nat’l Lifeline Ass’n v. FCC*, 983 F.3d 498, 515 (D.C. Cir. 2020) (“[W]hen an owner of property voluntarily participates in a regulated market, additional regulations that ‘may reduce the value of the property regulated’ do not result in a taking.” (quoting *Bowles*, 321 U.S. at 517)).

Moreover, we recently recognized in the context of a physical takings claim (specifically, a challenge to a New York rent control law) that such a claim cannot succeed when it is premised on a plaintiff’s voluntary participation in a price-regulated market. See *74 Pinehurst LLC v. New York*, 59 F.4th 557, 563 (2d Cir. 2023) (“[W]here . . . property owners *voluntarily* invite third parties to use their properties, regulations of those properties are ‘readily distinguishable’ from those that compel invasions of properties closed to the public.”) (quoting *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 157 (2021)), *cert. denied*, 218 L. Ed. 2d 66 (Feb. 20, 2024).

any other physicians, to provide services to Medicare beneficiaries.” *Id.* The statute “simply limit[ed] the amounts” that the anesthesiologists could “charge those Medicare beneficiaries whom they [chose] to serve.” *Id.* The anesthesiologists “retain[ed] the right to provide medical services to non-Medicare patients free of price regulations.” *Id.*

We rejected the anesthesiologists’ argument that other factors, if not the challenged statute itself, created a legal compulsion to participate in Medicare.⁸ For one, under their theory, it was New York State, a non-party, that “indirectly compel[led] anesthesiologists to treat Medicare patients and thus submit to price regulations, not the federal government.” *Id.* at 917. Moreover, as relevant here, we concluded that “even if the alleged compulsion to serve Medicare patients [in hospitals] were imputed to the federal government,” the anesthesiologists’ takings claim would fail because they could “avoid treating Medicare beneficiaries by practicing on an outpatient basis.” *Id.* Although the anesthesiologists insisted that “limiting themselves to outpatient practices [was] not an economically viable option,” we explained that “economic hardship is not equivalent to legal compulsion for purposes of takings analysis.” *Id.*

⁸ We assumed, without deciding, that New York law required hospitals to treat Medicare patients, but we were not persuaded that the law applied to the anesthesiologists because the statute “does not on its face apply to individual physicians.” *Id.* at 917. We went on to conclude that even if the New York law required hospital-based anesthesiologists to treat Medicare patients, their argument failed for the additional reasons discussed here. *See id.*

Participation in the Negotiation Program, like participation in Medicare as a whole, is voluntary. Nothing in the IRA, or in any other statute, compels pharmaceutical companies to offer products or services through Medicare, via the Negotiation Program or otherwise. Boehringer does not argue to the contrary; instead, it advances an economic hardship argument substantially like the one raised by the anesthesiologists, and rejected by this Court, in *Garelick*. Boehringer contends that the government has employed economic pressure to compel the company's participation in the Negotiation Program on CMS's preferred terms. The company submits that its only alternatives to participation, short of divesting its interest in Jardiance, are to decline to sign the Manufacturer Agreement and incur a significant excise tax on any future sales of Jardiance to Medicare beneficiaries, or withdraw all its products from Medicare and Medicaid.⁹ Putting aside the excise tax, the fact remains that Boehringer can simply opt out of Medicare and Medicaid. Boehringer estimates that if it took that route, it would lose more than half its U.S. net sales. That possibility, Boehringer argues, would bring economic "devastat[ion]," not mere economic hardship, "making any 'choice' to avoid the Program illusory." Appellant's Br. 48, 51. As we observed in *Garelick*, however, the choice to participate in a voluntary government program does not become involuntary simply because the alternatives to participation appear to entail worse, even

⁹ The parties dispute whether the possibility of divestment is relevant for purposes of our Fifth Amendment analysis, but we need not resolve that question given our conclusion that Boehringer's participation in the Negotiation Program is voluntary because no law requires the company to participate in Medicare generally or in the Negotiation Program specifically.

substantially worse, economic outcomes. *See* 987 F.2d at 917; *see also St. Francis Hosp. Ctr.*, 714 F.2d at 875 (“[T]he fact that practicalities may in some cases dictate participation [in Medicare] does not make participation involuntary.”).

The Supreme Court’s analysis in *National Federation of Independent Businesses v. Sebelius* (“*NFIB*”) does not command a different result. 567 U.S. 519 (2012). There, the Court considered a provision of the Affordable Care Act that required states to choose between accepting new Medicaid funding or losing all existing Medicaid funding. The Court held that the provision violated the Spending Clause because it amounted to “economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion.” *Id.* at 519.

Boehringer insists that the Negotiation Program is “similarly coercive.” Appellant’s Br. at 48. But the Supreme Court’s holding in *NFIB* very clearly derived from federalism concerns, i.e., the scope of the federal government’s authority to regulate the states. *See NFIB*, 567 U.S. at 578 (“Permitting the Federal Government to force the States to implement a federal program would threaten the political accountability key to our federal system.”); *id.* (“Spending Clause programs do not [threaten political accountability] when a State has a legitimate choice whether to accept the federal conditions in exchange for federal funds. . . . But when the State has no choice, the Federal Government can achieve its objectives without accountability.”) Such concerns are not present where, as here, the federal government program at issue sets the terms for how the federal government will

pay for goods sold by private parties. *See Northport Health Servs. of Arkansas, LLC v. U.S. Dep’t of Health & Hum. Servs.*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (noting Supreme Court in *NFIB* used “economic dragooning” language “to describe the federal government’s limited constitutional authority under the Spending Clause to regulate the states, not a federal agency’s ability to regulate [private parties’] use of federal funding”) (citation omitted).

Thus, even accepting Boehringer’s argument that the Negotiation Program presents the company with a choice between only bad options—opting into a government program with price controls or bowing out of the program entirely—that choice is nonetheless voluntary.

B. Direct Constitutional Claims

Having determined that participation in the Negotiation Program is voluntary, we now consider Boehringer’s direct constitutional claims in light of that conclusion.

1. Takings Claim

Boehringer argues that the Negotiation Program effects a *per se* physical taking of physical doses of its Jardiance product, in violation of the Takings Clause of the Fifth Amendment.¹⁰ The Takings Clause provides that “private property [shall not] be taken for public use,

¹⁰ Boehringer expressly disclaims any argument that the program effects a regulatory taking. *See* Appellant’s Br. 21 n.6 (“Boehringer has asserted only a *per se* [physical] takings claim.”); *see also id.* at 19 (noting that “regulatory takings claims . . . are not at issue here”).

without just compensation.” U.S. Const. amend. V. “When the government effects a physical appropriation of private property for itself or another—whether by law, regulation, or another means—a *per se* physical taking has occurred.” 74 *Pinehurst LLC*, 59 F.4th at 563. Here, because Boehringer voluntarily chose to participate in the Negotiation Program, no taking has occurred. See *Garelick*, 987 F.2d at 916–17 (“Because they voluntarily choose to provide services in the price-regulated Part B program, the plaintiff anesthesiologists do not have a viable takings claim.”).

Boehringer’s arguments that *Garelick* does not apply are unavailing. First, the company asserts that because that case involved a regulatory takings theory, it is “not ‘controlling precedent’ for Boehringer’s *per se* [physical] takings claim.” Appellant’s Br. 51 (quoting *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg’l Plan. Agency*, 535 U.S. 302, 323 (2002)). It is true that “[i]t is inappropriate to treat cases involving physical takings as controlling precedents for the evaluation of a claim that there has been a regulatory taking, and vice versa.” *Horne v. Dep’t of Agric.*, 576 U.S. 350, 361 (2015) (internal quotation marks omitted). But we agree with the district court that “*Garelick* stands for a broader principle that participation in Medicare is voluntary and conditions placed on such participation therefore cannot constitute a taking.” *Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *14 n.12. Indeed, no part of our analysis in *Garelick* regarding the voluntariness of participation in Medicare implicated the differences between regulatory and physical takings, and Boehringer points to none. Boehringer also argues that, unlike the

plaintiffs in *Garelick*, it is subject to “coercive mechanisms” that give it no choice but to keep participating in Medicare. Appellant’s Br. 51. As discussed above, however, this argument is merely a variation of the economic hardship theory rejected in *Garelick*. See 987 F.3d at 916.

Boehringer also argues that the Supreme Court’s decision in *Horne* undermines the reasoning in *Garelick*. In *Horne*, a family of raisin growers challenged a program by the Department of Agriculture requiring them to set aside a percentage of their raisin crop in certain years for the government, without compensation. 576 U.S. at 355-56. The program, which was intended to maintain a stable raisin market, required raisin growers to “physical[ly] surrender” the raisins and transfer title to the government, which in turn would sell, allocate, or otherwise dispose of the reserve raisins as it deemed appropriate. *Id.* at 354–55, 364. Raisin growers retained only an interest in any net proceeds from sales of the raisins by the government, after deductions for certain expenses. See *id.* at 355. The Supreme Court concluded that the program deprived raisin growers of “the entire ‘bundle’ of property rights in the appropriated raisins . . . with the exception of the speculative hope that some residual proceeds may be left when the Government is done with the raisins and has deducted the expenses of implementing all aspects of the [program].” *Id.* at 361–62. The Court rejected the government’s argument that raisin growers voluntarily chose to participate in the raisin market, and dismissed its suggestion that raisin growers could simply “plant different crops, or sell their raisin-variety grapes as table grapes or for use in juice or wine.” *Id.* at 365 (internal quotation

marks omitted). The Court explained that “[s]elling produce in interstate commerce, although certainly subject to reasonable government regulation, is . . . not a special governmental benefit that the Government may hold hostage.” *Id.* at 366. Boehringer contends that this analysis governs its takings claim because the Negotiation Program appropriates its rights “to possess, use and dispose of” its Jardiance products, and its right to exclude others from possessing those products, by “giv[ing] every Medicare enrollee a right to take possession of Jardiance products on terms set by the Government.” Appellant’s Br. 22 (internal quotation marks omitted) (citing *Horne*, 576 U.S. at 361–62; *Cedar Point Nursery*, 594 U.S. at 149–52).

But *Horne* is materially different from both *Garelick* and this case. Whereas the *Horne* plaintiffs challenged an actual seizure of their personal property (raisins) without compensation, the *Garelick* plaintiffs challenged regulations that merely limited the price they could charge under Medicare. In other words, while the government in *Horne* was directly appropriating the plaintiffs’ property, the government in *Garelick* was setting the price that it would pay for certain services in its commercial capacity.¹¹ It is well established

¹¹ Boehringer argues that the government is not acting as a market participant but instead as a market regulator that is “exercis[ing] [its] sovereign powers by ‘employ[ing] . . . coercive mechanism[s] available to no private party.’” Appellant’s Br. 56 (quoting *Am. Trucking Ass’n v. City of Los Angeles*, 569 U.S. 641, 651 (2013)). Thus, Boehringer argues, “a market-participant theory cannot excuse the Program’s constitutional violations.” *Id.* But in negotiating prices for pharmaceuticals for Medicare beneficiaries, the government acts as a market participant, not a regulator. *Cf. United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 438 F.3d 150, 158 (2d Cir. 2006) (“It is plain that the Authority

that, “[l]ike private individuals and businesses, the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.” *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940); *see also Engquist v. Oregon Dep’t of Agric.*, 553 U.S. 591, 598 (2008) (recognizing that “there is a crucial difference, with respect to constitutional analysis, between the government exercising ‘the power to regulate or license, as lawmaker,’ and the government acting ‘as proprietor’”) (quoting

participates in the marketplace as any other economic actor would when, after having employed its regulatory powers to compel delivery of the waste generated within the Counties to its processing facilities, it contracts with private parties to deliver its processed wastes to landfill sites that meet its requirements.”), *aff’d*, 550 U.S. 330 (2007). Like any other private party seeking to leverage its purchasing power to get a better bargain, the government through the Negotiation Program forces pharmaceutical manufacturers to decide whether to do business according to its terms. *See Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (noting that in its capacity as a market participant, the government may set the terms under which it will purchase goods and services). Although the government acts as a market regulator when it employs tools “that no private actor could wield,” such as civil fines, that activity is “evaluate[d] separately” from its activity as a market participant. *Id.* at 157–58 (internal quotation marks omitted).

Pharmaceutical manufacturers, such as Boehringer, furthermore are not without leverage in these negotiations. While the government has a strong interest in using its purchasing power to drive drug costs down, the Negotiation Program can cover only drugs without generic alternatives, so that the government will be incentivized to reach a deal with drug manufacturers to avoid leaving Medicare beneficiaries without viable substitutes. The ramifications of Boehringer’s withdrawal from Medicare and Medicaid would be significant, and potentially harmful to the Medicare program, in that it would result in 20 drugs falling out of those programs and “more than 1.3 million Americans losing insurance coverage for Jardiance alone.” Chamber of Commerce Amicus Curiae Br. at 15.

Cafeteria & Restaurant Workers v. McElroy, 367 U.S. 886, 896 (1961)). Moreover, the raisin growers in *Horne* faced a choice between surrendering a portion of their raisin crop to the government without compensation as a condition of being able to sell raisins to any buyer, on the one hand, and exiting the raisin market altogether, on the other; by contrast, the physicians in *Garelick* could still offer their full suite of services (or products) to buyers in the private sector even if they withdrew from Medicare. See *Garelick*, 987 F.2d at 916 (noting that the plaintiffs “retain[ed] the right to provide medical services to non-Medicare patients free of price regulations”). Because the two cases required different constitutional analyses, see *Engquist*, 553 U.S. at 598, Boehringer’s argument that *Horne* somehow rejected the reasoning in *Garelick* is not persuasive.

In summary, the district court properly dismissed Boehringer’s takings claim on the ground that participation in Medicare, and thus in the Negotiation Program, is voluntary.

2. Due Process Claim

Boehringer also argues that the Negotiation Program deprives it of constitutionally protected property interests without procedural due process, in violation of the Due Process Clause of the Fifth Amendment. To prevail on a procedural due process claim, Boehringer must “(1) identify a liberty or property interest, (2) show that the state has deprived [it] of that interest, and (3) show that the deprivation was [e]ffected without due process.” *Wheatley v. N.Y. State United Tchrs.*, 80 F.4th 386, 392 (2d Cir. 2023). The threshold

“inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest” in liberty or property. *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). Boehringer asserts that it has protected property interests in: (1) its “physical doses of Jardiance,” (2) the ability to “decid[e] the price at which [it] will sell its Jardiance products,” and (3) “its confidential data regarding Jardiance.” Appellant’s Br. 26–27 (internal quotation marks omitted).

Boehringer’s claim fails because the Negotiation Program does not deprive it of any protected property interest. Although *Garelick* involved a takings claim, our analysis in that context is equally applicable in the context of a due process claim: A company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program.¹² Indeed, several courts have

¹² Boehringer cites the Fifth Circuit’s opinion in *National Infusion Center Association v. Becerra* (“NICA”), 116 F.4th 488 (5th Cir. 2024), in support of its due process argument. In *NICA*, the Fifth Circuit reversed an order dismissing a challenge to the IRA for lack of standing and lack of statutory jurisdiction. In doing so, the court recognized that the plaintiff—a trade association whose members provide infusion treatments for cancer and chronic diseases—had standing to challenge the Negotiation Program because it sufficiently alleged that it had been deprived of an opportunity to protect its concrete interest in “not seeing its members’ revenue decrease as a result of allegedly unconstitutional government action.” *Id.* at 503. But even if the Fifth Circuit correctly decided the standing question, whether a party bringing a due process claim has a “colorable claim” to a protected property interest for purposes of standing is a different question from whether, on consideration of the merits, the party in fact has a protected property interest. *Booker-El v. Superintendent, Ind. State Prison*, 668 F.3d 896, 899–901 (7th Cir. 2012) (holding that for purposes of standing the plaintiff had adequately pleaded an injury-in-fact based on “a substantial risk [of] losing benefits” to which he was allegedly entitled, and then holding that the plaintiff in

dismissed due process claims arising under Medicare and Medicaid on this basis. *See, e.g., Baptist Hosp. E. v. Sec’y of Health & Hum. Servs.*, 802 F.2d 860, 869–70 (6th Cir. 1986) (rejecting due process claim by hospitals seeking reimbursement from Medicare because “participation in the Medicare program is wholly voluntary” and “any obligations are as freely accepted as the benefits”); *Kaiser Found. Health Plan, Inc. v. Burwell*, 147 F. Supp. 3d 897, 911 (N.D. Cal. 2015) (regulation of Medicare Advantage organization’s expenditure of Medicare funds did not violate the organization’s procedural due process rights because “[p]articipation in the Medicare program is a voluntary undertaking”); *Idaho Health Care Ass’n v. Sullivan*, 716 F. Supp. 464, 472 (D. Idaho 1989) (rejecting due process challenge to Medicaid regulations because the plaintiffs voluntarily participated in the program and thereby agreed to “accept imposition of governmental regulation” under the program). Boehringer had the choice to opt out of the Negotiation Program and withdraw from Medicare and Medicaid before the deadlines to sign the Manufacturer Agreement and submit relevant data to CMS, and long before it would begin selling Jardiance products at the “maximum fair price” established during its negotiations with CMS. The company instead chose to participate in the program. That voluntary decision did not give rise to any protected property interest. Accordingly, the district court committed no error in dismissing Boehringer’s due process claim.

fact lacked a protected property interest in those same benefits). In any event, the Fifth Circuit did not address the fact that participation in the Negotiation Program is voluntary, which is dispositive of Boehringer’s claim under *Garelick*.

3. First Amendment Claim

Additionally, Boehringer argues that the Negotiation Program violates its First Amendment right to free speech by compelling it to adopt the government's views as set forth in the Manufacturer Agreement. In particular, Boehringer takes issue with the Manufacturer Agreement's references to "negotiations" and "maximum fair price," and any statement that Boehringer "agree[d]" (that is, voluntarily) to the program's terms. Appellant's Br. 36–38. The company argues that the Negotiation Program does not involve "genuine negotiation" because "the 'severe' consequences for manufacturers that do not reach 'agreement' effectively ensure that manufacturers cannot walk away." *Id.* at 37 (quoting *NICA*, 116 F.4th at 500). The company also "disagrees that the prices set through the Program are 'fair,' much less the 'maximum fair price[s],'" because "the IRA requires prices set through the Program to be at least 25-60% below the market-based rate paid by wholesalers, and CMS must go as far below that ceiling as possible." *Id.* (citing 42 U.S.C. § 1320f-3(b)(1), (c)). Further, Boehringer argues that it did not "agree" to participate in the program, again insisting that it was "coerced into doing so." *Id.* at 38. The company notes that it "signed the Manufacturer Agreement under protest, and only as a means of avoiding even larger penalties." *Id.*

"[T]he First Amendment protects the right to decide what to say and what not to say." *Burns v. Martuscello*, 890 F.3d 77, 84 (2d Cir. 2018) (internal quotation marks omitted). Any "Government action that . . . requires the utterance of a particular message favored by the

Government[] contravenes this essential right.” *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994); *see also* 303 *Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023) (“[T]he government may not compel a person to speak its own preferred messages.”) (citations omitted)). Corporations and individuals equally enjoy the protection of this right. *See Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n of Cal.*, 475 U.S. 1, 16 (1986) (plurality op.) (“For corporations as for individuals, the choice to speak includes within it the choice of what not to say.”); *Citizens United v. Fed. Election Comm’n*, 558 U.S. 310, 343 (2010) (rejecting “the argument that political speech of corporations or other associations should be treated differently under the First Amendment simply because such associations are not natural persons” (internal quotation marks omitted)). A violation of this right occurs only when “the application of the law at issue *actually compels* [] expressive conduct.” *Emilee Carpenter, LLC v. James*, 107 F.4th 92, 96 (2d Cir. 2024) (emphasis added); *see also* *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005) (“[A] violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion.”). To constitute actual compulsion, “the governmental measure must punish, or threaten to punish, protected speech by governmental action that is regulatory, proscriptive, or compulsory in nature.” *Ridgewood Bd. of Educ.*, 430 F.3d at 189 (internal quotation marks omitted).

Boehringer argues that it suffered legal compulsion for purposes of its First Amendment claim because it “could not have withdrawn from the [Negotiation] Program before the deadlines to

sign the Manufacturer Agreement and participate in the negotiation process.” Appellant’s Br. 55 n.25. The company contends that “[t]he IRA suspends the excise tax only when a *manufacturer* terminates its Medicare and Medicaid agreements,” and at the same time delays the effective date of manufacturer withdrawal by eleven to twenty-three months. *Id.* (citing 26 U.S.C. § 5000D(c); 42 U.S.C. § 1395w-114a(b)(4)(B)(ii)). Yet CMS has established a process through which a manufacturer can substantially expedite its withdrawal. Per CMS guidance, when a manufacturer provides notice that it does not intend to participate in the Negotiation Program and wishes to terminate its Medicare and Medicaid agreements, the agency “will automatically grant such termination requests upon receipt,” and “will expedite the effective date of the . . . termination” so that termination occurs thirty days after receipt of the notice. Joint App’x 217.

Boehringer contends that CMS’s expedited termination guidance conflicts with the text of the IRA and thus did not offer a legitimate alternative to participating in the Negotiation Program. But as the district court explained, “[n]othing in the statute prohibits CMS from commencing the 30-day good cause termination process upon receiving a notice from the manufacturer; it simply precludes the manufacturer from opting for the 30-day termination process unilaterally.” *Boehringer*, 2024 WL 3292657, at *9. The statute expressly provides that “[t]he Secretary may provide for termination of an agreement under [the Medicare Coverage Gap Discount Program] for a knowing and willful violation of the requirements of

the agreement or other good cause shown,” 42 U.S.C. § 1395w-114a(b)(4)(B)(i), and that “[t]he Secretary shall provide for termination of an agreement” under the Manufacturer Discount Program for the same reasons, *id.* § 1395w-114c(b)(4)(B)(i). The term “good cause” is “a uniquely flexible and capacious concept, meaning simply a legally sufficient reason.” *United States, ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 429 n.2 (2023) (internal quotation marks omitted). Boehringer does not contest that a manufacturer’s wish to withdraw from the Negotiation Program before it becomes subject to any new obligation or penalty constitutes good cause. Accordingly, Boehringer’s argument that it could not, in fact, withdraw from the Negotiation Program within the thirty-day period offered by CMS is not persuasive.

Because Boehringer’s assent to the Manufacturer Agreement did not occur in the context of actual compulsion, the company suffered no First Amendment violation. *See Corren v. Condos*, 898 F.3d 209, 220 (2d Cir. 2018) (rejecting First Amendment freedom of speech challenge to a campaign public financing program because the plaintiffs voluntarily chose to participate in the program and “remain[ed] free to reject the [program’s] funding . . . if they believe[d] that private financing of their campaigns [would] facilitate greater speech”); *cf. Grove City Coll. v. Bell*, 465 U.S. 555, 575–76 (1984)

(rejecting First Amendment freedom of association claim premised on participation in voluntary government program).¹³

C. Unconstitutional Conditions Claims

In the alternative to its argument that the Negotiation Program directly violates its rights under the First and Fifth Amendments, Boehringer contends that even if the program were voluntary, the program indirectly violates the company's rights by imposing unconstitutional conditions on its ability to participate in Medicare and Medicaid.

The unconstitutional conditions doctrine prevents the government from "burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013). Put differently, the government may not produce indirectly "a result which [it] could not command directly," *Speiser v. Randall*, 357 U.S. 513, 526 (1958), by requiring a regulated party to give up its constitutional rights in exchange for a government benefit. This occurs when, for example, the government places "a condition on the *recipient* of the [benefit] rather than on a particular program or service, thus effectively prohibiting the recipient from engaging in the

¹³ Having disposed of Boehringer's First Amendment claim on the grounds explained above, we need not address the government's contention that the Manufacturer Agreement explicitly excludes any interpretation to the effect that it expresses views of Boehringer.

protected conduct outside the scope of the federally funded program.” *Rust v. Sullivan*, 500 U.S. 173, 197 (1991).

The Supreme Court has applied this “overarching principle” of constitutional law in “a variety of contexts.”¹⁴ *Koontz*, 570 U.S. at 604 (collecting cases). The doctrine applies even when a party has no right to the benefit at issue—that is, even when a party voluntarily participates in a government program. Indeed, the Supreme Court recognized in *Koontz* that “[v]irtually all of [its] unconstitutional conditions cases involve a gratuitous governmental benefit of some kind,” and that it has “repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights.” 570 U.S. at 608; *see also O’Connor v. Pierson*, 426 F.3d 187, 201 (2d Cir. 2005) (“It is settled law that the government may not, as a general rule, grant even a gratuitous benefit on condition that the beneficiary relinquish a constitutional right.”) (internal quotation marks omitted).

Supreme Court precedent makes clear that laws establishing conditions on spending under federally funded programs without implicating recipients’ activity in the private market do not run afoul of the unconstitutional conditions doctrine. For example, in *Regan v.*

¹⁴ The government contends that Boehringer offers no support for applying the doctrine when, as here, the government contracts for goods. The cases on which Boehringer relies, the government submits, involved plaintiffs who, unlike Boehringer, were either a beneficiary of discretionary benefits or a government employee or independent contractor. We need not decide whether the doctrine is so limited, however, because we conclude that the Negotiation Program withstands scrutiny under the doctrine in any event.

Taxation With Representation of Washington, the Supreme Court upheld a regulation prohibiting nonprofit organizations seeking tax-exempt status under 26 U.S.C. § 501(c)(3) from engaging in lobbying. 461 U.S. 540, 543–44 (1983). “In rejecting the nonprofit’s First Amendment claim, the Court highlighted . . . the fact that the condition did not prohibit that organization from lobbying Congress altogether.” *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.* (“USAID”), 570 U.S. 205, 215 (2013) (discussing *Regan*). The nonprofit had the option to divide its operations between “a § 501(c)(3) organization for non-lobbying activities and a § 501(c)(4) organization for lobbying,” the Court explained. *Regan*, 461 U.S. at 544. Put simply, Congress did not completely prevent the nonprofit from lobbying; it “merely refused to pay for the lobbying out of public monies.” *Id.* at 545.

Similarly, in *Rust v. Sullivan*, the Supreme Court considered a challenge to HHS regulations implementing Title X of the Public Health Service Act. 500 U.S. at 177–78. Title X authorizes HHS to make grants to nonprofit healthcare organizations “to assist in the establishment and operation of voluntary family planning projects [to] offer a broad range of acceptable and effective family planning methods and services.” *Id.* at 178 (internal quotation marks omitted). The statute prohibits the funds from being “used in programs where abortion is a method of family planning.” *Id.* (internal quotation marks omitted). The challenged regulations prohibited Title X from “provid[ing] counseling concerning the use of abortion as a method of family planning or provid[ing] referral for abortion,” and from “engaging in activities that encourage, promote or advocate abortion

as a method of family planning.” *Id.* at 179–80 (internal quotation marks omitted). The regulations also “require[d] that Title X projects be organized so that they are physically and financially separate from prohibited abortion activities.” *Id.* at 180 (internal quotation marks omitted). The Supreme Court rejected the challenge to these regulations, explaining that the regulations governed only the scope of a grantee’s Title X projects, leaving it “unfettered in its other activities.” *Id.* at 196. Because the regulations did not “prohibit[] the recipient from engaging in the protected conduct outside the scope of the federally funded program,” the Court reasoned, the regulations did not violate the First Amendment. *Id.* at 197.

In *FCC v. League of Women Voters of California*, on the other hand, the Supreme Court invalidated a statutory provision that forbade noncommercial broadcast television and radio stations to engage in any editorializing, including with private funds, if the stations received any federal grants. 468 U.S. 364, 399–401 (1984). The Court explained that in contrast to the situation faced by the plaintiff charitable organization in *Regan*, which remained free to use private funds without restriction, the broadcasting stations covered by the blanket ban on editorializing were “barred from using even wholly private funds to finance [their] editorial activity.” *Id.* at 400.

As the Supreme Court observed in *USAID*, “the relevant distinction that has emerged from [the Court’s unconstitutional conditions] cases is between conditions that define the limits of the government spending program—those that specify the activities Congress wants to subsidize—and conditions that seek to leverage

funding to regulate speech outside the contours of the program itself.” 570 U.S. at 214–15. Although this distinction emerged in First Amendment cases, the same core logic applies with equal force in other constitutional contexts: Congress has considerable authority to impose reasonable conditions on parties’ conduct within the four corners of federally funded programs, but it may not condition parties’ ability to participate in such programs on compliance with conditions that burden the parties’ constitutionally protected conduct beyond those programs.¹⁵

The Negotiation Program does not impose unconstitutional conditions on Boehringer’s rights under the First and Fifth Amendments. The program simply establishes a price structure to limit CMS’s costs for certain high-expenditure drugs. Whatever its merits as a matter of policy, the program is plainly related to the government’s legitimate goal of controlling Medicare costs. Moreover, the program applies only to sales of the selected drugs that occur within the four corners of Medicare; it does not regulate Boehringer’s sales of Jardiance in the private market. Accordingly,

¹⁵ With respect to the unconstitutional conditions analysis of its takings claim, Boehringer argues that we should apply the nexus-and-proportionality test set forth in *Dolan v. City of Tigard*, 512 U.S. 374 (1994), and *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987). The Supreme Court has applied that test only in “the special context of exactions—land-use decisions conditioning approval of development on the dedication of property to public use,” and has explained that the test “was not designed to address, and is not readily applicable to, . . . much different questions arising [in other contexts].” *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702–03 (1999). We see no basis for extending the nexus-and-proportionality test to the wholly different context here. This case has nothing to do with land use permitting, let alone excessive exactions.

the program is a lawful exercise of Congress's spending power under the statute.

D. APA Claim

Lastly, Boehringer argues that CMS violated the APA by issuing the Manufacturer Agreement without providing the public notice and an opportunity to comment. The APA requires "legislative rule[s]" that "impose legally binding obligations . . . on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements"—to undergo a notice-and-comment process. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014); *see also White v. Shalala*, 7 F.3d 296, 303–04 (2d Cir. 1993). This requirement also generally applies to government "contract provisions that are legislative." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1054 (D.C. Cir. 1987). But the APA provides that a subsequent statute may supersede the APA's rulemaking provisions, including the notice-and-comment requirement, provided that the subsequent statute "does so expressly." 5 U.S.C. § 559. Courts have emphasized that exemptions from the APA's rulemaking requirements "are not lightly to be presumed in view of the statement in [the APA] that modifications must be express." *Asiana Airlines v. Fed. Aviation Admin.*, 134 F.3d 393, 397 (D.C. Cir. 1998) (quoting *Marcello v. Bonds*, 349 U.S. 302, 310 (1955)). An exemption is express when Congress "has established procedures so clearly different from those required by the APA that it must have intended to displace the norm." *Id.*

The IRA expressly exempts CMS from the APA’s rulemaking requirements, including the notice-and-comment requirement, with respect to the Negotiation Program, including the Manufacturer Agreement, through 2028. Specifically, the IRA states that CMS “shall implement this section . . . for 2026, 2027, and 2028 by program instruction or other forms of program guidance.” IRA § 11001(c), 136 Stat. at 1854. This section and others that authorize the use of guidance stand in contrast to the provisions that expressly require the promulgation of rules, which strongly indicates that Congress displaced the APA’s requirements for certain provisions of the IRA. *Compare id.* § 11003, 136 Stat. at 1864 (stating that “[t]he Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section,” which establishes the excise tax), *with id.* § 11201, 136 Stat. at 1892 (providing for the implementation of a subsidy program “for 2024, 2025, and 2026 by program instruction or other forms of program guidance”). Moreover, the fact that Section 11001 authorizes the use of guidance only for the program’s first three pricing periods underscores that Congress made a deliberate decision to authorize an exemption (albeit temporary) from the APA’s requirements. And although Boehringer argues that, in any event, Section 11001 does not encompass the Manufacturer Agreement, that argument is unpersuasive because Section 11001 sets forth the provisions governing CMS’s implementation of the agreement. *See id.* § 11001(c), 136 Stat. at 1841–42 (codified at 42 U.S.C. § 1320f-2).

III. Conclusion

In summary, we hold:

1. Participation in the Negotiation Program is voluntary because there is no legal compulsion to offer products or services through the program.

2. Because participation in the Negotiation Program is voluntary, the program neither effects an unlawful taking or deprivation of property interests under the Fifth Amendment nor compels speech in violation of the First Amendment.

3. The Negotiation Program does not violate the unconstitutional conditions doctrine because the program is designed to promote the legitimate government purpose of controlling Medicare spending and does not regulate conduct outside the scope of Medicare and Medicaid.

4. CMS's issuance of the Manufacturer Agreement fell within the IRA's exemption from the APA's notice-and-comment requirement.

For the foregoing reasons, we AFFIRM the district court's judgment.

**United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007**

DEBRA ANN LIVINGSTON
CHIEF JUDGE

CATHERINE O'HAGAN WOLFE
CLERK OF COURT

Date: August 7, 2025

Docket #: 24-2092

Short Title: Boehringer Ingelheim Pharmaceuticals, Inc. v.
United States Department of Health and Human Services

DC Docket #: 3:23-cv-1103

DC Court: DISTRICT OF
CONNECTICUT (NEW HAVEN)

DC Judge: Trial Judge - Michael P.
Shea

BILL OF COSTS INSTRUCTIONS

The requirements for filing a bill of costs are set forth in FRAP 39. A form for filing a bill of costs is on the Court's website.

The bill of costs must:

- * be filed within 14 days after the entry of judgment;
- * be verified;
- * be served on all adversaries;
- * not include charges for postage, delivery, service, overtime and the filers edits;
- * identify the number of copies which comprise the printer's unit;
- * include the printer's bills, which must state the minimum charge per printer's unit for a page, a cover, foot lines by the line, and an index and table of cases by the page;
- * state only the number of necessary copies inserted in enclosed form;
- * state actual costs at rates not higher than those generally charged for printing services in New York, New York; excessive charges are subject to reduction;
- * be filed via CM/ECF or if counsel is exempted with the original and two copies.

**United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007**

DEBRA ANN LIVINGSTON
CHIEF JUDGE

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CONNECTICUT (NEW HAVEN)

DC Judge: Trial Judge - Michael P.
Shea

VERIFIED ITEMIZED BILL OF COSTS

Counsel for

respectfully submits, pursuant to FRAP 39 (c) the within bill of costs and requests the Clerk to
prepare an itemized statement of costs taxed against the

and in favor of

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(VERIFICATION HERE)

Signature

**UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT**

At a Stated Term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 7th day of August, two thousand twenty-five.

Before: Pierre N. Leval,
Joseph F. Bianco,
William J. Nardini,
Circuit Judges.

Boehringer Ingelheim Pharmaceuticals, Inc.,

Plaintiff - Appellant,

v.

United States Department of Health and Human
Services, Robert F. Kennedy, Jr., in his official
capacity as Secretary of Health and Human
Services, Centers for Medicare and Medicaid
Services, Mehmet Oz, in his official capacity as
Administrator of Centers for Medicare and
Medicaid Services,

Defendants - Appellees.



JUDGMENT

Docket No. 24-2092

The appeal in the above captioned case from a judgment of the United States District Court for the District of Connecticut was argued on the district court's record and the parties' briefs.

IT IS HEREBY ORDERED, ADJUDGED and DECREED that the district court's judgment is AFFIRMED.

For the Court:
Catherine O'Hagan Wolfe,
Clerk of Court



U.S. Department of Health and Human Services

Enhancing the health and well-being of all Americans



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FOR IMMEDIATE RELEASE

August 29, 2023

Contact: HHS Press Office

202-690-6343

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HHS Selects the First Drugs for Medicare Drug Price Negotiation

For the first time, Medicare will be able to negotiate prices directly with drug companies, lowering prices on some of the costliest prescription drugs.

For the first time, thanks to President Biden's Inflation Reduction Act – the historic law lowering health care costs – Medicare is able to negotiate the prices of prescription drugs. Today, the U.S. Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), announced the first 10 drugs covered under Medicare Part D selected for negotiation. The negotiations with participating drug companies will occur in 2023 and 2024, and any negotiated prices will become effective beginning in 2026. Medicare enrollees taking the 10 drugs covered under Part D selected for negotiation paid a total of \$3.4 billion in out-of-pocket costs in 2022 for these drugs.

"For far too long, pharmaceutical companies have made record profits while American families were saddled with record prices and unable to afford life-saving prescription drugs. But thanks to the landmark Inflation Reduction Act, we are closer to reaching President Biden's goal of increasing availability and lowering prescription drug costs for all Americans," said HHS Secretary Xavier Becerra. "Although drug companies are attempting to block Medicare from being able to negotiate for better drug prices, we will not be deterred. The Biden-Harris Administration will continue working to ensure that Americans with Medicare have access to innovative, life-saving treatments at lower costs."

The Biden-Harris Administration has made lowering prescription drug costs and improving access to innovative therapies a key priority. Alongside other provisions in the new law that increase the affordability of health care and prescription drugs, allowing Medicare to negotiate prescription drug prices will strengthen the program's ability to serve people with Medicare now and for generations to come. The negotiation process will consider the selected drug's clinical benefit, the extent to which it fulfills an unmet medical need, and its impact on people who rely on Medicare, among other considerations, such as costs associated with research and development as well as production and distribution for selected drugs. As a result of negotiations, people with Medicare will have access to innovative, life-saving treatments at lower costs to Medicare.

The selected drug list for the first round of negotiation is:

- Eliquis
- Jardiance
- Xarelto
- Januvia
- Farxiga
- Entresto
- Enbrel
- Imbruvica
- Stelara
- Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill

These selected drugs accounted for \$50.5 billion in total Part D gross covered prescription drug costs, or about 20%, of total Part D gross covered prescription drug costs between June 1, 2022 and May 31, 2023, which is the time period used to determine which drugs were eligible for negotiation. CMS will publish any agreed-upon negotiated prices for the selected drugs by September 1, 2024; those prices will come into effect starting January 1, 2026. In

future years, CMS will select for negotiation up to 15 more drugs covered under Part D for 2027, up to 15 more drugs for 2028 (including drugs covered under Part B and Part D), and up to 20 more drugs for each year after that, as outlined in the Inflation Reduction Act.

View a fact sheet from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at: <https://aspe.hhs.gov/reports/aspe-ira-drug-negotiation-fact-sheet>.

View a CMS fact sheet on the drugs selected for the Medicare Drug Price Negotiation Program at: <https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf> - PDF.

More information on the Medicare Drug Price Negotiation Program is available at <https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation>.

###

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no. 24-2092,
archived on 8/7/2025

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: March 15, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

10. Introduction

The purpose of this memorandum is to provide interested parties with initial guidance regarding implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA) (P.L. 117-169), signed into law on August 16, 2022, which establish the Medicare Drug Price Negotiation Program (hereafter the “Negotiation Program”) to negotiate maximum fair prices (MFPs)¹ for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereafter “the Act”) as added by sections 11001 and 11002 of the IRA.

Sections 11001(c) and 11002(c) of the IRA direct the Secretary to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing this initial guidance for implementation of the Negotiation Program for initial price applicability year 2026. CMS is also voluntarily soliciting comment on certain topics in this memorandum where noted.² Please send comments pertaining to this memorandum to IRAREbateandNegotiation@cms.hhs.gov with the following subject line “Medicare Drug Price Negotiation Program Guidance.” Comments received by April 14, 2023

¹ In accordance with section 1191(c)(3) of the Social Security Act, (“the Act”), maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

² Because the Treasury Department and the Internal Revenue Service (IRS) anticipate issuing guidance separate from this document regarding the administration of the excise tax, CMS is not soliciting comment on section 90.3.

will be considered. CMS will issue revised guidance for initial price applicability year 2026 after considering the public comments received in response to this initial guidance.

In order to facilitate the timely implementation of the Negotiation Program, CMS is issuing guidance on section 30 of this memorandum as final, without a comment solicitation (with the exception of the Small Biotech Exception Information Collection Request (ICR) for which comments should be made in response to the ICR, as discussed in section 30.2.1 of this memorandum). This guidance is not subject to the notice-and-comment requirement of the Administrative Procedure Act or the Medicare statute, due to the Congressional direction in section 11001(c) of the IRA to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. Moreover, to the extent that this guidance establishes or changes any substantive legal standard, CMS finds that notice and public procedure on this guidance would be impracticable, unnecessary, and contrary to the public interest, in light of this Congressional direction and in light of the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by September 1, 2023. There is accordingly good cause to issue those parts of this guidance that are final (i.e., section 30), without public comment and without a delayed effective date. 5 U.S.C. § 553(b)(B) & (d)(3); *see also* section 1871(b)(2)(C) of the Act.

In the revised guidance, CMS may make changes to any policies, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issues.

This initial guidance describes how CMS intends to implement the Negotiation Program for initial price applicability year 2026 (January 1, 2026 to December 31, 2026), and specifies the requirements that will be applicable to manufacturers of Medicare Part D drugs that are selected for negotiation and the procedures that may be applicable to manufacturers of Medicare Part D drugs, Medicare Part D plans (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs)), and providers and suppliers (including retail pharmacies) that furnish Medicare Part D drugs.

The table of contents for this memorandum is as follows:

- Section 10 – Introduction
- Section 20 – Overview
- Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2026
 - 30.1 Identification of Qualifying Single Source Part D Drugs for Initial Price Applicability Year 2026
 - 30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs
 - 30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs
 - 30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs
 - 30.2 Identification of Negotiation-Eligible Part D Drugs for Initial Price Applicability Year 2026
 - 30.2.1 Exception for Small Biotech Drugs

- 30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026
 - 30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry
 - 30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026
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 - 30.3.1.3 Submitting an Initial Delay Request for Initial Price Applicability Year 2026
 - 30.3.1.4 Process and Timing After Submission of an Initial Delay Request for Initial Price Applicability Year 2026
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- 60.6 Publication of the MFP
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- Appendix A – Email Template for Biosimilar Manufacturer to Indicate Intent to Submit an Initial Delay Request for Initial Price Applicability Year 2026
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20. Overview

In accordance with sections 11001 and 11002 of the IRA, which created Part E under Title XI of the Act (sections 1191 through 1198), the Secretary of the Department of Health and Human Services is required to establish the Negotiation Program to negotiate MFPs for certain high expenditure, single source Medicare drugs. With respect to each initial price applicability year, CMS shall (1) publish a list of selected drugs in accordance with section 1192 of the Act; (2) enter into agreements with manufacturers of selected drugs in accordance with section 1193 of the Act; (3) negotiate and, if applicable, renegotiate MFPs for such selected drugs, in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) enforce civil monetary penalties (CMPs) in accordance

with section 1197 of the Act. Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

As noted above, in order to facilitate the timely implementation of the Negotiation Program, CMS is issuing guidance in section 30 of this memorandum as final, without a comment solicitation (with the exception of the Small Biotech Exception ICR, as discussed in section 30.2.1 of this memorandum). To allow for public input, CMS is voluntarily soliciting comments on all other sections except for section 90.3 (which states that the Treasury Department and the IRS anticipate issuing separate guidance on the administration of the excise tax), and specifically on certain topics in this memorandum, including:

- Terms and conditions contained in the manufacturer agreement, including the manufacturer's and CMS' responsibilities (included in section 40 of this memorandum);
- Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments (included in section 60 of this memorandum);
- Process for the offer and counteroffer exchange between CMS and manufacturers (included in section 60 of this memorandum);
- Content of an explanation for the MFP (included in section 60 of this memorandum);
- Method for applying the MFP across different dosage forms and strengths of a selected drug (included in section 60 of this memorandum);
- Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198 (included in section 60 of this memorandum); and
- Processes for compliance monitoring and imposition of CMPs for violations (included in section 90 of this memorandum).

More specific comment solicitations are included in certain sections of the memorandum. Topics that are not relevant to the Negotiation Program for initial price applicability year 2026, such as the selection of Medicare Part B drugs and renegotiation, will not be addressed in the guidance issued by CMS for initial price applicability year 2026. CMS will provide additional information in the future related to implementation for initial price applicability years 2027 and beyond.

30. Identification of Selected Drugs for Initial Price Applicability Year 2026

In order to facilitate the timely implementation of the Negotiation Program in accordance with statutory deadlines, CMS is issuing the guidance in this section 30 as final, without a comment solicitation (with the exception of the Small Biotech Exception ICR, as discussed in section 30.2.1 of this memorandum).

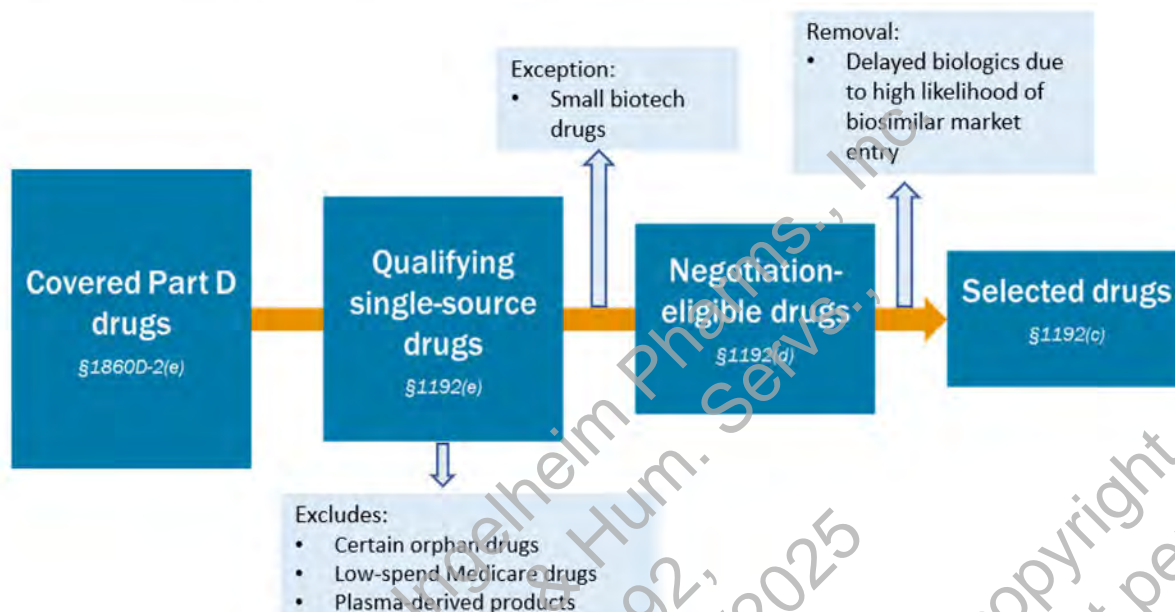
Section 1192 of the Act establishes the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs for an initial price applicability year. First, CMS will identify qualifying single source drugs in accordance with section 1192(e) of the Act, as described in section 30.1 of this memorandum. CMS will exclude certain drugs as required under the law. Next, in accordance with section

1192(d) of the Act, using Total Expenditures³ under Part D of Title XVIII for these qualifying single source drugs calculated using Part D prescription drug event (PDE) data for dates of service between June 1, 2022, and May 31, 2023, and other information described below, CMS will identify negotiation-eligible drugs for initial price applicability year 2026 as described in section 30.2 of this memorandum (in this step, CMS will also exclude certain drugs as required under the law).

In accordance with section 1192(d)(1) of the Act, CMS will rank negotiation-eligible drugs for initial price applicability year 2026 according to the Total Expenditures for such drugs under Part D of Title XVIII for the 12-month period described above (detailed in section 30.3 of this memorandum). In accordance with section 1192(a) of the Act and subject to the Special Rule to delay the selection and negotiation of biologics for biosimilar market entry described in section 1192(f) of the Act, CMS will select the 10 negotiation-eligible Part D drugs with the highest Total Expenditures under Part D of Title XVIII for negotiation for initial price applicability year 2026 (described in section 30.3 of this memorandum) and publish a list of those ten selected drugs not later than September 1, 2023 (described in section 30.4 of this memorandum). Figure 1 provides a visual depiction of this process, and detailed guidance pertaining to this process for initial price applicability year 2026 is included below.

³ For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) as total gross covered prescription drug costs (as defined in section 1860D-15(b)(3)). The term gross covered prescription drug costs is also defined in the Part D regulations at 42 CFR § 423.308. CMS has proposed to update this regulatory definition of gross covered prescription drug costs to eliminate any potential ambiguity in the regulation text and help to ensure there is a consistent understanding of the term for purposes of both the Part D program and the IRA. (See 87 FR 79611 through 79613, Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule).

Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2026



30.1 Identification of Qualifying Single Source Part D Drugs for Initial Price Applicability Year 2026

In accordance with section 1192(e)(1) of the Act, CMS will define a qualifying single source Part D drug as a covered Part D drug (as defined in section 1860D-2(e) of the Act) that meets the following criteria:

- For drug products, a qualifying single source drug is a drug (1) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and marketed pursuant to such approval; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the date of such approval; and (3) that is not the listed drug for any drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act.
- For biological products, a qualifying single source drug is a biological product (1) that is licensed under section 351(a) of the Public Health Service Act (PHS Act) and marketed pursuant to such licensure; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 11 years have elapsed since the date of such licensure; and (3) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act.

Section 1192(d)(3)(B) of the Act states that CMS shall use data that are aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation, package size, or

package type of the drug for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug under section 1192(d)(1) of the Act and applying the exception for small biotech drugs under section 1192(d)(2) of the Act.

Identifying potential qualifying single source drugs:

In accordance with the statutory language cited above, for purposes of the Negotiation Program, CMS will identify a potential qualifying single source drug using:

- For drug products, all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA)⁴, inclusive of products that are marketed pursuant to different NDAs. The potential qualifying single source drug will also include all dosage forms and strengths of the drug with the same active moiety and marketed pursuant to the same NDA(s) described in the prior sentence that are: (1) repackaged and relabeled products that are marketed pursuant to such NDA(s), (2) authorized generic drugs that are marketed pursuant to such NDA(s), and (3) multi-market approval (MMA) products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s);
- For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA)⁵, inclusive of products that are marketed pursuant to different BLAs. The potential qualifying single source drug will also include all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s) described in the prior sentence that are: (1) repackaged and relabeled products that are marketed pursuant to such BLA(s), (2) authorized biologic products that are marketed pursuant to such BLA(s), and (3) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such BLA(s).

As an example, entity A holds three NDAs for drug products with the same active moiety approved in NDA-1, NDA-2, and NDA-3. Entity A manufactures and markets three different strengths as an immediate release tablet pursuant to NDA-1, three different strengths as an extended release tablet pursuant to NDA-2, and three different strengths as a subcutaneous injectable pursuant to NDA-3. Additionally, entity B repackages three strengths of the immediate release tablets manufactured by entity A and markets them pursuant to NDA-1. In this scenario, all 12 of these drug products, including the repackaged products, will be aggregated as a single potential qualifying single source drug for purposes of identifying negotiation-eligible drugs.

This approach to identifying a potential qualifying single source drug aligns with the requirement in section 1192(d)(3)(B) of the Act to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug. Consistent with this statutory instruction, this approach is also appropriate because the agency is aware that new dosage forms or different routes of administration of the same active moiety / active ingredient have been submitted by the same NDA/BLA holder and approved under different NDAs or BLAs.

⁴ As described in section 505(c) of the FD&C Act.

⁵ As described in 351(a) of the PHS Act.

Section 1192(e)(2)(A) of the Act states that an authorized generic drug and the qualifying single source drug that is the listed drug or reference product of that authorized generic drug shall be treated as the same qualifying single source drug. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act as (1) in the case of a drug product, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act), and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act⁶ and is marketed, sold, or distributed, directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trade mark.

If a drug is a fixed combination drug⁷ with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying qualifying single-source drugs. Therefore, all formulations of this distinct combination offered by the same NDA/BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not both) of the active moieties / active ingredients that is offered by the same NDA/BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate potential qualifying single source drug. For example, a long acting corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA/BLA holder that contains the same corticosteroid combined with a long acting beta agonist. In this example, the long acting corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

Applying statutory criteria for qualifying single source drugs:

In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, at least 7 years (for drug products) or 11 years (for biological products) must have elapsed between the U.S. Food and Drug Administration (FDA) date of approval or licensure, as applicable, and the selected drug publication date. To determine the date of approval or licensure for a potential qualifying single source drug with more than one FDA application number, CMS intends to use the earliest date of approval or licensure of the initial FDA application number assigned to the NDA/BLA holder for the active moiety / active ingredient, or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients. The selected drug publication date for initial price applicability year 2026 is September 1, 2023, as specified in section 1191(d)(1) of the Act. As such, for initial price applicability year 2026, the initial approval for a drug product to be considered a qualifying single source drug must have been on or before September 1, 2016, and the date of initial licensure for a biological product to be considered a qualifying single source drug must have been on or before September 1, 2012.

⁶ CMS is interpreting the reference to “licensed under section 351(a) of such Act” to mean licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.

⁷ For purposes of the Negotiation Program, the term “fixed combination drug” has the meaning specified in 21 CFR 300.50.

For example, if 12 years had elapsed between the original approval for NDA-1 cited in the previous example above and September 1, 2023, then the potential qualifying single source drug defined above would meet this statutory criterion for qualifying single source drugs (even if less than seven years had elapsed between the approval dates for NDA-2 or NDA-3 and September 1, 2023).

In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, a product cannot be the listed drug for any drug approved and marketed under an ANDA under section 505(j) of the FD&C Act, and a biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act. CMS will use FDA reference sources, including the Orange Book⁸ and Purple Book⁹, to determine whether a generic drug or biosimilar biological product has been approved or licensed for any of the strengths or dosage forms of the potential qualifying single source drugs for initial price applicability year 2026.

In accordance with section 1192(c) and (e) of the Act for the purpose of identifying qualifying single source drugs for initial price applicability year 2026, CMS will review PDE data for a given generic drug or biosimilar biological product during the 12-month period beginning August 16, 2022 and ending August 15, 2023—using PDE data available on August 16, 2023, and will consider a generic drug or biosimilar biological product to be marketed when that data reveal that the manufacturer of that drug or product has engaged in bona fide marketing of that drug or product. CMS has chosen this time period to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list published on September 1, 2023 in accordance with section 1192(a) of the Act.

If any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar biological products that CMS determines are approved and marketed based on the process described above, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026. CMS will monitor the manufacturers of generics or biosimilar biological products to ensure they are engaging in bona fide marketing of the generic or biosimilar biological product (see section 90.4 of this memorandum for details).

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(A) of the Act, CMS will exclude certain orphan drugs when identifying qualifying single source drugs, referred to as the orphan drug exclusion. Specifically, CMS will exclude a drug or biological product that is designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and that is approved for only an indication (or indications) for such disease or condition. To be considered for the orphan drug exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and (2) be approved by the FDA only

⁸ <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>

⁹ <https://purplebooksearch.fda.gov/>

for one or more indications within such designated rare disease or condition. In order to qualify for the orphan drug exclusion, all dosage forms and strengths and different formulations of the qualifying single source drug described in section 30.1 of this memorandum must meet the criteria for exclusion. CMS will use the FDA Orphan Drug Product designation database¹⁰ and approvals on the FDA website¹¹ to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the orphan drug exclusion. CMS will also consult with FDA as needed. CMS is considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development.

30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(B) of the Act, CMS will also exclude low-spend Medicare drugs with less than \$200,000,000 in combined expenditures under Medicare Parts B and D when identifying qualifying single source drugs. For initial price applicability year 2026, CMS will identify low-spend Medicare drugs as follows:

- CMS will identify Part D PDE data combined with Part B claims data for each potential qualifying single source drug for dates of service during the 12-month period beginning June 1, 2022, and ending May 31, 2023. To allow a reasonable amount of time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that have been submitted no later than 30 days after May 31, 2023, i.e., by June 30, 2023. To allow a reasonable amount of time for providers and suppliers to submit Part B claims, CMS will use Part B claims data for the dates of service described above that have been submitted no later than 30 days after May 31, 2023, i.e. by June 30, 2023.
- For each potential qualifying single source drug as described in section 30.1 of this memorandum, CMS will use the PDE data to calculate the Total Expenditures under Part D and CMS will use the Part B claims data to calculate the total allowed charges, inclusive of beneficiary cost sharing under Part B.
- CMS will exclude from the final list of qualifying single source drugs for initial price applicability year 2026 any drugs for which the sum of Total Expenditures under Part D and total allowed charges, inclusive of beneficiary cost sharing, under Part B are less than \$200 million.

30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(C) of the Act, CMS will exclude plasma-derived products when identifying qualifying single source drugs as described in section 30.1 of this memorandum. For purposes of this exclusion, a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling. CMS will refer to product information available on the FDA Approved Blood Products

¹⁰ <https://www.accessdata.fda.gov/scripts/opdlisting/ood/>

¹¹ Drugs at FDA: <https://www.accessdata.fda.gov/scripts/cder/daf/>

website¹² to identify approved blood products regulated as biological products and the FDA Online Label Repository¹³ to verify if the product is derived from human whole blood or plasma. CMS will also consult with FDA as needed.

30.2 Identification of Negotiation-Eligible Part D Drugs for Initial Price Applicability Year 2026

In accordance with section 1192(d)(1) of the Act, a negotiation-eligible drug for initial price applicability year 2026 is a qualifying single source drug that is among the 50 qualifying single source drugs with the highest Total Expenditures under Part D. CMS will identify the negotiation-eligible drugs for initial price applicability year 2026 as follows:

- CMS will identify all covered Part D drugs that are qualifying single source drugs for initial price applicability year 2026 using the process described in section 30.1 of this memorandum. CMS will exclude any drugs that qualify for the exclusions listed in sections 30.1.1 – 30.1.3 of this memorandum.
- CMS will identify Part D PDE data for each qualifying single source drug for dates of service during the applicable 12-month period beginning June 1, 2022 and ending May 31, 2023. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that have been accepted no later than 30 days after May 31, 2023, i.e., by June 30, 2023.
- CMS will use this PDE data to calculate the Total Expenditures under Part D for each qualifying single source drug during the 12-month applicable period.
- CMS will (1) remove drugs that are subject to the exception for small biotech drugs, discussed in section 30.2.1 of this memorandum; (2) rank the remaining qualifying single source drugs by Total Expenditures under Part D during the applicable 12-month period; and (3) identify the 50 qualifying single source drugs that have the highest Total Expenditures under Part D during the applicable 12-month period.
- These 50 drugs will be considered negotiation-eligible drugs for initial price applicability year 2026.

When two or more qualifying single source drugs have the same Total Expenditures to the dollar under Part D, and such Total Expenditures are the 50th highest among qualifying single source drugs, CMS will rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, for the initial FDA application number with its active moiety(ies) / active ingredient(s), until CMS has identified 50 negotiation-eligible drugs. CMS believes that this approach would not be likely to alter which drugs are selected drugs because a maximum of 10 drugs will be selected for initial price applicability year 2026 (see section 30.3 of this memorandum for details).

30.2.1 Exception for Small Biotech Drugs

In accordance with section 1192(d)(2) of the Act, the term “negotiation-eligible drug” excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source

¹² <https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products>

¹³ <https://labels.fda.gov/>

drug that meets the requirements for the exception for small biotech drugs (“the Small Biotech Exception”). The statute requires that CMS consider, for Part D drugs, Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures for the qualifying single source drug under Part D during 2021, and Total Expenditures under Part D for all covered Part D drugs for which the manufacturer that had a Coverage Gap Discount Program agreement (CGDP agreement) in effect under section 1860D-14A of the Act for the qualifying single source drug during 2021 also had a CGDP agreement in effect during 2021.¹⁴ To identify and exclude such small biotech drugs, CMS will consider whether, for dates of services in calendar year 2021, the Total Expenditures under Part D for the qualifying single source drug (1) were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and (2) were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer of the drug had a CGDP agreement in effect during 2021. The Total Expenditures used in this calculation will not include any expenditures for products of repackers and relabelers who had CGDP agreements for the qualifying single source drug during 2021 subject to the aggregation rule at section 1192(d)(2)(B)(i) of the Act discussed below.

For the purposes of the Small Biotech Exception for initial price applicability year 2026, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all entities that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 with the entity that had the CGDP agreement for the qualifying single source drug on that date. However, CMS does not have information about which entities were treated as a single employer under the applicable IRC provisions. Therefore, a manufacturer that seeks the Small Biotech Exception for its qualifying single source drug (“Submitting Manufacturer”) must submit information to CMS about the company and its products in order for the drug to be considered for the exception. To the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the NDA(s)/BLA(s) for the qualifying single source drug may be the Submitting Manufacturer. CMS has made this decision to ensure that only the entity with which CMS would negotiate in the event that the qualifying single source drug is selected for negotiation, as described in section 40 of this memorandum, is able to seek the Small Biotech Exception.

On January 24, 2023, CMS released the Small Biotech Exception ICR (CMS-10844 / OMB 0938-NEW) to detail the specific data that CMS are requesting for purposes of implementing this exception. Comments on the Small Biotech Exception ICR may be submitted according to the directions listed in the 60-day notice that appeared in the Federal Register on January 24, 2023 (88 FR 4184).¹⁵ Comments in response to the 60-day notice must be submitted by March 27, 2023. The public will have an additional opportunity to submit comments for 30 days following issuance of the 30-day Federal Register notice for this ICR.

¹⁴ For the purposes of this determination, a manufacturer who participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer’s CGDP agreement would be considered to have had an agreement in effect during 2021.

¹⁵ <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pa-listing/cms-10844>

The Small Biotech Exception ICR addresses the collection of information for initial price applicability year 2026 only. As, in accordance with section 1192(a)(3) of the Act, Part B drugs are not selected for negotiation until initial price applicability year 2028, this ICR does not address the collection of information relevant to Part B drugs. Additionally, this ICR does not address the collection of information relevant to the statutory limitation found in section 1192(d)(2)(B)(ii) of the Act (which precludes the application of the Small Biotech Exception to a qualifying single source drug if the manufacturer of that drug is acquired after 2021 by a manufacturer that does not meet the definition of a specified manufacturer under section 1860D-14C(g)(4)(B)(ii)) because the earliest effective date specified in that limitation (January 1, 2025) has no impact until initial price applicability year 2027 (the first initial price applicability year with a selected drug publication date after January 1, 2025).

To receive consideration for the Small Biotech Exception for initial price applicability year 2026, the Submitting Manufacturer must submit the Small Biotech Exception Information Collection Request Form using the CMS Health Plan Management System (HPMS) by the deadline established by CMS; CMS anticipates that this deadline will be in June 2023 but will publish a specific deadline on the CMS IRA website in the future.¹⁶ This due date will be in advance of the date on which CMS is required to publish the list of selected drugs for initial price applicability year 2026 and will allow sufficient time for CMS to consider whether the qualifying single source drug qualifies for the Small Biotech Exception.

CMS does not plan to consider incomplete submissions. Upon receipt of a complete Small Biotech Exception Information Collection Request Form, CMS plans to take the following approach to identify whether a drug qualifies for the Small Biotech Exception:

- CMS plans to identify the manufacturer that had a CGDP agreement for the drug in effect as of December 31, 2021 (“2021 Manufacturer”) based on the information submitted in the Small Biotech Exception Information Collection Request Form.
- CMS plans to use the identifying information (manufacturer name, P-number, and labeler codes) submitted in that form to identify the complete set of 11-digit National Drug Codes (NDC-11s)¹⁷ for which any member of the 2021 Manufacturer’s controlled group as of December 31, 2021 had a CGDP agreement as of December 31, 2021. “Controlled group” means all corporations or partnerships, proprietorships and other entities treated as a single employer under 26 U.S.C. § 52(a) or (b).
- Using the complete set of NDC-11s for which the 2021 Manufacturer or any member of the 2021 Manufacturer’s controlled group had a CGDP agreement in effect on December 31, 2021, CMS plans to identify Part D PDE data for dates of service during the 12-month period beginning January 1, 2021 and ending December 31, 2021.
- Using the PDE data for (1) the qualifying single source drug, (2) the complete set of covered Part D drugs for which the 2021 Manufacturer or any member of the 2021

¹⁶ <https://www.cms.gov/inflation-reduction-act-and-medicare>

¹⁷ NDC-9 and NDC-11 numbers are identical except for two numbers in NDC-11s that indicate package size. Because of this, NDC-11 is more granular than NDC-9, and multiple NDC-11 numbers can aggregate under a single NDC-9 number.

Manufacturer's controlled group had a CGDP agreement as of December 31, 2021, and (3) all covered Part D drugs, CMS plans to determine whether:

- The Total Expenditures under Part D for the qualifying single source drug were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and
- The Total Expenditures under Part D for the qualifying single source drug were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect during 2021.

For initial price applicability year 2026, the term "negotiation-eligible drug" will exclude any covered Part D drugs that are qualifying single source drugs that meet these criteria to qualify for the Small Biotech Exception.

A determination by CMS that a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 does not mean that this drug will continue to qualify for the Small Biotech Exception for future initial price applicability years. The Submitting Manufacturer must resubmit a request for the drug to be considered for the exception for initial price applicability years 2027 and 2028. The process for resubmitting a request will be addressed in future guidance.

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026

In accordance with sections 1192(a) and 1192(b) of the Act, CMS will select 10 (or all, if such number is less than 10) negotiation-eligible Part D drugs for initial price applicability year 2026 as follows:

- CMS will rank the 50 negotiation-eligible drugs identified in section 30.2 of this memorandum by Total Expenditures under Part D (based on the data described in section 30.2 of this memorandum) in descending order: the negotiation-eligible drug with the highest Total Expenditures under Part D will be listed first and the negotiation-eligible drug with the lowest Total Expenditures under Part D will be listed last.
- CMS will remove any biological products that qualify for delayed selection under section 1192(f) of the Act as described in section 30.3.1 of this memorandum.
- CMS will select for negotiation the 10 (or all, if such number is less than 10) highest ranked negotiation-eligible drugs remaining on the ranked list for initial price applicability year 2026.
 - In the event that two or more negotiation-eligible drugs have the same Total Expenditures to the dollar under Part D and such Total Expenditures are the 10th highest among negotiation-eligible drugs, CMS will rank those negotiation-eligible drugs based on which drug has the earlier approval or licensure date, as applicable, associated with the initial FDA application number for its active moiety(ies) / active ingredient(s), and select based on that ranking until there are 10 selected drugs (or all drugs are selected if the number of negotiation-eligible drugs is less than 10).

30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

In accordance with section 1192(b)(1)(C) of the Act, CMS will remove from the ranked list of 50 negotiation-eligible drugs described in section 30.3 of this memorandum any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with section 1192(f) of the Act. This section 30.3.1 describes the implementation of section 1192(f) of the Act (the “Biosimilar Delay”).

Under section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product (“Biosimilar Manufacturer” of a “Biosimilar”) may submit a request, prior to the selected drug publication date, for CMS’ consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a “Reference Drug”) on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by FDA. CMS believes that this approach is appropriate because (1) it clearly identifies one manufacturer who may submit a Biosimilar Delay request for a given Biosimilar, avoiding the possibility that CMS would receive two such requests naming the same Biosimilar for the same initial price applicability year, and (2) the status of the application for licensure for the Biosimilar is material to CMS’ consideration of a Biosimilar Delay request, as described in this section 30.3.1.

Section 1192(f) of the Act contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year (“Initial Delay Request”), as stated in section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year (“Additional Delay Request”) as stated in section 1192(f)(1)(B)(i)(II) of the Act.

The following subsections of this section 30.3.1 include details on the implementation of the Biosimilar Delay for initial price applicability year 2026. Topics related to future initial price applicability years (including Additional Delay Requests) will be covered in future guidance.

30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026

The statute specifies that the following requirements must be met in order for CMS to grant an Initial Delay Request:

1. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be, absent the Biosimilar Delay, a selected drug for the initial price applicability year.
 - Biosimilar Manufacturers who think that a Reference Drug for their Biosimilar may be a selected drug for initial price applicability year 2026 may submit an Initial Delay Request, and CMS will disregard that application if the Reference

Drug would not, in fact, be a selected drug for initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, which may allow them to determine the likelihood that a given drug may be a selected drug.

2. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act, included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay. For Initial Delay Requests submitted with respect to initial price applicability year 2026, this means that the Reference Drug must have received its initial BLA licensure between January 1, 2010, and January 1, 2014.
 - Section 1194(c)(4)(B)(ii) of the Act specifies that selected drugs for which a manufacturer had an agreement under the Negotiation Program for an initial price applicability year prior to 2030 are excluded from the definition of extended-monopoly drugs. Importantly, however, an Initial Delay Request must be submitted by a Biosimilar Manufacturer before the selected drug publication date for an initial price applicability year and before the Primary Manufacturer (as defined in section 40 of this memorandum) of the Reference Drug (“Reference Manufacturer”) would have entered into an agreement under the Negotiation Program. Therefore, CMS believes the exception to the definition of “extended-monopoly drug” in section 1194(c)(4)(B)(ii) of the Act will not apply at the time that a delay would be requested for initial price applicability years 2026 through 2029. Accordingly, CMS believes that the Biosimilar Delay under section 1192(f) of the Act is applicable beginning with initial price applicability year 2026. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2026, provided that the Reference Drug named in the request will have been licensed for between 12 and 16 years prior to the start of the initial price applicability year on January 1, 2026.
3. In accordance with section 1192(f)(1)(A) of the Act, the Reference Drug must include the reference product identified in the Biosimilar’s application for licensure under section 351(k) of the PHS Act that has been approved by the FDA or accepted for review, as described below in section 30.3.1.2 of this memorandum.
 - Please note that in order for CMS to grant an Initial Delay Request, the licensure application for the Biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval.
4. In accordance with section 1192(f)(2)(D)(iii) of the Act, an Initial Delay Request cannot be granted if more than one year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
 - For Initial Delay Requests submitted with respect to initial price applicability year 2026, this requirement means that if the Biosimilar has already received approval by the FDA for its application for licensure under section 351(k) of the PHS Act, the date of such licensure must be on or after September 1, 2022 for a delay to be granted. If the Biosimilar is already licensed and marketed by September 1, 2023,

the selected drug publication date for initial price applicability year 2026, the Reference Drug would by definition no longer be a qualifying single source drug and therefore would fail requirement #1 on this list. If the Biosimilar was licensed prior to September 1, 2022 and is not marketed before September 1, 2023, more than one year would have elapsed since the licensure of the Biosimilar without marketing of the Biosimilar having commenced.

5. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same pursuant to section 1192(f)(1)(C) of the Act.
 - For the purposes of this determination, all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC of 1986, or in a partnership, shall be treated as one manufacturer, as stated in section 1192(f)(1)(C) of the Act.
 - For the purposes of this determination, “partnership” is defined at section 1192(f)(1)(C)(ii) of the Act as a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the Reference Manufacturer and the Biosimilar Manufacturer.
6. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that either:
 - requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or
 - directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time. For Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS will consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar that the Biosimilar Manufacturer may sell during any period of time on or after September 1, 2023 as violating this requirement.
7. In accordance with section 1192(f)(1)(A) of the Act and as described in detail in section 30.3.1.2 of this memorandum, CMS must determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year.

30.3.1.2 High Likelihood

In accordance with section 1192(f)(1)(A) of the Act, CMS will review Initial Delay Requests to determine whether there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year. Accordingly, for Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS must find a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, in order to grant the request. If CMS does not find that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, based on the criteria described below, CMS will deny the Initial Delay Request.

In accordance with section 1192(f)(3) of the Act, Initial Delay Requests must demonstrate both of the following in order to meet the high likelihood threshold:

1. An application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA.
 - For Initial Delay Requests submitted with respect to initial price applicability year 2026, the Biosimilar's application for licensure must be approved or accepted for review by the FDA no later than August 15, 2023, in order to permit CMS time to review the information and finalize the selected drug list prior to the selected drug publication date of September 1, 2023.
 - Please note that if the Biosimilar's application for licensure has not been accepted for review by August 15, 2023, including in the case where the Biosimilar Manufacturer has submitted an application for licensure that has not been accepted for review by the FDA or for which a filing determination is pending, CMS will deny the Initial Delay Request for initial price applicability year 2026.
2. Clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025 (the date that is two years after the selected drug publication date for the initial price applicability year), based on the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS.

For Initial Delay Requests submitted for initial price applicability year 2026, to demonstrate clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025, CMS will require that the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS by the Biosimilar Manufacturer as part of its Initial Delay Request demonstrates both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. CMS has chosen these two requirements because they represent the two primary contributing factors to delays in marketing of biosimilars approved in the U.S. to date.

First, the Initial Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before September 1, 2025. Specifically, CMS will consider this requirement met if (1) there are no non-expired approved patent applications relating to the Reference Drug that are applicable to the Biosimilar; (2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable non-expired patent relating to the Reference Drug that the patent holder asserted was applicable to the Biosimilar; or (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar in one or more dosage form(s), strength(s), and indication(s) before September 1, 2025, without imposing improper constraints on the Biosimilar Manufacturer.¹⁸ CMS will deny

¹⁸ As noted in section 30.3.1.1 of this memorandum, an Initial Delay Request will not be granted if the Biosimilar Manufacturer enters into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar

all Initial Delay Requests that do not meet this requirement including, for example, if the Biosimilar Manufacturer is engaged in active litigation with the Reference Manufacturer with respect to the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act. CMS will consider active litigation to be determinative that there is not clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025, because litigation, including patent litigation, is historically highly unpredictable with respect to both the outcome of the litigation and the timing for resolution.

Second, the Initial Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before September 1, 2025. To assess this requirement, CMS will consider the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before September 1, 2025, and (2) a manufacturing schedule consistent with the public-facing statements and any revenue expectations. CMS has chosen these criteria because they are indicative of operational readiness and should be available in the elements that CMS must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act.

In determining whether an Initial Delay Request satisfies the high likelihood threshold, CMS may use all the information outlined in section 30.3.13 of this memorandum to determine whether an application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA. In accordance with section 1192(f)(3)(B) of the Act, CMS is required to use information from the following items when assessing whether there is clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025:

- All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and
- Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies.

Manufacturer to submit an Initial Delay Request or directly or indirectly restricts the quantity of the Biosimilar sold in the United States on or after September 1, 2023.

In accordance with section 1198(2) of the Act, there will be no administrative or judicial review of CMS' determinations under section 1192(f) of the Act.

30.3.1.3 Submitting an Initial Delay Request for Initial Price Applicability Year 2026

A Biosimilar Manufacturer should submit an Initial Delay Request for initial price applicability year 2026 only if it (1) plans for its Biosimilar to be licensed and marketed before September 1, 2025, (2) believes its request will satisfy the statutory requirements for granting an Initial Delay Request, as described in section 30.3.1.1 of this memorandum, and (3) believes that its request demonstrates that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, based on the criteria described in section 30.3.1.2 of this memorandum.¹⁹

CMS has designed the process for Initial Delay Request submission for initial price applicability year 2026 to allow CMS time to adjudicate all requests in advance of September 1, 2023, the selected drug publication date, and to be operationally feasible. For initial price applicability year 2026, CMS will accept Initial Delay Requests submitted via email and Box²⁰ as described below, whereas, for future initial price applicability years, CMS plans to issue guidance on use of the CMS HPMS to receive and process these requests in the future.

Accordingly, Initial Delay Requests for initial price applicability year 2026 may be submitted via the following process:

1. The Biosimilar Manufacturer should send an email to IRAREbateandNegotiation@cms.hhs.gov to indicate its intention to submit an Initial Delay Request for initial price applicability year 2026. The Biosimilar Manufacturer is encouraged to use the template, including subject line and body content, described in Appendix A of this memorandum. Emails should be received by 11:59 pm PT on May 10, 2023.
2. Within 5 business days of receipt, CMS will respond by providing the Biosimilar Manufacturer with (1) a fillable template for the Initial Delay Request form, available in Appendix B of this memorandum, and (2) access to a Box folder specific to the Biosimilar Manufacturer's Initial Delay Request. No parties other than the Biosimilar Manufacturer and CMS and its contractors will have access to this folder.
3. The Biosimilar Manufacturer should upload a complete Initial Delay Request with the following documentation to the Box folder or using an alternative submission approach approved by CMS by 11:59 pm PT on May 22, 2023. CMS will deem an Initial Delay Request to be complete if it includes:

¹⁹ For initial price applicability year 2026, an Initial Delay Request would be submitted by a Biosimilar Manufacturer that anticipates the reference product for its Biosimilar will be included in one of the ten covered Part D Drugs that will be a selected drug for this initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, which may allow them to determine the likelihood that a given drug may be a selected drug.

²⁰ <https://www.box.com/>; if a Biosimilar Manufacturer is unable to use Box, it should include an explanation in its email in step #1 below and request an alternative submission method.

- a. A complete Initial Delay Request form using the fillable template that the Biosimilar Manufacturer receives from CMS. This template can be used to submit:
 - i. information used to identify the Biosimilar Manufacturer, the Biosimilar, the Biosimilar's reference product, and the Reference Manufacturer;
 - ii. attestations that the Initial Delay Request meets the statutory requirements listed in section 30.3.1.1 of this memorandum; and
 - iii. information on the status of licensure for the Biosimilar under section 351(k) of the PHS Act;
- b. All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- c. The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act, to the extent available; and
- d. Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.

In accordance with section 1192(f)(1)(B)(ii) of the Act, Initial Delay Requests for initial price applicability year 2026 that are not submitted by 11:59 pm PT on May 22, 2023 or that do not include all elements will be denied.

30.3.1.4 Process and Timing After Submission of an Initial Delay Request for Initial Price Applicability Year 2026

Within 5 business days after the Biosimilar Manufacturer uploads the required documentation to its Box folder or using an alternative submission approach approved by CMS, CMS will send an email confirming receipt to the email address used by the Biosimilar Manufacturer in its initial email to CMS expressing its intent to submit an Initial Delay Request. In accordance with section 1192(f)(1)(B)(ii)(II) of the Act, after reviewing an Initial Delay Request, inclusive of the materials submitted therein, CMS may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request. For initial price applicability year 2026, CMS will make any such follow-up request in writing to the Biosimilar Manufacturer via the same email address on or before June 20, 2023. Any such written request will specify the additional information required, the format and manner in which the Biosimilar Manufacturer must provide the additional information, and the deadline for providing such information, which will be no later than July 3, 2023. The one exception to these

deadlines is as follows: per section 30.3.1.2 of this memorandum, for CMS to determine that there is a high likelihood of the Biosimilar being licensed and marketed prior to September 1, 2025, the Biosimilar's application for licensure must be accepted for review or approved by the FDA no later than August 15, 2023. CMS will permit the Biosimilar Manufacturer to update CMS on the status of the Biosimilar's application for licensure before 11:59 pm PT on August 15, 2023, in order to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list published on September 1, 2023, in accordance with section 1192(a) of the Act.

Prior to September 1, 2023, the selected drug publication date for initial price applicability year 2026, CMS will review each Initial Delay Request in the following manner. First, CMS will review each Initial Delay Request to determine whether it includes all of the elements for an Initial Delay Request and was submitted by the applicable deadline in accordance with section 30.3.1.3 of this memorandum. Second, if an Initial Delay Request includes all required elements and was timely submitted, CMS will review the Initial Delay Request to determine if it meets all of the statutory requirements described in section 30.3.1.1 of this memorandum, with the exception of the high likelihood requirement. Third, if the Initial Delay Request meets all statutory requirements other than the high likelihood requirement, CMS will review the Initial Delay Request to determine whether it demonstrates a high likelihood that the Biosimilar will be licensed and marketed by September 1, 2025, as described in section 30.3.1.2 of this memorandum. In considering an Initial Delay Request, CMS will cease consideration upon finding that the Initial Delay Request has failed to meet any of these requirements. For example, if CMS determines an Initial Delay Request was not submitted by the established deadline, CMS will not review that request against other statutory requirements, if CMS determines an Initial Delay Request fails to meet one or more of the statutory requirements described in section 30.3.1.1 of this memorandum, with the exception of the high likelihood requirement, CMS will not consider whether that Initial Delay Request demonstrates a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

The list of selected drugs published for initial price applicability year 2026 will reflect the results of CMS' determinations with respect to any Initial Delay Requests that are submitted, i.e., a Reference Drug that, absent a successful Initial Delay Request, would have been selected, will not appear on the selected drug list published by September 1, 2023 if it is named in a successful Initial Delay Request.

After completing its review, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2026 in writing of CMS' determination regarding such request. This notification will occur on or after September 1, 2023, but no later than September 30, 2023, and will include a brief summary of CMS' determination, including:

- Whether the Initial Delay Request was successful or unsuccessful; and
- If unsuccessful, the reason CMS determined that the Initial Delay Request was unsuccessful, including but not limited to:
 - failure to submit all elements of the Initial Delay Request by the applicable deadline;

- failure to meet another statutory requirement for granting a request (other than the high likelihood requirement), including in the case that the Reference Drug would not have been a selected drug for initial price applicability year 2026 absent the Initial Delay Request; or
- failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

CMS will also notify each Reference Manufacturer named in a successful Initial Delay Request using the CMS HPMS to identify the relevant point(s) of contact. Such notification will be in writing and will identify the Reference Drug that would have been a selected drug in initial price applicability year 2026, absent the successful Initial Delay Request. Reference Manufacturers named in unsuccessful Initial Delay Requests will not be notified.

In accordance with section 1192(f)(2)(B) of the Act, CMS must determine whether each Biosimilar named in a successful Initial Delay Request is licensed and marketed during the initial delay period. For successful Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS will make this determination by mid-2024 (note: CMS plans to publish a specific date in future guidance as this deadline remains over one year away and CMS is still determining the appropriate date by which this determination should be made). The timing, content, and format of this notification will be specified in future guidance.

The following table provides a summary of key dates specified in this section 30.3.1:

Date	Deadline / milestone
11:59 pm PT on May 10, 2023	Deadline for Biosimilar Manufacturer to email CMS regarding intent to submit Initial Delay Request for initial price applicability year 2026
11:59 pm PT on May 22, 2023	Deadline for Biosimilar Manufacturer to submit the documentation for its Initial Delay Request as specified in section 30.3.1.3 of this memorandum
June 20, 2023	Deadline for CMS to request follow-up information for a submitted Initial Delay Request, if applicable
July 3, 2023	Deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS, if applicable
11:59 pm PT on August 15, 2023	Deadline for Biosimilar application for licensure to be accepted for review or approved by the FDA; deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS related to the Biosimilar application for licensure
September 1, 2023	Statutory deadline for CMS to publish the selected drug list for initial price applicability year 2026
September, 2023	CMS informs each Biosimilar Manufacturer that submitted an Initial Delay Request of the results of such request, in writing; for successful Initial Delay Requests, CMS also informs the Reference Manufacturer
Mid-2024 ²¹	For successful Initial Delay Requests, CMS determines whether the Biosimilar has been licensed and marketed during the initial delay period

²¹ CMS plans to publish a specific date in future guidance.

Information on other policies related to section 1192(f) of the Act will be included in future guidance, including, but not limited to:

- the deadline and process for submitting an Initial Delay Request for initial price applicability year 2027;
- the deadline and process for submitting an Additional Delay Request for initial price applicability year 2027, in the event an Initial Delay Request for initial price applicability year 2026 is granted and CMS determines by mid-2024 that the Biosimilar was not licensed and marketed during the initial delay period;²²
- the criteria for adjudicating Additional Delay Requests;
- the impact of Initial Delay Requests and Additional Delay Requests on the selected drug list for initial price applicability year 2027; and
- the application and calculation of rebates for a Reference Drug for 2026, as applicable.

30.4. Publication of the Selected Drug List

In accordance with section 1192(a) of the Act, CMS will publish the selected drug list for initial price applicability year 2026 no later than September 1, 2023. This list will include the 10 (or all, if such number is less than 10) drugs selected for negotiation for initial price applicability year 2026. CMS will post the selected drug list on the [CMS IRA webpage](#).²³

40. Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026

In accordance with section 1193(a) of the Act, the Secretary shall enter into agreements with manufacturers of selected drugs. In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of “manufacturer” established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with “the manufacturer” of the selected drug. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS intends to designate the entity that holds the NDA(s)/BLA(s) for the selected drug to be “the manufacturer” of the selected drug (hereinafter “Primary Manufacturer”). Likewise, for initial price applicability year 2026, CMS intends to refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer as a “Secondary Manufacturer.” Secondary Manufacturers would include any manufacturer of any authorized generics and any repacker or relabeler of the selected drug that meet these criteria.

In the example discussed in section 30.1 of this memorandum, if the potential qualifying single source drug described was selected for negotiation, entity A would be considered the Primary Manufacturer while entity B would be considered a Secondary Manufacturer either because it was listed as a manufacturer in NDA-1 or if it was not listed as a manufacturer in NDA-1

²² CMS plans to publish a specific date in future guidance.

²³ <https://www.cms.gov/inflation-reduction-act-and-medicare>

because it markets the three strengths of the immediate release tablets manufactured by entity A pursuant to an agreement with entity A.

CMS intends to sign an agreement (a “Medicare Drug Price Negotiation Program Agreement,” herein referred to as an “Agreement”), with the Primary Manufacturer of each selected drug and believes this approach aligns with the statute’s requirement to negotiate to determine an MFP with “the manufacturer” of a selected drug in accordance with section 1193(a) of the Act. This Agreement, as described in this section 40, will contain the requirements of the Primary Manufacturer with respect to its participation in the Negotiation Program.

CMS does not intend to enter into an Agreement with any Secondary Manufacturer of a selected drug. As such, under section 1193(a)(4), CMS intends to include in the Agreement with the Primary Manufacturer several requirements pertaining to Secondary Manufacturers of the selected drug, as applicable, including that a Primary Manufacturer that enters into an Agreement must: (1) report to CMS a list of any Secondary Manufacturer(s) and the applicable NDC-11s of the selected drug marketed by each such Secondary Manufacturer(s); and (2) collect and report necessary information applicable to any Secondary Manufacturer(s) as described in section 40.2 of this memorandum. Further, in accordance with section 1193(a)(1) of the Act and section 40.4 of this memorandum, CMS intends to require that the Primary Manufacturer ensure that any Secondary Manufacturer(s) make the MFP available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers. CMS reiterates that the requirement to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual, as discussed in section 80 of this memorandum.

CMS intends that for initial price applicability year 2026, the Primary Manufacturer of a selected drug will be the entity that does each of the following:

1. Signs the Agreement with CMS, as described in section 40.1 of this memorandum;
2. Collects and reports all data required for negotiation under section 1193(a)(4) of the Act, including the negotiation data elements, as described in section 40.2, section 50.1, and Appendix C of this memorandum;
3. Negotiates an MFP with CMS, as described in section 40.3 of this memorandum;
4. Ensures the MFP is made available to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that dispense the selected drug to those individuals, as described in section 40.4 of this memorandum; and
5. Responds to CMS requests within specified timeframes with documentation demonstrating compliance and remedial actions, as applicable, pursuant to reports of noncompliance or other CMS compliance and oversight activities, and pays any CMPs for violations, including violating the terms of the Agreement, providing false information, failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but that has since undergone negotiation as described in section 1192(f)(4) of the Act, or not providing access to the MFP to MFP-eligible individuals, and to pharmacies, mail order services, and other dispensers, as described in section 40.5, section 90, and section 100 of this memorandum.

Termination of an Agreement for the Negotiation Program is discussed in section 40.6 of this memorandum and other relevant provisions from the Agreement are discussed in section 40.7. CMS is seeking comment on the policies described in this section 40 of this memorandum, including on other ways it might operationalize the statutory requirement to negotiate a single MFP with “the manufacturer” of a selected drug.

40.1 Entrance into an Agreement with CMS

Section 1193(a) of the Act instructs CMS to enter into agreements with manufacturers of selected drugs for a price applicability period. The deadline for the Primary Manufacturer of a selected drug to enter into an Agreement for initial price applicability year 2026 is October 1, 2023. CMS intends to use the CMS HPMS to identify the relevant points of contact, effectuate the Agreement, and store the Agreement.²⁴ Further, CMS intends for the Agreement to contain the requirements discussed in sections 40.1 through 40.7 of this memorandum.

Within 5 days following publication by CMS of the list of selected drugs for an initial price applicability year, if the Primary Manufacturer of a selected drug elects to enter into an Agreement with CMS to negotiate an MFP, the Primary Manufacturer must submit to CMS all names, titles, and contact information for representatives authorized to execute the Agreement and conduct the negotiation. This person or persons must be legally authorized to bind the Primary Manufacturer to the terms and conditions contained in the Agreement. At least one authorized representative of the Primary Manufacturer must access the CMS HPMS and sign the Agreement by October 1, 2023.

The negotiation period for initial price applicability year 2026 will begin on the earlier of two dates: the date on which the Agreement is executed (i.e., signed by both CMS and the Primary Manufacturer) or October 1, 2023. If an Agreement is fully executed before October 1, 2023, the negotiation period (as defined in 1191(b)(4) of the Act) would begin on the date on which the Agreement is signed by the last party to sign it. If the Agreement is not fully executed by October 1, 2023, then pursuant to 26 U.S.C. § 5000D(b)(1), a noncompliance period would begin on October 2, 2023, and could result in excise tax liability (see section 90.3 of this memorandum). CMS notes that entering into an Agreement is voluntary.

CMS will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list for initial price applicability year 2026 is published.

40.2 Submission of Data to Inform Negotiation

After entering in an Agreement with CMS and in accordance with section 1193(a)(4) of the Act, the Primary Manufacturer of each selected drug must submit to CMS the following information with respect to the selected drug: information on the non-Federal average manufacturer price (defined in section 8126(h)(5) of title 38, United States Code) as described in section 50.1.1 of this memorandum; and any information that CMS requires to carry out negotiation, including the factors listed in section 1194(e)(1) of the Act, as described in section 50.1 and Appendix C of

²⁴ <https://hpms.cms.gov/app/ng/home/>

this memorandum. This information must be submitted by the Primary Manufacturer to CMS no later than October 2, 2023, for initial price applicability year 2026.

CMS intends to require that the Agreement be fully executed, meaning both the Primary Manufacturer and CMS have signed the Agreement, before the Primary Manufacturer may submit the data elements described in this section. While these data elements may not be submitted prior to execution of the Agreement, CMS intends for Primary Manufacturers to be able to access the data elements template in the CMS HPMS and believes Primary Manufacturers will be able to gather these data prior to the Agreement being executed.

Importantly, certain data, as described in section 50.1 and Appendix C of this memorandum, must reflect any products included in the selected drug marketed by a Secondary Manufacturer(s), as applicable, and the Primary Manufacturer is responsible for collecting such data from any Secondary Manufacturer(s) and including this information in its submission to CMS.

CMS intends to populate the CMS HPMS with a list of the approved and marketed NDC-11s used to calculate the Total Expenditures for each selected drug (see additional details in sections 30.2 and 30.3 of this memorandum). A Primary Manufacturer must either attest that the listed NDC-11s are correct and marketed by the Primary Manufacturer or any Secondary Manufacturer(s) and that no NDC-11s are incorrectly included or missing from the list or provide any corrections to CMS. CMS intends to collect this information in the CMS HPMS concurrent with the collection of the other data elements specified in section 50.1 of this memorandum. In order to ensure accuracy of payment systems, CMS intends to require a Primary Manufacturer to report to CMS in writing any new approved and marketed NDC-11s of the selected drug at least 30 days prior to their first marketed date for any Primary Manufacturer or Secondary Manufacturer. CMS also intends to require the Primary Manufacturer to report to CMS in writing the delisting of any NDC-11 of the selected drug that is no longer marketed by the Primary Manufacturer or any Secondary Manufacturer(s) within 30 days after its discontinuation.

CMS is seeking comment on this section. Specifically, CMS is seeking comment on the requirement that Primary Manufacturers submit data under section 1193(a)(4) of the Act, including the factors listed in section 1194(e)(1) of the Act, for the Primary Manufacturer and any Secondary Manufacturer(s). CMS is also seeking comment on the requirement for Primary Manufacturers to report to CMS any new approved and marketed NDC-11s, or discontinued NDC-11s, of the selected drug for the Primary Manufacturer and on behalf of any Secondary Manufacturer(s).

40.2.1 Confidentiality of Proprietary Information

Section 1193(c) of the Act states that CMS must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information of that manufacturer. Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secret and confidential commercial or financial

information, would also be protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(4)).²⁵

CMS intends to implement a confidentiality policy that is consistent with existing requirements for protecting proprietary information, such as Exemption 4 of FOIA, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary.

Thus, for initial price applicability year 2026, CMS intends to treat information on non-Federal average manufacturer price (“non-FAMP”) (as defined in section 8126(h)(5) of title 38 of the U.S. Code) as proprietary.

For initial price applicability year 2026, CMS also intends to treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) of the Act as proprietary if the information constitutes commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that cannot be found publicly. Specifically, CMS intends to treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, and market data and revenue and sales volume data to be proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS intends to treat the data on prior Federal funding and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS believes these data are available publicly.

Pursuant to section 1195(a)(2) of the Act, CMS is required to publish the explanation for the MFP by March 1, 2025 for initial price applicability year 2026 (see section 60.6.1 of this memorandum). In this public explanation and any other public documents discussing the MFP, CMS intends to make high-level comments about the data submitted to CMS, without sharing any proprietary information reported to CMS under section 1193(a)(4) for purposes of the negotiation. For example, CMS does not intend to make public the research and development costs reported by a Primary Manufacturer, as CMS would treat that data as proprietary, but CMS may say “the manufacturer has recouped its research and development costs.”

With respect to information disclosed under the terms of the Agreement, CMS intends for the confidentiality provisions of the Agreement to survive termination of the Agreement.

CMS is seeking comment on the confidentiality policy described in this section 40.2.1. Specifically, CMS is seeking comment on which manufacturer data elements require submission of proprietary information and the basis for such conclusion. CMS is also requesting comment on the type of information that would not be considered proprietary and that CMS could include in the public explanation of MFP. In addition, CMS is seeking comment about the proper

²⁵ <https://www.justice.gov/archives/oip/foia-guide-2004-edition-exemption-4#:~:text=Exemption%20of%20the%20FOIA,government%20and%20submitters%20of%20information>

balance between the public's interests in transparency and the protection of business information in this context.

40.2.2 Data Use Provisions and Limitations

Under section 1193(a)(5) of the Act, the manufacturer of a selected drug must comply with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program. Pursuant to this authority, CMS intends to impose certain requirements on the Primary Manufacturer related to the submission of data and the use, disclosure, and destruction of data and other information received during the negotiation process in order to align with how negotiations are typically conducted by other entities. CMS also believes these requirements are in furtherance of the statutory instruction that CMS develop a process that aims to achieve the lowest MFP for each selected drug.

CMS intends to require that by signing the Agreement, a Primary Manufacturer agrees to use the CMS HPMS and comply with all relevant procedures and policies set forth in the CMS HPMS for utilizing the system.

CMS intends to require that a Primary Manufacturer shall not disclose to the public any information in the initial offer or any subsequent offer by CMS, the ceiling price contained in any offer, or any information contained in any concise justification provided with an offer. Further, a Primary Manufacturer shall not disclose to the public any information exchanged verbally during the negotiation period. CMS intends to prohibit audio or video recording of any oral conversations between CMS and a Primary Manufacturer. CMS also intends to require that a Primary Manufacturer shall not use information in the initial offer, including the ceiling price, or the concise justification from the Secretary or any subsequent offer or concise justification, nor information derived from those justifications or offers, for any purposes other than the Medicare Drug Negotiation Program, except as may be required by applicable state or federal law.

Pursuant to section 1193(a)(5) of the Act, CMS intends to require that all information the Primary Manufacturer receives during the negotiation period from CMS shall be destroyed within 30 days of a determination by CMS that the drug or biologic no longer qualifies as a selected drug, except as may be required by applicable state or federal law. CMS believes these policies will increase the chances of effective and successful negotiation in furtherance of the statutory instruction that CMS develop a process that aims to achieve the lowest MFP for each selected drug. The Primary Manufacturer must submit a Certificate of Data Destruction to CMS certifying that all information received from CMS during the negotiation period and potential renegotiation period(s), including the initial offer and any subsequent offers, and the concise justification(s), and any written notes or emails pertaining to negotiations (or renegotiations) with CMS, has been destroyed. This Certificate of Data Destruction must be submitted to CMS within 30 days after a determination by CMS that the drug or biologic no longer qualifies as a selected drug.

CMS is seeking comment on this section. Specifically, CMS is seeking comment on the limitations CMS intends to put on the use of information in the initial offer, any subsequent offer,

and any concise justification. CMS is also seeking comment on whether there are possible scenarios where a manufacturer might need to disclose this information. CMS is also seeking comment on the data destruction policies and scenarios where a manufacturer might need to retain certain pieces of information, for example to comply with state or federal laws.

40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years

CMS intends to include the negotiation process and timeline outlined in the Act and in section 60 of this memorandum, including the offer and counteroffer process and the associated timelines, in the Agreement. CMS intends to use the CMS HPMS to share the initial offer and concise justification, any subsequent offer and justification, and to receive any counteroffer(s) from the Primary Manufacturer of a selected drug. A Primary Manufacturer that signs the Agreement would be required to adhere to the process and deadlines described in section 60 of this memorandum.

Under the conditions defined in section 1194(f)(2) of the Act, CMS and a Primary Manufacturer will renegotiate the MFP for a selected drug, beginning with 2028. CMS plans to release guidance related to the renegotiation process in future years.

40.4 Providing Access to the MFP

After entering in an Agreement with CMS and in accordance with section 1193(a) of the Act, the manufacturer of a selected drug that is a covered Part D drug (as defined in section 1860D-2(e) of the Act) must provide access to the MFP to MFP-eligible individuals (defined in section 1191(c)(2)(A) of the Act and section 80 of this memorandum) and to pharmacies, mail order services, and other dispensers with respect to such MFP-eligible individuals who are dispensed that drug during a price applicability period.

Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected Part D drug must not exceed the applicable MFP plus any dispensing fees for such drug. In Part D, the negotiated price of a Part D drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point of sale. Therefore, the requirement that the price used for beneficiary cost-sharing and benefit administration cannot exceed the MFP (plus dispensing fees) ensures that Part D MFP-eligible individuals will have access to the MFP at the point of sale. Therefore, while section 1193(a)(1)(A) of the Act specifies that manufacturers must provide access to the MFP to MFP-eligible individuals, as a practical matter that will be accomplished by Part D plan sponsors without additional steps required of the manufacturer.

However, section 1193(a)(1)(A) of the Act also requires that manufacturers provide access to the MFP for selected drugs to pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed such drugs. CMS intends to require that the Primary Manufacturer ensure that entities that dispense drugs to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers, have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further discussed in section 90.2 of

this memorandum. CMS intends to define “providing access to the MFP” as ensuring that the amount paid by the dispensing entity for the selected drug is no greater than the MFP.

CMS intends to require that Primary Manufacturers provide access to the MFP in one of two ways: (1) ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) providing retrospective reimbursement for the difference between the dispensing entity’s acquisition cost and the MFP. As part of this obligation, the Primary Manufacturer must ensure the MFP is made available to pharmacies, mail order services, and other dispensers for units of the selected drug for which there is a Secondary Manufacturer.

Further, CMS intends to require that a Primary Manufacturer achieve certain outcomes to comply with the requirement under section 1193(a)(1)(A) of the Act to provide access to the MFP:

1. A Primary Manufacturer would be required to submit its process for making the MFP available for the selected drug in writing to CMS at least 30 days before the start of the initial price applicability year for the selected drug. CMS intends to publish these processes on the CMS IRA website. For initial price applicability year 2026, a Primary Manufacturer of a selected drug must send its process for ensuring MFP availability to CMS in writing by December 2, 2025. A Primary Manufacturer would also be required to notify CMS of any changes to its process for making the MFP available at least 30 days before the change goes into effect.
2. CMS intends to monitor for compliance and audit, as needed, to ensure that the MFP is being made available for the selected drug. A Primary Manufacturer would be required to retain for at least ten years from the date of sale any records relating to sales of the selected drug to entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers for units of selected drug. See section 90.2 of this memorandum for additional details.
3. CMS intends to require that a Primary Manufacturer ensure that pharmacies, mail order services, and other dispensers as well as intermediate entities, such as wholesalers, as applicable, are reimbursed timely for the full amount of the difference between their acquisition cost for the selected drug and the MFP within 14 days. Manufacturers or their contracted entities shall not charge any transaction fee for this process.

CMS intends that the Agreement would not restrict the Primary Manufacturer or Secondary Manufacturer(s) from offering a price lower than the MFP. CMS reiterates that Primary Manufacturers would be responsible for ensuring that the MFP is made available to pharmacies, mail order services, and other dispensers that dispense the selected drug to MFP-eligible individuals, including ensuring that MFP is available for units of the selected drug for which there is a Secondary Manufacturer.

40.4.1 Nonduplication with 340B Ceiling Price

In accordance with 1193(d) of the Act and as further discussed in section 90.2 of this memorandum, the Primary Manufacturer of a selected drug is not required to provide access to

the MFP for a selected drug to MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the PHS Act, if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B ceiling price (defined in section 340B(a)(1) of the PHS Act) is lower than the MFP for such selected drug.

The Primary Manufacturer of a selected drug is required to provide access to the MFP to a covered entity described in section 340B(a)(4) of the PHS Act for MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such 340B ceiling price if the MFP is below the 340B ceiling price for such selected drug. If the 340B ceiling price is subsequently determined to be lower than the MFP, then the manufacturer would be responsible for providing to the covered entity the difference between the MFP and the 340B ceiling price.

40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program

After entering in an Agreement with CMS and in accordance with section 1193(a)(5) of the Act, the Primary Manufacturer must comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program. Please reference section 90 of this memorandum for additional details.

40.6. Termination of the Agreement

In accordance with section 1193(b) of the Act, when the Primary Manufacturer enters into the Agreement described in section 40.1 of this memorandum, the Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer considered a selected drug under section 1192(c) of the Act as described in section 70 of this memorandum or is terminated by either party.

40.7 Other Provisions in the Agreement

CMS intends to require that all notices and communications to CMS be sent via email to IRAREbateandNegotiation@cms.hhs.gov.

CMS intends to establish that if, after entering in an Agreement with CMS, the Primary Manufacturer of a selected drug transfers the NDA(s)/BLA(s) of the selected drug to another entity, CMS will continue to hold the Primary Manufacturer responsible for all requirements of the Agreement and the requirement to provide access to the MFP unless and until the Primary Manufacturer transfers such requirements to the new holder of the NDA(s)/BLA(s). Further, CMS intends to continue to hold the Primary Manufacturer responsible for any outstanding negotiation rebate liabilities related to the biosimilar delay provision under section 1192(f) of the Act unless and until such liabilities are transferred to the new holder of the NDA(s)/BLA(s). CMS intends to require that notice of any such transfer be sent to CMS at least 30 days before the effective date of such transfer.

CMS intends to require that if any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if the invalid or unenforceable provision(s) were eliminated, and without any effect on any other provisions.

CMS intends to define all days as calendar days unless otherwise specified in statute, guidance, or rulemaking.

50. Negotiation Factors

This section 50 includes additional details on the manufacturer-specific data referenced in section 40.2 of this memorandum. In accordance with sections 1193(a)(4) and 1194(b)(2) of the Act, the Primary Manufacturer of a selected drug that has chosen to sign the Agreement must submit, in a form and manner specified by CMS, information on the non-FAMP for the selected drug (described in section 50.1.1 of this memorandum). The Primary Manufacturer must also submit information on certain factors (described in section 1194(e)(1) of the Act and discussed further in section 50.1 of this memorandum). The Primary Manufacturer will be responsible for aggregating and reporting information from any applicable Secondary Manufacturer(s). In addition, the statute prescribes that CMS also consider available evidence about therapeutic alternatives to the selected drug(s) (described in section 1194(e)(2) of the Act and discussed further in section 50.2 of this memorandum).

While the statute prescribes that CMS consider manufacturer-specific data for the factors described at section 1194(e)(1) of the Act, the statute does not specify what sources CMS must use for the factors described at section 1194(e)(2) regarding therapeutic alternatives to a selected drug. CMS intends to consider evidence about therapeutic alternatives relevant to the factors described in section 1194(e)(2) of the Act submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties. CMS believes that by allowing any interested party to submit data, CMS will be best positioned to identify all available evidence for the factors described at section 1194(e)(2).

CMS intends to release a Negotiation Data Elements ICR, which will describe how CMS intends to collect the data described at sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act. This ICR will include instructions on how Primary Manufacturers and members of the public may submit the relevant data. Comments on the Negotiation Data Elements ICR may be submitted according to the directions listed in the Federal Register once posted. The public will have an opportunity to submit comments on this ICR for 60 days after notice is published in the Federal Register followed by an additional opportunity to submit comments for 30 days after revisions and republication.

CMS is including the definitions that CMS intends to adopt for the purposes of describing the data to be collected for use in the Negotiation Program under sections 1193(a)(4)(A) and 1194(e)(1) of the Act in Appendix C of this memorandum.

In accordance with section 1191(d)(5)(A) of the Act, the data described in sections 50.1 and 50.2 of this memorandum for drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023.

50.1 Manufacturer-Specific Data

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP of a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offers, as discussed in section 60 of this memorandum. These factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. Submission of these data is required by the Primary Manufacturer if an Agreement is signed; details related to the submission process are discussed in section 40.2 of this memorandum.

These data include the following and are required to be reported by the Primary Manufacturer to CMS by October 2, 2023:

1. Research and development costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
2. Current unit costs of production and distribution of the selected drug, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
3. Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and
5. Market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer(s) (with the exception of costs related to the acquisition of the selected drug, which would be reported only for the Primary Manufacturer).

As noted above, CMS intends for the Primary Manufacturer to aggregate data from both the Primary Manufacturer and any Secondary Manufacturer(s) for the following: non-FAMP, current unit costs of production and distribution, and certain data within market data and revenue and sales volume data for the selected drug.

Please see Appendix C of this memorandum for a list of definitions that CMS intends to adopt for the purposes of describing these data to be collected for use in the Negotiation Program.

50.1.1 *Non-FAMP Data*

The Primary Manufacturer must submit data on non-FAMP for the selected drug for the Primary Manufacturer and any Secondary Manufacturer(s), as required under section 1193(a)(4)(A) of the Act. CMS will be collecting these data through the Negotiation Data Elements ICR described above. Specifically, for initial price applicability year 2026, the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of calendar year 2021, or in the case there is no non-FAMP for the selected drug in calendar year 2021, the non-FAMP,

unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of the first full year following market entry of such drug. The use of these data to calculate the ceiling for the MFP is further described in section 60.2 of this memorandum. Details on how CMS intends to define the parameters of the non-FAMP data collection are included in Appendix C of this memorandum and will also be included in the forthcoming Negotiation Data Elements ICR.

50.2 Evidence About Therapeutic Alternatives for the Selected Drug

As noted above, section 1194(e)(2) of the Act directs CMS to consider evidence about alternative treatments to the selected drug, as available, including:

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
2. FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
3. Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations, herein referred to as “specific populations”); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Section 1194(e)(2) of the Act additionally requires that CMS not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Information submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties, or other information found by CMS that treats extending the life of individuals in these populations as of lower value, for example certain uses of quality-adjusted life-years (QALYs), will not be used in the negotiation process. In instances where a study uses QALYs in a life-extension context but has clearly separated this use of QALYs from other evidence in the report (e.g., clinical effectiveness, risks, harms, etc.) that is relevant to the factors listed in section 1194(e)(2) of the Act, CMS intends to consider such separate evidence. CMS will ask entities submitting information to indicate whether or not their submission contains information from studies that use QALYs in a life-extension context. CMS is soliciting comment on other metrics, in addition to QALYs, that may treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill and that CMS should also exclude from consideration when developing offers and reviewing counteroffers.

The Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties, may submit information on selected drugs and their therapeutic alternatives (specifically pharmaceutical therapeutic alternatives, as described in detail in section 60.3.1 of this memorandum), including information

on whether the selected drug represents a therapeutic advance over its therapeutic alternatives, prescribing information for the selected drug and its therapeutic alternatives, comparative effectiveness data for the selected drug and its therapeutic alternatives, information about the impact of the selected drug and its therapeutic alternatives on specific populations, and/or information on whether the selected drug and its therapeutic alternatives address unmet medical need, as described in section 1194(e)(2) of the Act.

CMS additionally intends to review existing literature and real-world evidence, conduct internal analytics, and consult subject matter and clinical experts on these topics (described in section 60.3.1 of this memorandum) in considering available evidence about alternative treatments to the selected drug. When reviewing the literature, CMS intends to consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. CMS will prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (i.e., has sufficient sample size) to answer the primary clinical question of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses.

In particular, CMS intends to consider research on and real-world evidence relating to Medicare populations, including on individuals with qualifying disabilities, patients with end-stage renal disease (ESRD), and Medicare-aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, CMS will prioritize research specifically designed to focus on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus.

All information on the factors described in section 1192(e)(2) of the Act related to drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023.

60. Negotiation Process

In accordance with section 1194(b)(1) of the Act, CMS intends to develop and use a consistent methodology and process for negotiation that “aims to achieve the lowest maximum fair price for each selected drug.” This section 60 describes the negotiation process, including the development of the written initial offer, the process for making such offer and providing a concise justification to the Primary Manufacturer of a selected drug, the process and requirements for accepting an offer or providing a counteroffer, the potential for 1-3 meetings between CMS and the Primary Manufacturer, the conclusion of negotiation, and the publication of the MFP.

60.1 Establishment of a Single Proposed MFP for Negotiation Purposes

In accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b), as applicable, for such drug and year. CMS interprets this language to refer to a single price negotiation for a selected drug with respect to its price applicability period. Accordingly, CMS intends to identify a single price for use at each step in the negotiation process described in this section 60, meaning each offer and counteroffer, described in section 60.4 of this memorandum, would include a single price, even for a selected drug with multiple dosage forms and strengths. Once the MFP has been determined, section 1196(a)(2) of the Act directs CMS to establish procedures to compute and apply the MFP across different dosage forms and strengths of a selected drug, as applicable.

For the purposes of determining a single price included in an initial offer (including evaluating clinical benefit compared to therapeutic alternatives, as discussed in section 60.3 of this memorandum) and conducting the negotiation, CMS intends to base the single price on the cost of the selected drug per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection – or per volume or weight-based metric), weighted across dosage forms and strengths, as applicable. For example, if the selected drug is available in a tablet form taken daily as well as an injection form taken every other month, CMS would base the single price for the initial offer on the average cost of (1) 30 tablets and (2) one injection divided by 2 (half the cost of one injection), weighted by number of 30-day equivalents for each presentation as reflected in Medicare Part D utilization during the 12-month period ending May 31, 2023. This approach of negotiating a single price across all dosage forms and strengths aligns with the statutory requirement to negotiate an MFP for a selected drug. CMS believes this will also allow for a more direct comparison with therapeutic alternatives, which might have different dosage forms, strengths, and frequency of use than the selected drug.

CMS is soliciting comment on its intended approach to identify a single price for use at each step in the negotiation process. Specifically, CMS seeks comment on the advantages and disadvantages of converting to a price per 30-day equivalent supply. CMS also solicits comment on whether there are other approaches that allow CMS to calculate a single price across dosage forms and strengths and allow for a more direct comparison with therapeutic alternatives, which might have different dosage forms, strengths, and frequency of use than the selected drug.

Section 60.5 of this memorandum describes the methodology to translate the MFP once finalized (which, per above, CMS intends to be an average price per 30-day equivalent supply for the selected drug) back into per unit (e.g., tablet) prices at the dosage form and strength level for the purposes of publishing per unit MFPs for the different dosage forms and strengths of the selected drug. In addition to the description of that methodology included in this memorandum, CMS will share the inputs behind that methodology specific to the selected drug with the Primary Manufacturer of the selected drug during the negotiation such that the Primary Manufacturer will have visibility into the implied unit prices based on the MFP for each dosage form and strength throughout the negotiation process (i.e., any offer or counteroffer that identifies a single price

would be clearly translatable to per unit prices at the dosage form and strength unit level). Please see Section 60.5 of this memorandum for details.

60.2 Limitations on Offer Amount

In accordance with section 1194(b)(2)(F)(i) of the Act, in negotiating the MFP of a selected drug, with respect to initial price applicability year 2026, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. This section 60.2 of this memorandum provides details on the determination of the ceiling for the MFP and comparison of the ceiling to the MFP.

60.2.1 Determination of the Ceiling for the MFP

In accordance with section 1194(c) of the Act, for initial price applicability year 2026, the ceiling for the MFP for a selected drug shall not exceed the lower of the following:

- As described in section 60.2.2 of this memorandum, an amount equal to the sum of the plan specific enrollment weighted amounts; or
- As described in section 60.2.3 of this memorandum, an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP as defined in section 1194(c)(6) of the Act for such drug for calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2022.²⁶

CMS interprets the language in section 1194(c)(1)(A) of the Act to mean it should calculate a single amount across all dosage forms and strengths of the selected drug for the sum of the plan specific enrollment weighted amounts and for the applicable percent of the average non-FAMP in order to determine which one is lower and will serve as the ceiling for the MFP. In order to determine whether the sum of the plan specific enrollment weighted amounts or the applicable percent of the average non-FAMP will be used to calculate the ceiling for the MFP, CMS intends to aggregate the amounts determined for each applicable NDC-11 for the selected drug to calculate a single amount – separately for each methodology – across dosage forms, strengths, and package sizes of the selected drug. These amounts can then be directly compared, and the ceiling for the single MFP of the selected drug (including all of its dosage forms and strengths) would be based on the lower amount.

Once the ceiling has been established (based on either the sum of plan specific enrollment weighted amounts or the applicable percent of the average non-FAMP), CMS plans to apply the

²⁶ The September 2021 CPI-U, not seasonally unadjusted, was 274.310; the September 2022 CPI-U, not seasonally adjusted, was 296.808. The percentage increase was 8.202 percent. Data retrieved from <https://www.bls.gov/cpi/data.htm> on March 8, 2023.

single ceiling across dosage forms and strengths to yield dosage form and strength-specific ceilings. As described in section 60.2.4 of this memorandum, these dosage form and strength-specific ceilings would then be applied to the MFP per 30-day equivalent supply for each dosage form and strength calculated in step 9 of section 60.5, to ensure the MFP applied to each dosage forms and strength does not exceed the ceiling.

To calculate dosage form and strength-specific ceilings and a single ceiling across dosage forms and strengths of the selected drug, CMS intends to do the following:

1. calculate a single ceiling price per 30-day equivalent supply across the NDC-11s for each specific dosage form and strength of the selected drug; and
2. calculate a single ceiling price per 30-day equivalent supply across all dosage forms and strengths of the selected drug.

Using the price per 30-day equivalent supply to calculate these two amounts facilitates aggregation across dosage forms and strengths of a selected drug where units (e.g., mg versus ml) and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) differ. Sections 60.2.2 and 60.2.3 of this memorandum describe this process for calculating the sum of plan specific enrollment weighted amounts and for calculating the applicable percent of the average non-FAMP, respectively, and section 60.2.4 describes the selection of the ceiling for the single MFP and comparison of the dosage form and strength-specific ceiling to the MFP applied across dosage forms and strengths.

60.2.2 Sum of Plan Specific Enrollment Weighted Amounts

In accordance with section 1194(c)(1)(B)(i) of the Act, CMS will calculate for a selected drug an amount equal to the sum of the plan specific enrollment weighted amounts determined using the methodology described in section 1194(c)(2) of the Act. Plan sponsors report Part D PDE data to CMS at the NDC-11 level. Sponsors also report Direct and Indirect Remuneration (DIR) data to CMS at the NDC-11 level in the annual Detailed DIR Report. CMS intends to use these reported data for plan year 2022, which is the most recent year for which data will be available, for the purpose of determining the sum of plan specific enrollment weighted amounts for a selected drug for initial price applicability year 2026.

CMS intends to calculate the sum of plan specific enrollment weighted amounts in two stages for purposes of determining the ceiling for the MFP and, if applicable, to compare this ceiling to the MFP applied across dosage forms and strengths as described in section 60.2.4 of this memorandum. First, CMS would calculate the sum of plan specific enrollment weighted amounts for each dosage form and strength of the selected drug. Second, CMS would calculate the sum of plan specific enrollment weighted amounts across dosage forms and strengths of the selected drug. The amounts calculated at each stage are for a 30-day equivalent supply.

To determine the sum of plan specific enrollment weighted amounts for each dosage form and strength and across all dosage forms and strength of the selected drug, CMS intends to conduct the following steps.

Steps 1 through 7 would result in the sum of the plan specific enrollment weighted amounts for each dosage form and strength of the selected drug:

1. For each Part D plan, CMS would identify the PDE data for the selected drug for 2022 (that is, PDE records with dates of service during the period beginning on January 1, 2022 and ending on December 31, 2022).
2. For each Part D plan, CMS would sum the negotiated price amounts (as defined in 42 CFR 423.100) and the estimated rebate at point of sale amounts (ERPOSA) across the PDE records for each of the NDC-11s of each dosage form and strength. CMS would also calculate the 30-day equivalent supply for each PDE record and sum the 30-day equivalent supply across the PDE records for each of the NDC-11s of each dosage form and strength.
3. For each Part D plan, CMS would sum the total DIR amounts found in the 2022 Detailed DIR Report for all NDC-11s of each dosage form and strength and subtract the total ERPOSA calculated in step 2 to avoid double counting price concessions applied at the point of sale to calculate the total DIR amount for each dosage form and strength of the selected drug.
4. For each Part D plan and each dosage form and strength of the selected drug, CMS would subtract the total DIR amount calculated in step 3 from the sum of the negotiated price amounts calculated in step 2 and then divide by the total 30-day equivalent supply of the dosage form and strength, also determined in step 2. This calculation results in the price per 30-day equivalent supply of the dosage form and strength of the selected drug, net of all price concessions received by such Part D plan or pharmacy benefit manager on behalf of such Part D plan.
5. Separately, CMS would identify the total number of individuals enrolled in all Part D plans in December 2022, and the total number of individuals enrolled in each Part D plan in that month.²⁷
6. For each Part D plan, CMS would divide the total number of Part D beneficiaries enrolled in the Part D plan during December 2022 as identified in step 5 by the total number of individuals enrolled in all Part D plans in December 2022 also as identified in step 5, and multiply this quotient by the price for a 30-day equivalent supply, net of all price concessions received by such plan or pharmacy benefit manager on behalf of such Part D plan, calculated in step 4, to arrive at the plan specific enrollment weighted amount.
7. CMS would then sum the amounts calculated in step 6 across all Part D plans to calculate the sum of the plan specific enrollment weighted amounts for each dosage form and strength of the selected drug.

Steps 8 through 10 result in the sum of the plan specific enrollment weighted amounts for the selected drug across all dosage forms and strengths:

²⁷ CMS conducted an analysis of monthly Part D plan enrollment changes during 2022 and determined that monthly enrollment changes were the lowest from November to December, so CMS chose December as the most stable month to identify enrollment. The choice of one month to identify enrollment also allows the weights calculated in step 6 to sum to one.

8. CMS would use the Part D PDE data for 2022 to calculate the total 30-day equivalent supply for each dosage form and strength of the selected drug across all Part D plans. Also, CMS would use the same data to calculate the total 30-day equivalent supply of the selected drug across all dosage forms and strengths and all Part D plans.
9. For each dosage form and strength of the selected drug, CMS would divide the total 30-day equivalent supply for the dosage form and strength by the total 30-day equivalent supply across all dosage forms and strengths of the selected drug as identified in step 8, and multiply this quotient by the sum of the plan specific enrollment weighted amounts for the dosage form and strength as calculated in step 7.
10. CMS would then sum amounts calculated in step 9 across all dosage forms and strengths of the selected drug to calculate the sum of the plan specific enrollment weighted amounts for the selected drug.

CMS would include all Part D plans that have PDE data for the selected drug in this calculation. Because CMS would have no PDE data for Part D plans in the following circumstances, such Part D plans would, by definition, be excluded from the calculation of the plan specific enrollment weighted amounts: (1) plans that have no utilization for the selected drug and (2) plans that have no enrollment for 2022.²⁸

60.2.3 Average Non-Federal Average Manufacturer Price

In accordance with section 1194(c)(1)(C)(i) of the Act, for initial price applicability year 2026, CMS will calculate an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP in calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2022.²⁹

For this calculation, CMS intends to use the non-FAMP of each NDC-11 for the selected drug for each quarter of calendar year 2021 that is submitted to CMS by the Primary Manufacturer pursuant to section 1193(a)(4)(A) of the Act (as described in section 50.1 of this memorandum). CMS also intends to use NDC-11 level unit volume data for each quarter of calendar year 2021 submitted to CMS by the Primary Manufacturer (also described in section 50.1 of this memorandum). Lastly, CMS would use 2022 Part D PDE data submitted to CMS at the NDC-11 level by Part D plan sponsors to determine the 30-day equivalent supply for each NDC-11 of the selected drug. In order to directly compare the amount calculated based on the applicable percent of average non-FAMP and the amount calculated based on the sum of the plan-specific enrollment weighted amounts (as described in this section 60.2.2 above), CMS intends to base the average non-FAMP calculations on a 30-day equivalent supply and intends to use the same

²⁸ CMS notes that employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage are not included because they are not Part D plans.

²⁹ The September 2021 CPI-U, not seasonally adjusted, was 274.310; the September 2022 CPI-U, not seasonally adjusted, was 296.808. The percentage increase was 8.2 percent. Data retrieved from <https://www.bls.gov/cpi/data.htm> on March 8 2023.

data source for weighting both the sum of the plan-specific enrollment weighted amounts and the average non-FAMP to determine which amount is lower.

CMS intends to calculate the applicable percent of the average non-FAMP in two stages for purposes of determining the ceiling for the MFP and, if applicable, to compare the applicable percent of the average non-FAMP to the MFP applied across dosage forms and strengths as described in section 60.2.4 of this memorandum. First, CMS would calculate the applicable percent of the average non-FAMP for each dosage form and strength of the selected drug. Second, CMS would calculate the applicable percent of the average non-FAMP across dosage forms and strengths of the selected drug. The amounts calculated in each stage are for a 30-day equivalent supply.

To determine the applicable percent of the average non-FAMP for each dosage form and strength and across all dosage forms and strengths of the selected drug, CMS intends to conduct the following steps.

Steps 1 through 9 would result in the applicable percent of the average non-FAMP for each dosage form and strength of the selected drug:

1. In order to calculate an average non-FAMP that is comparable to the sum of plan specific enrollment weighted amounts described in section 60.2.2 of this memorandum, CMS would compare the non-FAMP unit type (e.g., tablet) to the PDE units (i.e., each, milliliter, and grams). In instances where the units are different, CMS would convert the non-FAMP unit type to the PDE units so that the two amounts (average non-FAMP and sum of plan specific enrollment weighted amounts) represent the same quantity of the selected drug.³⁰
2. CMS would calculate the non-FAMP per unit by dividing the non-FAMP per package by the total number of units per package for that NDC-11.
3. For each NDC-11 of the selected drug and for each quarter during calendar year 2021, CMS would divide the total unit volume (calculated as the product of the total number of packages sold by the number of units per package for that NDC-11) in that quarter by the total unit volume across all four quarters during calendar year 2021, and multiply this quotient by the non-FAMP.
 - Note: In the case that there is not a non-FAMP available for such drug for calendar year 2021, CMS would use the non-FAMP and total unit volumes for the quarters of the first full year following the market entry for such drug.
4. For each NDC-11 of the selected drug, CMS would sum the amounts calculated in step 3 across quarters to calculate the average non-FAMP for that NDC-11 in calendar year 2021. CMS believes steps 3 and 4 are necessary to account for unit volume fluctuations that may occur across quarters for each NDC-11.

³⁰ PDE units are industry standard National Council for Prescription Drug (NCPDP) defined values of each, milliliter, and grams: <https://standards.ncdpd.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22>.

5. For each NDC-11 of the selected drug, CMS would divide the total unit volume in calendar year 2021 for that NDC-11 by the total unit volume in calendar year 2021 for all NDC-11s of the same dosage form and strength, and multiply this quotient by the average non-FAMP in calendar year 2021 for that NDC-11 calculated in step 4.
6. For each dosage form and strength of the selected drug, CMS would sum the amounts calculated in step 5 to calculate the average non-FAMP for that dosage form and strength in calendar year 2021. CMS believes steps 5 and 6 are necessary to account for unit volume fluctuations that may occur across NDC-11s of a dosage form and strength.
7. For each dosage form and strength of the selected drug, CMS would then multiply the average non-FAMP in calendar year 2021 calculated in step 6 by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 to September 2022 as specified in section 1194(c)(1)(C)(i) of the Act.
 - Note: In the case that there is not a non-FAMP available for that dosage form and strength of the selected drug for calendar year 2021, CMS would use the percentage increase from December of the first full year following the market entry for that dosage form and strength instead of September 2021, as required under section 1194(c)(1)(C)(i) of the Act.
8. After CMS has calculated the average non-FAMP in calendar year 2021 for each dosage form and strength of the selected drug, adjusted for inflation, CMS would apply the applicable percent specified in section 1194(c)(1)(C) of the Act for the monopoly type determined for the selected drug based on its initial approval date (described in section 30.1 of this memorandum). CMS believes applying the applicable percent in this step for each dosage form and strength is appropriate because it would allow CMS to apply the amount determined in the following step (step 9) to the MFP applied across dosage forms and strengths as described in section 60.2.4 of this memorandum. Furthermore, applying the applicable percent here, in step 8, results in the same step 11 amount as would result if CMS were to apply the applicable percent in step 11. The definition of each monopoly type and the applicable percentage are described below for initial price applicability year 2026. CMS notes that the extended monopoly type is not discussed below because the definition of extended-monopoly drug under section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an agreement with the Secretary with respect to an initial price applicability year that is before 2030. CMS intends to interpret this to mean that no selected drug would be considered an extended-monopoly drug for purposes of the Negotiation Program prior to initial price applicability year 2030.

Figure 2: Monopoly Types and Applicable Percentage for Initial Price Applicability Year 2026

Monopoly Type	Definition	Applicable Percentage	Note
Short-monopoly drugs and vaccines (section 1194(c)(3)(A) of the Act) ³¹	For initial price applicability year 2026, a selected drug or vaccine that is not a long-monopoly drug.	75%	The first approval date, under section 505(c) of the FD&C Act, associated with the initial FDA application number for the active moiety (or fixed combination drug) must be after September 1, 2007 and before September 1, 2016. The first licensure date, under section 351(a) of the PHS Act, associated with the initial FDA application number for the active ingredient (or fixed combination drug) must be after September 1, 2007 and before September 1, 2012.
Long-monopoly drug (section 1194(c)(5)(A) of the Act)	A selected drug for which at least 16 years have elapsed since the date of approval under section 505(c) of the FD&C Act or since the date of licensure under section 351(a) of the PHS Act, as applicable. The term 'long-monopoly drug' does not include a vaccine that is licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	40%	The first approval date under section 505(c) of the FD&C Act or the first licensure date under section 351(a) of the PHS Act, as applicable, associated with the initial FDA application number for the active moiety / active ingredient (or fixed combination drug) must be on or before September 1, 2007.

9. CMS would then multiply the average non-FAMP for calendar year 2021 for each dosage form and strength of the selected drug, adjusted for inflation and with the applicable percent applied calculated in step 8, by the quotient of the total number of units of that dosage form and strength divided by the total 30-day equivalent supply (i.e., this quotient would represent the average units per 30-day supply equivalent) for that dosage form and strength calculated from Part D PDE data for 2022 to determine the average non-FAMP

³¹ Because the definition of extended-monopoly drug at section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an agreement with the Secretary with respect to an initial price applicability year before 2030, for initial price applicability 2026, any drug, biological product, or vaccine that is not considered a long-monopoly drug will be considered a short monopoly drug.

for a 30-day equivalent supply of that dosage form and strength of the selected drug. As noted above in section 60.2.1 of this memorandum, CMS believes calculating the average non-FAMP for a 30-day equivalent supply is necessary to account for potential different units and treatment regimens across dosage forms and strengths.

Steps 10 and 11 would calculate the applicable percent of the average non-FAMP across all dosage forms and strengths of the selected drug:

10. For each dosage form and strength of the selected drug, CMS would divide the total 30-day equivalent supply for the dosage form and strength by the total 30-day equivalent supply across all dosage forms and strength of the selected drug calculated from Part D PDE data for 2022, and multiply this quotient by the average non-FAMP for that dosage form and strength calculated in step 9.
11. CMS would then sum amounts calculated in step 10 across dosage forms and strengths of the selected drug to calculate the applicable percent of the average non-FAMP for the selected drug.

60.2.4 Selection and Application of the Ceiling for the MFP

CMS intends to compare the values calculated in step 10 of section 60.2.2 of this memorandum (sum of plan specific enrollment weighted amounts) and step 11 of section 60.2.3 of this memorandum (applicable percent of the average non-FAMP) and select the lower value as the ceiling price for the selected drug. Once CMS has identified whether the ceiling price would be determined by the sum of plan specific enrollment weighted amounts or the applicable percent of the average non-FAMP, CMS intends to ensure that the MFP per 30-day equivalent supply for each dosage form and strength of the selected drug calculated in step 9 of the methodology described in section 60.5 of this memorandum is not above the statutorily defined ceiling by comparing it to the applicable ceiling for a 30-day equivalent supply for that dosage form and strength of the selected drug calculated in either step 7 of section 60.2.2 or step 9 of section 60.2.3 (depending on which ceiling is selected).

This approach would allow for selection of a single ceiling for the MFP for the selected drug as required by section 1194(c)(1)(A), but also enable CMS to determine if the initial offer or counteroffer, as applicable, applied across dosage forms and strengths, is at or below the ceiling price specific to each dosage form and strength of the selected drug.

CMS considered the alternative of applying a single ceiling on the MFP across all dosage forms and strengths of the selected drug, but concluded that prices may vary across dosage forms and strengths in a meaningful way, and that this variation should be maintained.

For example, the ceiling price specific to a given dosage form and strength of the selected drug (as calculated in step 7 of section 60.2.2 or step 9 of section 60.2.3, depending on which ceiling is selected) may be higher than the single ceiling price for the selected drug (as calculated in step 10 of section 60.2.2 or step 11 of section 60.2.3, depending on which ceiling is selected). The alternative approach of applying a single ceiling to the MFP across all dosage forms and

strengths of the selected drug would constrain the MFP for that dosage form and strength more significantly than the approach of applying a ceiling price specific to that dosage form and strength.

The counterexample where the ceiling price specific to a given dosage form and strength of the selected drug (as calculated in step 7 of section 60.2.2 or step 9 of section 60.2.3, depending on which ceiling is selected) is lower than the single ceiling price for the selected drug (as calculated in step 10 of section 60.2.2 or step 11 of section 60.2.3, depending on which ceiling is selected) is also possible. Under this example, the alternative approach of applying a single ceiling to the MFP across all dosage forms and strengths of the selected drug would constrain the MFP for that dosage form and strength less significantly than the approach of applying a ceiling price specific to that dosage form and strength.

Under both examples, the alternative of applying a single ceiling price for the selected drug would limit the degree to which price variation between different dosage forms and strengths is maintained in the application of the ceiling price to the MFP.

60.3 Methodology for Developing an Initial Offer

Section 1194(e) of the Act directs CMS to consider certain factors related to manufacturer-specific data and available evidence about therapeutic alternatives as the basis for determining offers and counteroffers in the negotiation process. While the statute requires CMS to provide an initial offer and a justification, it does not specify how CMS should determine an initial offer nor how or to what degree each factor should be considered.

As discussed in greater detail below, for the purposes of determining an initial offer, CMS intends to (1) identify therapeutic alternative(s), if any, for the selected drug as described in section 60.3.1 of this memorandum; (2) use the Part D net price for the therapeutic alternative(s) that is a Part D drug and/or the Part B average sales price (ASP) for the therapeutic alternative(s) that is a Part B drug to determine a starting point for developing an initial offer as described in section 60.3.2 of this memorandum; (3) evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternative(s)) for the purposes of adjusting the starting point using the negotiation factors outlined in section 1194(e)(2) of the Act, including whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations, as described in section 60.3.3 of this memorandum (resulting in the "preliminary price"); and (4) further adjust the preliminary price by the negotiation factors outlined in section 1194(e)(1) of the Act (described in section 60.3.4 of this memorandum) to determine the initial offer price.

CMS will not make or accept any offers for the MFP that are above the statutorily defined ceiling price described in section 60.2.1 of this memorandum.

60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication

For initial price applicability year 2026, CMS intends to identify the FDA-approved indication(s) not otherwise excluded from coverage or otherwise restricted under section 1860D-2(e)(2) of the Act for a selected drug, using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. CMS intends to consider off-label use when identifying indications if such use is included in nationally recognized, evidence-based guidelines and recognized by CMS-approved Part D compendia.³²

For each indication of the selected drug, CMS then intends to identify a pharmaceutical therapeutic alternative(s). CMS considered evaluating non-pharmaceutical therapeutic alternatives; however, for initial price applicability year 2026, the agency plans to only consider therapeutic alternatives that are covered Part D or Part B drugs or biologics. CMS believes that pharmaceutical therapeutic alternatives will be the most analogous alternatives to the selected drug when considering treatment effect and price differentials. To identify potential therapeutic alternatives for the indications of a selected drug, CMS intends to use data submitted by the Primary Manufacturer and the public, FDA-approved indications, indications included in CMS-approved Part D compendia, widely accepted clinical guidelines, and peer-reviewed studies.

CMS also intends to consider clinical evidence available through literature searches when a therapeutic alternative has not yet been incorporated into nationally recognized, evidence-based guidelines. CMS intends to begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes.

60.3.2 Developing a Starting Point for the Initial Offer

CMS considered several options for what price should be used as the starting point for developing the initial offer. Options considered include the use of the Part D net price(s) and/or the ASP(s) of therapeutic alternative(s), if any, to the selected drug, the unit cost of production and distribution for the selected drug, the ceiling price for the selected drug (as described in section 60.2 of this memorandum), a domestic reference price for the selected drug (e.g., the Federal Supply Schedule price), or a “fair profit” price for the selected drug based on whether research and development costs have been recouped and margin on unit cost of production and distribution. Under any of these options, the initial offer and final MFP would be capped at the statutory ceiling.

After considering these options, CMS intends to use the Part D net price(s) (“net price(s)”) and/or ASP(s) of therapeutic alternative(s) for the selected drug, as applicable, as the starting point for developing the MFP initial offer unless this net price or ASP is greater than the statutory ceiling (described in section 60.2 of this memorandum). CMS intends to identify the

³² CMS-approved Part D compendia are listed in Chapter 6 of the [Prescription Drug Benefit Manual](#) as described in 1927(g)(1)(B)(i) of the Act.

price of each therapeutic alternative that is a covered Part D drug net of all price concessions received by any Part D plan or pharmacy benefit manager on behalf of the Part D plan by using Part D PDE data and detailed DIR report data, similar to the calculation of the ceiling price using the sum of plan specific enrollment weighted amounts described in section 60.2.2 of this memorandum. In taking this approach, CMS acknowledges that the therapeutic alternative(s) for a selected drug may not be priced to reflect its clinical benefit, however, using net prices and ASPs of therapeutic alternatives enables CMS to start developing the initial offer within the context of the cost and clinical benefit of a group of drugs that treat the same disease or condition. By using the price(s) of the selected drug's therapeutic alternative(s), CMS would be able to focus the initial offer on clinical benefit by adjusting this starting point relative to whether the selected drug offers more, less, or similar clinical benefit compared to its therapeutic alternatives. The other potential options considered do not reflect the cost of therapeutic alternatives, which is an important factor when considering the overall benefit that a treatment brings to Medicare beneficiaries.

If there is one therapeutic alternative for the selected drug, CMS intends to use the net price or ASP, as applicable, of the therapeutic alternative as the starting point to develop CMS' initial offer for the MFP if it is lower than the ceiling. If there are multiple therapeutic alternatives, CMS intends to consider the range of net prices and/or ASPs as well as the utilization of each therapeutic alternative to determine the starting point within that range. If the selected drug has no therapeutic alternative, if the price of the therapeutic alternatives identified is above the statutory ceiling for the MFP (described in section 60.2 of this memorandum), or if there is a single therapeutic alternative with a price above the statutory ceiling, then CMS intends to determine the starting point for the initial offer based on the Federal Supply Schedule³³ (FSS) or "Big Four Agency"³⁴ price ("Big Four price"). If the FSS and Big Four prices are above the statutory ceiling, then CMS intends to use the statutory ceiling as the starting point for the initial offer.

CMS is soliciting comment on this intended approach to determining a starting point for developing the initial offer. Specifically, CMS is soliciting comments on the advantages and disadvantages of using net prices and/or ASPs as the starting point for the initial offer for selected drugs with at least one therapeutic alternative and the Federal Supply Schedule or Big Four price for selected drugs with no therapeutic alternative or for selected drugs with therapeutic alternatives with net prices and/or ASPs greater than the statutory ceiling. CMS is also soliciting comment on other starting points for the initial offer, including but not limited to other domestic reference prices, along with their disadvantages and advantages. Lastly, in the

³³ The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: <https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/about-gsa-schedule#:~:text=The%20GSA%20Schedule%2C%20also%20known,reasonable%20prices%20to%20the%20government.>

³⁴ The Big Four price is the maximum price that any "Big Four Agency" (the Department of Veteran's Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard) is required to pay. See: <https://www.cbo.gov/publication/57007>.

event that there are multiple therapeutic alternatives for the selected drug, CMS is soliciting comment on how to consider the range of net prices and/or ASPs and utilization of each therapeutic alternative to determine a single starting point for developing the initial offer.

60.3.3 Adjusting the Starting Point Based on Clinical Benefit

To evaluate the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), as applicable, CMS intends to broadly evaluate the body of clinical evidence, including data received from the public and manufacturers as described in section 50.2 of this memorandum, and data identified through a CMS-led literature review. CMS may also analyze Medicare claims or other pharmaceutical drug datasets for utilization patterns, clinical data, or other information relevant to the selected drug and its therapeutic alternative(s) and may consult with clinical and academic experts.

This approach provides a pathway for CMS to consider the multitude of information expected from public input, including but not limited to peer-reviewed research, expert reports or whitepapers, clinician expertise, real-world evidence, and patient experience. This approach also provides flexibility to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

Once the starting point for the initial offer has been established and evidence on clinical benefit has been considered, CMS intends to adjust the starting point for the initial offer based on the review of the clinical benefit (this adjusted price is referred to herein as the “preliminary price”). Per statute, CMS will not use evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill; this includes QALYs when used in association with life extension. CMS considered employing both a qualitative approach (e.g., adjusting the starting point upward or downward relative to the clinical benefit offered by the selected drug compared to its therapeutic alternatives) and a more thoroughly pre-specified quantitative approach. CMS intends to use a qualitative approach to preserve flexibility in negotiation, including the ability to consider nuanced differences between different drugs, for example interactions with other treatments commonly prescribed simultaneously for a condition or disease, and other factors that might not be captured in a more thoroughly pre-specified quantitative approach.

60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)

To consider comparative effectiveness between a selected drug and its therapeutic alternative(s), CMS intends to (1) identify outcomes to evaluate for each indication of the selected drug, and (2) consider the safety profile of the selected drug and the therapeutic alternative(s). CMS intends to consider health outcomes, intermediate outcomes, surrogate endpoints,³⁵ patient-reported

³⁵ A surrogate endpoint is an indirect measure of whether a treatment works. Surrogate endpoints may be used in clinical trials when a clinical outcome would take too long to study, in cases where the relationship between the

outcomes, and patient experience when reviewing the clinical benefit of the selected drug and its therapeutic alternative(s). When reviewing such information, as noted above CMS will not use evidence in a manner that treats extending the life of any individual as lower value than the life of another individual; this includes QALYs when used in association with life extension. Health outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to therapeutic alternatives. CMS also intends to consider validated surrogate endpoints that predict a relevant health outcome (e.g., lower blood pressure reducing the risk of stroke) and intermediate outcomes that indicate a change in health outcomes. Health outcomes such as changes in symptoms or other factors that are of importance to a person, and patient-reported outcomes would also be considered. CMS intends to focus the review of clinical benefit on outcomes of particular importance to the condition or disease being treated by the selected drug and will determine such outcomes from the CMS-led literature review and information submitted by manufacturers and the public through the Negotiation Data Elements ICR, described in section 50 of this memorandum.

In all cases, CMS intends to consider applicable evidence and other input collectively and within the context of the course of care for the condition(s) or disease(s) that the selected drug is indicated to treat. As noted previously, this approach provides flexibility to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

CMS will also consider the effects of the selected drug and its therapeutic alternative(s) on specific populations as required by section 1194(e)(2)(C) of the Act. To do so, CMS intends to prioritize studies focused on the impact of the selected drug and its therapeutic alternative(s) on individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations represented among Medicare beneficiaries. Further, CMS will consider whether the selected drug fills an unmet medical need, which CMS intends to define as treating a disease or condition in cases where very limited or no other treatment options exist.

CMS intends to determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression). CMS understands that a selected drug can be first in class,³⁶ however, if other drugs have become available since the selected drug's initial release, CMS will compare therapeutic alternatives with the same indication within or beyond the selected drug's class as described in this section. In accordance with section 1194(e)(2)(A) of the Act, CMS will review the analyses detailed above for each indication for the selected drug and its therapeutic alternative(s) and determine, based on the

surrogate endpoint and clinical benefit is well understood, or in cases where using a clinical endpoint would be unethical. See: <https://www.fda.gov/drugs/development-resources/surrogate-endpoint-resources-drug-and-biologic-development>.

³⁶ First in class drugs are those that have a new mechanism of action, defined by the National Cancer Institute as "a term used to describe how a drug or other substance produces an effect in the body." See <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action>.

relevant information and evidence, what the difference in clinical benefit is between the selected drug and the therapeutic alternative(s).

As previously noted, CMS intends to take a qualitative approach to adjusting the starting point based on the unique characteristics of the drug and its therapeutic alternative(s) as well as the patient population(s) taking the selected drug. For each selected drug, the applicable starting point would be adjusted based on the totality of the relevant information and evidence submitted and gathered through the agency's analysis based on the clinical benefit the selected drug provides. Because the extent of clinical benefit may vary across different indications, CMS may adjust the initial offer based on the clinical benefit for an individual indication in cases where the clinical benefit of the selected drug is notably different than the therapeutic alternative for that specific indication.

60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives

For selected drugs with no therapeutic alternatives, CMS intends to adjust the starting point for the initial offer based on the extent to which the selected drug fills an unmet medical need. CMS will consider unmet medical need separately for each indication. A selected drug will be considered to meet an unmet medical need for an indication included in the analysis in cases where limited or no treatment options exist.

Similar to a selected drug with at least one therapeutic alternative, the starting point for a selected drug without a therapeutic alternative would also be adjusted based on the totality of relevant information and evidence submitted and gathered through the agency's analysis based on the clinical benefit the selected drug provides.

60.3.4 Consideration of Manufacturer-Specific Data

Under section 1194(e)(1) of the Act, CMS must also consider factors reported by the Primary Manufacturer, described in section 50.1 of this memorandum. CMS will consider these data and may adjust the preliminary price (described in section 60.3.3 of this memorandum), as needed to address these manufacturer-specific data elements. These data elements include (1) research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs; (2) current unit costs of production and distribution of the drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the drug; (4) data on pending and approved patent applications or exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the drug; and (5) market data and revenue and sales volume data for the drug in the United States.

In considering element (1) above on research and development costs, CMS intends to consider the extent to which the Primary Manufacturer has recouped its research and development costs. CMS will compare the research and development costs and the global, net revenue reported by the Primary Manufacturer to determine the extent to which the Primary Manufacturer has recouped its research and development costs. For example, if a Primary Manufacturer has not

recouped its research and development costs, CMS could consider adjusting the preliminary price upward. Conversely, if a Primary Manufacturer has recouped its research and development costs, CMS may consider adjusting the preliminary price downward. CMS intends to use the research and development costs reported by the Primary Manufacturer, including the assumptions and calculations in the accompanying narrative text, the indication(s) for the selected drug, and other factors as described in the forthcoming Negotiation Data Elements ICR and in Appendix C of this memorandum.

In considering element (2) on current unit costs of production and distribution, CMS intends to consider the relationship between the preliminary price and the unit price of production and distribution. For example, CMS may consider adjusting the preliminary price downward if the unit cost of production and distribution is lower than the preliminary price, or upward if the preliminary price is close to the unit costs of production and distribution. Again, CMS may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug when determining if an adjustment would be appropriate.

In considering element (3) on prior Federal financial support, CMS intends to consider the extent to which the Primary Manufacturer benefited from Federal financial support. For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

In considering element (4) on patent applications, exclusivities, and applications and approvals for the selected drug, CMS intends to consider the length of the available patents and exclusivities before the selected drug may no longer be single source. For example, if the selected drug has patents and exclusivities that will last for a number of years, CMS may consider adjusting the preliminary price downward.

Finally, in considering element (5) on market data and revenue and sales volume data for the U.S., CMS intends to consider how the data compare to the CMS preliminary price. For example, if the average commercial net price is lower than the preliminary price, CMS may consider adjusting the preliminary price downward.

Appendix C of this memorandum includes a list of definitions that CMS intends to adopt for the purposes of describing the data to be collected with respect to the data elements listed in section 1194(e)(1) of the Act.

After any adjustments to the preliminary price are made under this section 60.3.4 of this memorandum, the result is the initial offer price.

60.4 Negotiation Process

In accordance with section 1191(b)(4) of the Act, and as described in section 40.1 of this memorandum, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into an Agreement, or, for initial price applicability year 2026, October 1,

2023. CMS intends to implement the offer and counteroffer process consistent with the requirements of the statute, with the goal of negotiating “the lowest maximum fair price for each selected drug” consistent with section 1194(b)(1) of the Act. In accordance with sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug for initial price applicability year 2026 no later than February 1, 2024. CMS plans to publish the Drug Price Negotiation Process Information Collection Request in Spring 2023 to capture information related to this process that will be submitted by the Primary Manufacturer.

After the written initial offer from CMS, the negotiation process would include:

- (1) in accordance with section 1194(b)(2)(C) of the Act, an optional written counteroffer from the Primary Manufacturer (if CMS’ written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer;
- (2) in accordance with Section 1194(b)(2)(D) of the Act, a written response from CMS to the optional written counteroffer;
- (3) if the Primary Manufacturer’s written counteroffer is not accepted by CMS, up to three possible in-person or virtual negotiation meetings between the Primary Manufacturer and CMS;
- (4) a final written offer made by CMS to the Primary Manufacturer; and,
- (5) a response by the Primary Manufacturer to CMS’ final written offer, either accepting or rejecting this final offer.

If at any point during the negotiation process, the Primary Manufacturer accepts CMS’ latest written offer by signing the written offer, or CMS accepts the Primary Manufacturer’s counteroffer by countersigning that written counteroffer, an agreement for the MFP would be reached. That MFP will apply for the selected drug for initial price applicability year 2026, but will be updated according to section 1195(b)(1)(A) of the Act. During the entire negotiation process, CMS cannot offer or agree to any manufacturer counteroffer that exceeds the statutorily determined ceiling price as defined in section 1194(c) of the Act and as described in section 60.2 of this memorandum.

60.4.1 Provision of an Initial Offer and Justification

In accordance with section 1194(b)(2)(B) of the Act, the written initial offer from CMS, made no later than February 1, 2024, must include a concise justification for the offer based on the factors described in section 50 of this memorandum. The concise justification for the offer would be based on the analysis described in section 60.3 of this memorandum. No offer can exceed the statutorily determined ceiling price as defined in section 1194(c) of the Act and as described in section 60.2 of this memorandum. CMS intends to provide the Primary Manufacturer with information about the statutorily determined ceiling price for the selected drug in its written initial offer to enable the Primary Manufacturer to better understand the context for the MFP offer made by the agency.

60.4.2 Required Components of a Counteroffer

In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will have no more than 30 days from receipt of the written initial offer from CMS to respond in writing by either accepting the initial offer for the selected drug or making a written counteroffer and providing a justification for such counteroffer based on the factors described in section 50 of this memorandum. Any counteroffer should also respond to the justification provided in CMS' written initial offer. The Primary Manufacturer's response should focus on the elements described in section 1194(e), and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the factors in section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS.

The Primary Manufacturer should provide a suggested MFP for the selected drug in its written counteroffer. As described in section 60.1 of this memorandum, the suggested MFP should be made consistent with the manner that CMS' initial written MFP offer was made; that is, a single price for the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths. In accordance with section 1194(b)(2)(F) of the Act, CMS cannot accept a manufacturer written counteroffer that exceeds the statutorily determined ceiling price as defined in section 1194(c) of the Act and as described in section 60.2 of this memorandum.

The Primary Manufacturer may request that certain details contained in the offer or counteroffer be included in the public explanation for the agreed-upon MFP for the selected drug. CMS intends to consider this request when drafting the public explanation, which is discussed further in section 60.6.1 of this memorandum. In accordance with section 1195(a)(2) of the Act, CMS intends to publish the public explanation for the agreed-upon MFPs for selected drugs for initial price applicability year 2026 no later than March 1, 2025.

60.4.3 Negotiation Process After Manufacturer Counteroffer

In accordance with section 1194(b)(2)(D) of the Act, CMS will respond in writing to a written counteroffer made by the Primary Manufacturer. Though the statute does not specify a timeframe for the CMS response to the counteroffer, negotiations for initial price applicability year 2026 must end prior to August 1, 2024, i.e., an agreement on MFP for the selected drug must be reached no later than July 31, 2024.

In the case CMS' written initial offer is not accepted, and the Primary Manufacturer submits a written counteroffer, CMS intends to consider the counteroffer and either accept or reject it. If CMS's written response to the counteroffer rejects the Primary Manufacturer's written counteroffer, the agency will extend an invitation to the Primary Manufacturer for a negotiation meeting to take place within 30 days of CMS' receiving the manufacturer's written counteroffer. CMS intends to hold a minimum of one meeting between CMS and the Primary Manufacturer to discuss CMS' written initial offer, the Primary Manufacturer's written counteroffer, and factors considered. After this initial meeting, CMS intends to give each party (CMS and the Primary Manufacturer) the opportunity to request one additional meeting, resulting in a maximum of

three meetings between CMS and the Primary Manufacturer. These meetings may be conducted in-person at CMS headquarters or virtually.

These meetings for initial price applicability year 2026 would occur between the time the Primary Manufacturer's written counteroffer is submitted, which must be no later than 30 days after receipt of the written initial offer, and June 30, 2024. There would be approximately four months' time between the Primary Manufacturer's written counteroffer to CMS and the deadline for negotiation meetings to conclude. CMS intends to require all negotiation meetings end no later than June 30, 2024, to allow CMS sufficient time to prepare a final offer, send such offer to the manufacturer by July 15, 2024, and to allow the Primary Manufacturer time to consider such final offer and accept or reject the offer by July 31, 2024, as all negotiations must be concluded prior to August 1, 2024.

CMS believes that the negotiation meeting process described above allows for a more efficient and effective approach than preparing and exchanging additional written offers and counteroffers. Negotiation meetings would also allow both parties to discuss any new information that may have become available about the selected drug or its therapeutic alternatives, consistent with the factors described in section 1194(e)(2) of the Act, that may affect the determination of the MFP. Negotiation meetings would be attended solely by representatives of both the Primary Manufacturer and of CMS, and details discussed during these meetings would not be made public by either CMS or the Primary Manufacturer. In the public explanation of the MFP (as discussed in section 60.6.1 of this memorandum) and any other public documents discussing the MFP, CMS may make high-level comments on the data submitted or discussed in negotiation meetings, without sharing any proprietary information (as described in section 40.2.1 of this memorandum).

When developing this negotiation process, CMS considered using solely a written offer and counteroffer approach. That is, CMS considered providing one written offer and allowing a Primary Manufacturer to make a single written counteroffer, as described in the statute. CMS also contemplated allowing each party to make up to two written offers or counteroffers (i.e., CMS makes an initial offer, Primary Manufacturer possibly makes a counteroffer, CMS possibly makes a second offer, Primary Manufacturer possibly makes a second counteroffer). However, CMS believes that an offer/counteroffer process that includes in-person or virtual meetings would most effectively facilitate the negotiation process to arrive at an MFP and is more consistent with current industry practices for drug price negotiation. CMS solicits comments on the proposed drug price negotiation process described in this section 60.4.3. Specifically, CMS is seeking comment on the advantages and disadvantages of the negotiation process described above, as well as whether there are alternatives that CMS should consider beyond those described in this section 60.4.3.

60.4.4 Determination that Negotiations Have Finished

In accordance with section 1194(b)(2)(E) and 1191(d)(2)(B) of the Act, all negotiations between CMS and the manufacturer of the selected drug must end prior to a certain date. For initial price applicability year 2026, the date is August 1, 2024. In the event that negotiation meetings have

occurred, CMS intends to send the Primary Manufacturer a “Notification of Final Maximum Fair Price Offer” by July 15, 2024. This would serve as the final offer to the Primary Manufacturer for the MFP for the selected drug. The Primary Manufacturer would be required to respond in writing to this final offer by either accepting or rejecting the offer by July 31, 2024. The following table details CMS’ intended timing for the negotiation process for initial price applicability year 2026:

Date	Milestone
February 1, 2024	Statutory deadline for CMS to send written initial offer to the Primary Manufacturer
30 days after receipt of written initial offer from CMS (March 2 nd if the offer is made by CMS on February 1, 2024)	Statutory deadline for the Primary Manufacturer to accept the initial offer or submit a written counteroffer to CMS
30 days after receipt of the manufacturer counteroffer (April 1 st if the manufacturer counteroffer is made on March 2, 2024)	Date by which CMS would provide a written response to manufacturer counteroffer
From the date that the Primary Manufacturer’s written counteroffer is not accepted by CMS through June 30, 2024	Negotiation meetings (in-person or virtual, maximum of three possible meetings), if necessary CMS would schedule the first meeting to occur within 30 days of receiving the written counteroffer from the Primary Manufacturer
July 15, 2024	Date by which CMS would issue a “Notification of Final Maximum Fair Price Offer” to the Primary Manufacturer, if the written initial offer or written counteroffer were not accepted and negotiations progressed to negotiation meetings
July 31, 2024	Date by which the Primary Manufacturer would respond to (accept/reject) CMS’ “Notification of Final Maximum Fair Price Offer,” if applicable
July 31, 2024	Statutory deadline for all negotiations to end; CMS will notify the Primary Manufacturer of any failure to meet the deadline and the possible consequences thereof if no MFP agreement by July 31, 2024
August 1, 2024	Statutory end of negotiation period

60.5 Application of the MFP Across Dosage Forms and Strengths

An MFP that is agreed upon as described in section 60.4 of this memorandum establishes one price for the selected drug. In accordance with section 1196(a)(2) of the Act, CMS has the administrative duty to establish procedures to compute and apply the MFP across different dosage forms and strengths of the selected drug and not based on the specific formulation or package size or package type of such drug.

As described in section 60.1 of this memorandum, the MFP would reflect a single price for the selected drug per 30-day equivalent supply. In order to ensure that the MFP is made available to MFP-eligible individuals at the point of sale (and to pharmacies, mail order services, or other dispensers, with respect to such MFP-eligible individuals), however, CMS intends to publish the MFP at the per unit (e.g., tablet) level for each dosage form and strength associated with the selected drug.

The following methodology would take the single MFP across dosage forms and strengths for a 30-day equivalent supply and calculate an MFP per unit for each dosage form and strength of the selected drug. CMS seeks to use a methodology that scales the MFP per unit based on price differentials across dosage forms and strengths. CMS is considering using the wholesale acquisition cost (WAC) of the selected drug in this calculation (and is soliciting comment on this approach, as noted below). If WAC is used, the WAC per unit cost for each NDC-9 of the selected drug would first be converted to an amount per dosage form and strength, to account for scenarios in which there are multiple NDC-9s for a selected drug that share a dosage form and strength. The WAC per unit cost for each dosage form and strength would then be converted into an amount for a 30-day equivalent supply, so that the WAC would represent an equivalent amount to the negotiated single MFP. The WAC per 30-day equivalent supply would then be used to calculate a WAC price ratio for each dosage form and strength of the selected drug. The ratio derived from the WAC per 30-day equivalent supply for each dosage form and strength would then be multiplied by the single MFP for the selected drug to calculate the MFP for a 30-day equivalent supply of each dosage form and strength of the selected drug. Lastly, to determine the per unit MFP for a dosage form and strength, CMS would convert from an MFP for a 30-day equivalent supply to an MFP per unit based on the average number of units in a 30-day equivalent supply.

The following steps provide additional detail behind the approach CMS is contemplating:

1. For each NDC-9 of the selected drug, CMS would divide the total number of units for the NDC-9 by the total number of units across all NDC-9s of that dosage form and strength using the Part D PDE data for 2022, then multiply that quotient by the WAC unit cost for that NDC-9.
 - Note: CMS is contemplating using the WAC unit cost for the period beginning January 1, 2022 and ending December 31, 2022 for purposes of this calculation to align with the time period of data used to calculate the ceiling for the MFP.
2. For each dosage form and strength of the selected drug, CMS would sum the amounts per NDC-9 from step 1 to yield a single WAC unit cost for that dosage form and strength of the selected drug.
3. For each dosage form and strength of the selected drug, CMS would divide the total number of units by the total 30-day equivalent supply calculated from Part D PDE data for 2022 to calculate the average number of units per 30-day equivalent supply.
4. For each dosage form and strength of each selected drug, CMS would multiply the WAC unit cost calculated in step 2 by the average number of units per 30-day equivalent supply calculated in step 3 to calculate the WAC per 30-day equivalent day supply.

5. For each dosage form and strength of the selected drug, CMS would divide the total 30-day equivalent supply for that dosage form and strength by the total 30-day equivalent supply across all dosage forms and strengths of the selected drug.
6. For each dosage form and strength of the selected drug, CMS would then multiply the amount calculated in step 5 by the WAC per 30-day equivalent supply as calculated in step 4.
7. CMS would then sum amounts calculated in step 6 across all dosage forms and strengths of the selected drug to calculate the WAC per 30-day equivalent supply across all dosage forms and strengths of the selected drug.
8. CMS would then divide the WAC per 30-day equivalent day supply for each dosage form and strength calculated in step 4 by the WAC per 30-day equivalent supply across dosage forms and strengths of the selected drug calculated in step 7, to calculate the WAC per 30-day equivalent supply ratio for each dosage form and strength of the selected drug.
9. For each dosage form and strength of the selected drug, CMS would multiply the single MFP for the selected drug by the relative WAC per 30-day equivalent supply ratio for that dosage form and strength calculated in step 8 to calculate the MFP per 30-day equivalent supply for that dosage form and strength.
10. CMS would divide the MFP per 30-day equivalent supply for each dosage form and strength of the selected drug calculated in step 9 by the quotient of the total number of units dispensed divided by the total 30-day equivalent supply to calculate the MFP per unit (e.g., tablet) for each dosage form and strength.

CMS intends to include the MFP per unit price for each dosage form and strength of the selected drug, calculated in step 10 of this section 60.5 of this memorandum, in the publication of MFPs, described in section 60.6 of this memorandum.

CMS is soliciting comment on this potential approach to computing the MFP across dosage forms and strengths of the selected drug. Specifically, CMS seeks comments on the advantages and disadvantages of using WAC in the computation of MFP at the per unit level. CMS seeks comments on any alternative approaches to the application of the MFP across dosage forms and strengths that could accurately and fairly compensate manufacturers and other entities throughout the supply chain. CMS also solicits comment on whether there are other approaches CMS should consider to apply the MFP across dosage forms and strengths that would be feasible, along with the disadvantages and advantages of the approaches. In particular, CMS would appreciate commenters' attention to the potential for disclosure of confidential or proprietary information (for example, manufacturer rebates) when considering other approaches.

60.5.1 Application of the MFP to New NDAs/BLAs or NDCs

Based on the definition of a qualifying single source drug described in section 30.1 of this memorandum, if the Primary Manufacturer for a selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety / active ingredient after the drug has been selected, CMS intends to require that the MFP apply to drug or biological products marketed pursuant to the new NDA or BLA. Similarly, after the drug is selected, if the Primary Manufacturer for such drug receives approval or licensure for a new drug or biological product

or NDC that is marketed pursuant to a supplement to an existing NDA or BLA, CMS intends to require that the MFP apply to such new drug or biological product.

CMS is soliciting comment on how to compute the MFP for a drug or biological product or NDC that is a selected drug and is marketed for the first time, pursuant to an existing or new NDA or BLA, after the drug is selected and an MFP has been agreed.

60.6 Publication of the MFP

In accordance with section 1191(d)(6) of the Act, CMS will publish by September 1, 2024 the MFP for each drug selected for initial price applicability year 2026 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Related to this requirement, CMS intends to publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file (which would be updated annually to show the inflation-adjusted MFP for a selected drug), and the explanation for the MFP (published at a later date – see section 60.6.1 of this memorandum). CMS also intends to publish on the CMS website: (1) when a drug is no longer a selected drug and the reason for that change and (2) when an MFP between a Primary Manufacturer and CMS is not agreed upon.

60.6.1 Explanation for the MFP

Section 1195(a)(2) of the Act requires CMS to publish an explanation for the MFP no later than March 1 of the year prior to the initial price applicability year, which will be March 1, 2025 for initial price applicability year 2026. CMS intends for the published explanation to summarize how relevant negotiation factors from section 1194(e) of the Act were considered during the negotiation process. The explanation would focus on the factors that had the greatest influence in determining the MFP and include the other factors, as applicable. As described in section 40.2.1 of this memorandum, in this public explanation, CMS intends to make high-level comments on the data submitted to CMS, without sharing any proprietary information.

To the degree each of the following are applicable to the negotiation for a selected drug, the published explanation of an MFP would, at a minimum, list the selected drug, discuss contributing negotiation factors from section 1194(e) of the Act, and note any factors or circumstances that may be unique to the selected drug.

If an agreement for an MFP is not reached for a selected drug, neither an MFP nor an explanation of the MFP would be published. Instead, CMS would indicate on the website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug. In circumstances where an MFP is finalized after the statutory deadline for the conclusion of negotiations, the MFP and an accompanying explanation of the MFP would be posted in accordance with section 60.8 of this memorandum.

60.7 Exclusion from the Negotiation Process

In accordance with section 1192(c)(2) of the Act, CMS will not begin or will suspend (as applicable) the negotiation for a selected drug, with respect to an initial price applicability year, if CMS determines that at least one drug or biological product satisfies the following criteria: (1)

it is approved under section 505(j) of the FD&C Act with at least one dosage form and strength of the selected drug as the listed drug, or licensed under section 351(k) of the PHS Act with at least one dosage form and strength of the selected drug as the reference product, and (2) is marketed pursuant to such approval or licensure. The approach CMS intends to take to make this determination is described in section 70 of this memorandum.

When the negotiation process is not started or is suspended, the selected drug will continue to be considered a selected drug with respect to such initial price applicability year (see section 70 of this memorandum for additional details).

60.8 Establishment of MFPs After the Negotiation Deadline

If the Primary Manufacturer of a selected drug would like to agree to an MFP after the end of the negotiation period, the Primary Manufacturer must notify CMS in writing that it would like to accept the last offer from CMS of an MFP, as reflected in the “Notification of Final Maximum Fair Price Offer.”

In accordance with section 1195(b)(2) of the Act, in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the MFPs are published for other selected drugs, CMS shall publish the MFP no later than 30 days after the date such MFP is so determined. In accordance with section 60.6 of this memorandum, CMS will publish the MFP and an accompanying explanation on the CMS website.

70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

In accordance with section 1192(c) of the Act, a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug, subject to the timeline and situations discussed below, if CMS determines (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure.

The approval (or licensure, as applicable) and marketing of an authorized generic drug (which includes authorized generic drugs and certain biological products as defined in section 1192(e)(2) of the Act) would not qualify as meeting the statutory requirement that a generic drug or a biosimilar biological product has been marketed. In accordance with section 1192(e)(2)(B)(i) of the Act, an authorized generic drug approved under section 505(t)(3) of the FD&C Act is treated as the same qualifying single source drug as a qualifying single source drug that is the listed drug, for the purposes of the Negotiation Program. Likewise, section 1192(e)(2)(B)(ii) of the Act indicates that the same rule applies to a biological product that is approved under section 351(a) of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under different labeling or packaging (other than

repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark.

Similar to the approach described in section 30.1 of this memorandum regarding how the agency determines whether a generic drug or biosimilar biological product is approved and marketed in order to identify qualifying single source drugs under section 1192(e) of the Act, for the purposes of determining whether a selected drug should not be subject to the negotiation process and ultimately removed from the selected drug list, CMS intends to review PDE data. CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when these data reveal that the manufacturer of the generic drug or biosimilar biological product has engaged in bona fide marketing of that drug or product. CMS will monitor the manufacturers of generic drugs or biosimilar biological products to ensure they are engaging in bona fide marketing of the generic or biosimilar biological product (see section 90.4 of this memorandum for details).

Starting in October 2023, and repeated each month thereafter, CMS intends to take the following approach in determining whether the statutory criteria in 1192(c)(1)(B) of the Act for an approved generic drug or licensed biosimilar to be marketed pursuant to such approval or licensure is being met. CMS would use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar biological product has been approved or licensed for any strength(s) or dosage form(s) of the selected drugs for initial price applicability year 2026.

If CMS determines that a generic drug or biosimilar biological product has been approved or licensed, CMS would review the PDE data with dates of service during the most recent 12-month period available to determine if the manufacturer of the generic drug or biosimilar biological product has engaged in bona fide marketing of that drug or product. For example, when CMS performs this assessment in October of 2023, CMS intends to use PDE data with dates of service from October, 2022 through September, 2023. When CMS performs this assessment in November, 2023, CMS intends to use PDE data for dates of service from November, 2022 through October, 2023.

Per section 1192(c)(2) of the Act, if CMS makes a determination regarding generic drug or biosimilar biological product availability on or after the selected drug publication date, and before or during the negotiation period for an initial price applicability year, the selected drug will not be subject to the negotiation process for the negotiation period, and an MFP will not be established. Accordingly, for initial price applicability year 2026, if CMS makes this determination between September 1, 2023, and August 1, 2024, the drug will remain a selected drug through 2026, but no MFP will apply and the drug will not be replaced with another selected drug.

In accordance with section 1192(c)(1) of the Act, a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least 9 months after the date

on which CMS determines the statutory criteria in section 1192(c) are met. Accordingly, if CMS makes this determination between August 2, 2024, and March 31, 2026, for a drug selected for initial price applicability year 2026, then the drug will cease to be a selected drug on January 1, 2027, and the MFP will apply for 2026. If CMS makes this determination between April 1, 2026, and March 31, 2027, then the selected drug will cease to be a selected drug on January 1, 2028, and the MFP will apply for 2026 and 2027. These results are summarized in the following table:

Date on which CMS determines that a generic drug or biosimilar biological product is approved and marketed	Result with respect to selected drug for the Negotiation Program
September 1, 2023 through August 1, 2024 (which includes Negotiation Period for initial price applicability year 2026)	Selected drug remains a selected drug for initial price applicability year 2026, though MFP <u>does not</u> apply; selected drug ceases to be a selected drug on January 1, 2027.
August 2, 2024 through March 31, 2026	Selected drug remains a selected drug and MFP applies for initial price applicability year 2026; selected drug ceases to be a selected drug on January 1, 2027.
April 1, 2026 through March 31, 2027	Selected drug remains a selected drug and MFP applies for initial price applicability year 2026 and calendar year 2027; selected drug ceases to be a selected drug on January 1, 2028.

In all cases, after CMS determines the statutory criteria in section 1192(c) for generic competition are met for a selected drug, CMS intends to publish such information on the CMS website.

80. MFP Eligible Individuals

In accordance with section 1191(c)(2) of the Act, the term “maximum fair price eligible individual” means, with respect to a selected drug, the following: in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under Medicare Part C (including enrollees in Employer Group Waiver Plans (EGWPs)) if coverage is provided under such plan for such selected drug; and/or in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under Medicare Part B, including an individual who is enrolled in an MA plan under Medicare Part C, if payment may be made under Part B for such selected drug.

90. Manufacturer Compliance and Oversight

In accordance with section 1196(b) of the Act, CMS intends to monitor compliance by a Primary Manufacturer with the terms of the Agreement and establish a mechanism through which violations of such terms shall be reported.

90.1 Monitoring of Manufacturer Compliance

CMS intends to closely monitor the Primary Manufacturer's compliance with the terms of the Agreement and other aspects of the Negotiation Program. Following the publication of selected drugs for each initial price applicability year, CMS intends to provide information about the negotiation process to the Primary Manufacturer of each selected drug (see section 40 of this memorandum for additional details). CMS anticipates this information will include operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact information. During the negotiation period, CMS plans to track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer. In addition, CMS intends to issue reminders and warning letters, as applicable, prior to various deadlines during the negotiation process.

Failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in excise tax liability (see section 90.3 of this memorandum).

As described in Section 100 of this memorandum, failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in civil monetary penalties (CMPs).

90.2 Monitoring of Access to the MFP

In accordance with section 1193(a)(3)(A) of the Act, under the Agreement with CMS with respect to a price applicability period, access to the MFP with respect to such a selected drug shall be provided by the Primary Manufacturer to MFP-eligible individuals at the pharmacy, mail order service, or other dispenser at the point of sale, and to the pharmacy, mail order service, or other dispenser with respect to such MFP-eligible individuals who are dispensed the selected drug.

Further, in accordance with section 1193(a)(5) of the Act, which requires that the manufacturer comply with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program, and section 40.4 of this memorandum, CMS intends to require that the Primary Manufacturer establish safeguards to ensure the MFP is available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers on units of the selected drug for which there are Secondary Manufacturers, as described in section 40.4 of this memorandum. CMS reiterates that the requirement to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual, as discussed in section 80 of this memorandum.

Moreover, in accordance with section 1196(a)(3)(A) of the Act, CMS intends to establish procedures for reporting violations related to access to the MFP with respect to MFP-eligible individuals who are enrolled in a PDP under Part D of title XVIII or MA-PD plan under Part C, as described later in this section.

Each component of the pharmaceutical supply chain may have a role in making the MFP available to MFP-eligible individuals, but it is ultimately the Primary Manufacturer's responsibility to ensure access to the MFP. There are various methods by which dispensing entities and MFP-eligible individuals can determine whether they are accessing the MFP for a selected drug.

For example, under section 1195(a) of the Act, the MFPs for selected drugs will be published by CMS, giving the public and other interested parties an opportunity to know the MFP for each selected drug, as well as the explanation for each MFP (see section 60.6 of memorandum for additional details). Under section 1191(d)(1), the MFPs for selected drugs for initial price applicability year 2026 must be published by September 1, 2024. In addition, CMS anticipates that pharmaceutical database companies will publish the MFPs such that they would become more readily accessible to pharmaceutical purchasers. CMS believes such transparency of the MFPs for selected drugs will help dispensing entities and MFP-eligible individuals to know the MFP for a selected drug and determine whether they are able to access the MFP. CMS is seeking comments on additional ways that CMS could help dispensing entities and MFP-eligible individuals know the MFP for a selected drug and determine whether they are able to access it.

Moreover, with respect to operationalizing access to the MFP, CMS intends to leverage existing mechanisms to ensure that dispensing entities have access to the MFP, and that the MFP for a selected drug is provided only to MFP-eligible individuals. For example, each Medicare Part D plan is required to use a unique Part D processor identification number (RxBIN) and Part D processor control number (RxPCN) combination to identify a Medicare Part D payer. This existing mechanism will ensure that the pharmacy is able to identify at the point of sale whether the individual is an MFP-eligible individual.

In addition, there is widespread use of chargeback payments and rebate mechanisms among the pharmaceutical stakeholders in the private sector, which allows for entities to receive rebates or discounts on their purchases after those purchases are made, based on the specific population to whom the drug or biological is dispensed. As appropriate, the private sector may make modifications to these existing mechanisms to effectuate access to the MFP.

For example, a pharmacy may purchase a medication for \$100 per bottle and the MFP as applied to this selected package is \$80. The Medicare beneficiary is enrolled in a Part D plan under which coverage of the selected drug is available, thus the beneficiary is an MFP-eligible individual. For this example, the plan has not negotiated a lower price for the medication. The pharmacy provides the negotiated price (i.e., MFP plus a dispensing fee) at the point of sale to the Medicare beneficiary. As a result of this transaction, the pharmacy is owed \$20 by the manufacturer. The pharmacy would submit the information regarding the \$20 chargeback amount to its wholesaler and receive a credit from the wholesaler for that amount. The wholesaler would be compensated by the manufacturer after billing the manufacturer for the chargeback amount.

CMS intends to establish a process by which beneficiaries, dispensing entities, and other providers and suppliers, would be able to report instances to CMS in which the MFP should have been made available to them but was not. CMS could establish a toll-free phone line and email box where an individual or a dispenser could communicate information to CMS regarding an incident in which the MFP was not provided. CMS anticipates the submissions would likely include the name of the individual reporting the incident, the nature of the incident, the date the incident occurred, the name and manufacturer of the drug, and contact information for follow-up.

Once received, CMS would review these email submissions, investigate reports of potential noncompliance, and if appropriate, impose CMPs on the Primary Manufacturer if CMS determines the Primary Manufacturer failed to provide an eligible dispenser access to the MFP for the selected drug, including in cases where there are one or more Secondary Manufacturers. CMS is seeking comment on how such a process would operate most effectively, including suggestions on ways that CMS could provide technical assistance to entities to ensure they are able to provide the MFP to MFP-eligible individuals and ways to ensure that MFP-eligible individuals whose cost-sharing was not consistent with MFP are made whole.

CMS would also expect manufacturers and other stakeholders to report instances in which a dispenser was not passing through the MFP to an MFP-eligible individual, or a dispenser was extending the MFP to non-MFP-eligible individuals.

CMS considered other options to ensure that manufacturers provide access to the MFP, but notes that the statute at section 1193(a)(3) of the Act specifies that it is the responsibility of the Primary Manufacturer, as part of its Agreement, to provide access to the MFP.

As discussed in section 40.4.1 of this memorandum and consistent with section 1193(d) of the Act regarding the manufacturer's Agreement with CMS, a manufacturer with an agreement with the Secretary under the 340B program is not required to provide a 340B covered entity with access to the MFP of a selected drug with respect to an MFP-eligible individual who is eligible to be furnished, administered, or dispensed such selected drug at the covered entity if the 340B ceiling price is lower than the MFP for such selected drug.

A manufacturer with an agreement with the Secretary under the 340B program is required to provide a 340B covered entity with access to the MFP of a selected drug with respect to an MFP-eligible individual who is eligible to be furnished, administered, or dispensed such selected drug at such covered entity if the MFP is below the 340B ceiling price for such selected drug.

Should it subsequently be determined that the 340B ceiling price is lower than the MFP for the selected drug, the manufacturer would have to provide to the covered entity the difference between the MFP and the 340B ceiling price. CMS intends to work with the Health Resources and Services Administration, which administers the 340B Drug Pricing Program, to help to ensure that the MFP is made available to 340B covered entities where appropriate.

CMS is seeking comments on other approaches the agency could consider that would be consistent with the statute to support the Primary Manufacturer in meeting its obligation to

ensure that any Secondary Manufacturer provides access to the MFP for dispensing entities. CMS is also aware that it is possible for an entity that meets the statutory definition of a manufacturer, but that is not the Primary Manufacturer or a Secondary Manufacturer, to market one or more drug or biological products pursuant to one or more NDA(s) or BLA(s) included in the selected drug.

For example, it is possible for an entity to purchase one or more drug or biological products included in the selected drug from a wholesaler, repackage or relabel such products, and then re-market them pursuant to one or more NDA(s) or BLA(s) included in the selected drug. CMS believes that the MFP should be made available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed units of the selected drug marketed by such manufacturers. CMS is soliciting comment on how it might monitor MFP access for these units of a selected drug, including how to identify the other manufacturers that market these selected drugs, and what mechanisms are available to ensure MFP is available for these units of the selected drug.

90.3 26 USC Section 5000D Excise Tax on Sale of Designated Drugs During Noncompliance Periods

The Internal Revenue Service (IRS) will administer the excise tax. The Treasury Department and the IRS anticipate issuing guidance separate from this document. As such, CMS is not soliciting comment on this section 90.3.

90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

In accordance with section 1192(c) of the Act, a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug, subject to the timeline and situations described in section 60.7 of this memorandum, if CMS determines (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure. Section 60.7 further describes the process by which CMS intends to determine whether a generic drug or biosimilar biological product is marketed. As described in section 30.1, CMS will review a generic drug's or biosimilar biological product's Total Expenditures under Part D as evidenced by PDE data in determining whether that drug or product has been marketed.

If CMS makes such a determination that a generic drug or biosimilar biological product has been marketed as evidenced by the PDE data, CMS intends to monitor whether robust and meaningful competition exists in the market once it makes such a determination, based on the process and timing described in section 60.7 of this memorandum. Examples of monitoring CMS may conduct include whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain, and whether it is available for purchase by community retail pharmacies in sufficient quantities from their

wholesale suppliers. In addition, CMS intends to analyze the share of generic drug or biosimilar biological product units identified in Part D PDE data as a percentage of total units of Part D expenditures.

CMS is seeking comment on the most effective ways to monitor whether robust and meaningful competition exists in the market after a selected drug ceases to be a selected drug.

100. Civil Monetary Penalties

In accordance with section 1197 of the Act, CMPs will be imposed on Primary Manufacturers of selected drugs that enter into an Agreement for (1) failure to ensure access to a price that is less than or equal to the MFP for MFP-eligible individuals and pharmacies, mail order services, and other dispensers who dispense the selected drug with respect to MFP-eligible individuals, (2) failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but has since undergone negotiation, as described in section 1192(f)(4) of the Act, and (3) violation of certain terms of the Agreement. In accordance with section 1197 of the Act, CMPs will be imposed on manufacturers for the provision of false information as described in section 100.3 below.

This memorandum addresses violations by a Primary Manufacturer with an Agreement in effect for failure to ensure access to a price for a selected drug less than or equal to the MFP, violation of terms of the Agreement, and provision of false information. Manufacturers will be subject to a CMP in accordance with section 1128A of the Act, described further in section 100.4 of this memorandum. Failure to pay a rebate for a biological product pursuant to section 1192(f)(4) of the Act will be addressed in future guidance.

100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP

In accordance with section 1197(a) of the Act, CMS will impose a CMP on a Primary Manufacturer of a selected drug that has entered into an Agreement with CMS and fails to provide access to a price that is less than or equal to the MFP to MFP-eligible individuals dispensed the selected drug, to pharmacies, mail order services, or other dispensers with respect to MFP-eligible individuals who are dispensed the selected drug or to hospitals, physicians, or other providers or suppliers that furnish or administer the selected drug to MFP-eligible individuals.

For this violation, the statute provides for a CMP equal to 10 times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered (during such year) and the difference between the price for such drug made available (for such year by such manufacturer) to MFP-eligible individuals or a hospital, physician, or other provider or supplier that furnishes or administers the selected drug to an MFP-eligible individual and the MFP for such drug for such year. For the purposes of calculating this CMP, CMS intends to use the net price to acquire the drug for the pharmacy, mail service, or dispenser, not including any service fees, as the price made available for the selected drug. As discussed in section 40.4 of

this memorandum, CMS intends to monitor for compliance and audit, as needed, to ensure that the MFP or a price lower than the MFP is being made available for the selected drug.

100.2 Violations of the Agreement

Per section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into an Agreement with CMS under section 1193 of the Act that fails to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program pursuant to section 1193(a)(5) or fails to provide the information required under section 1193(a)(4) will be subject to a CMP of \$1,000,000 for each day of such violation.

For example, as described in section 40.2 of this memorandum, information on each non-FAMP for the selected drug for the applicable period will be due to CMS as part of the forthcoming Negotiation Data Elements Information Collection Request no later than October 2, 2023 for initial price applicability year 2026. If the Primary Manufacturer fails to timely submit the required non-FAMP information, including the non-FAMP information for selected drug for which there is a Secondary Manufacturer, CMS will determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day after the applicable submission deadline (e.g., October 3, 2023 for initial price applicability year 2026) as the first day of violation with each additional day of violation thereafter counted until the day the Primary Manufacturer provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. Other examples of violations of the Agreement would include failure to comply with confidentiality requirements or data use and limitation requirements established in the Agreement.

Similarly, CMS will document requests for information required to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5). Such requests from CMS to the Primary Manufacturer will include a date by which any requested information must be submitted. Failure to provide requested information required to administer or monitor compliance with the Negotiation Program on or before the due date will result in a CMP. The first day of violation will be the day after the due date. For example, if CMS requests information for monitoring purposes by November 15, 2027, day one of the violation will be November 16, 2027. Each additional day of violation thereafter will be counted until the day the Primary Manufacturer provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement.

A Primary Manufacturer that knowingly submits false information that is required under the Agreement, will be out of compliance with the requirement to submit information and will be subject to this CMP. In instances of a Primary Manufacturer knowingly submitting false information that is required under the Agreement, CMS will determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day of submission of such false information under the Manufacturer Agreement, as the first day of violation with each additional day of violation thereafter counted until the day the Primary

Manufacturer provides a complete and accurate submission of the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement.

100.3 Provision of False Information

In accordance with section 1197(d) of the Act, if CMS determines that any manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) for the Small Biotech Exception, such manufacturer shall be subject to a CMP equal to \$100,000,000 for each item of such false information. Likewise, if CMS determines that any Biosimilar Manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Biosimilar Delay, such manufacturer shall be subject to a CMP equal to \$100,000,000 for each item of such false information.

100.4 Notice and Payment Procedures

For manufacturers that violate any of the provisions above, CMS will provide notice to the manufacturer with information regarding the CMP in accordance with section 1128A of the Act, including the option to either pay the CMP or to request a hearing as outlined in section 1128A. The CMP notice will include:

- Basis for the CMP;
- CMP amount due;
- Deadline for the manufacturer to respond with a hearing request or submit the CMP payment;
- Method to submit CMP payment(s); and
- Information on the right to request a hearing.

The manufacturer will have 60 days from the date of receipt of the CMP notice to request a hearing. The date of receipt is defined as the calendar day following the day on which the CMP notice is issued. If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act will apply. If the manufacturer does not request a hearing within 60 days, the CMP will be considered due on day 60 following the date of receipt of the CMP notice. As set forth in section 1128A(f), if the manufacturer does not pay the CMP timely, the CMP amount may be deducted from any sum then or later owing by the United States. CMP funds will be deposited in accordance with section 1128A(f).

110. Part D Formulary Inclusion of Selected Drugs

In accordance with section 1860D-4(b)(3)(I) of the Act, Medicare Part D plans shall include each covered Part D drug that is a selected drug on Part D formularies during Contract Year (CY) 2026 and all subsequent years for which the MFP of the selected drug is in effect during the price applicability period.

120. Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs

This section of the memorandum describes the application of Medicare Part B and Part D inflation rebates to selected drugs. As background, Section 11101 of the IRA added a new section 1847A(i) to the Act to require that manufacturers of Part B rebatable drugs pay inflation rebates to Medicare for certain Part B rebatable drugs based on specific requirements and formulas. Likewise, Section 11102 of the IRA added a new Section 1860D-14B to the Act, which requires that manufacturers of Part D rebatable drugs pay inflation rebates to Medicare for certain Part D rebatable drugs based on specific requirements and formulas.³⁷

Given that Part B drugs are subject to the negotiation process starting in initial price applicability year 2028, this guidance describes the interaction between the Negotiation Program and the Part D inflation rebate program. CMS is soliciting comment, however, as to whether guidance would be appropriate or necessary with respect to the interaction between the Negotiation Program and the Part B inflation rebate program for years before initial price applicability year 2028.

The Part D drug inflation rebate program is applicable to certain Part D drugs that meet the definition of a Part D rebatable drug and are dispensed under Part D and covered and paid for by Part D plans beginning for each 12-month applicable period, beginning October 1, 2022. These rebates are paid by manufacturers to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

The Part B and Part D inflation rebate programs apply to selected drugs, regardless of the status of the drug as a selected drug. Alternatively said, whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Part B and Part D inflation rebate programs. However, when a selected drug is no longer considered to be a selected drug, certain components of the applicable rebate amount formula are recalculated as discussed further below.

The statutory formula to determine the Part D drug inflation rebate amount owed by manufacturers for each Part D rebatable drug consists of various components, including the calculation of a benchmark period manufacturer price. This “benchmark period manufacturer price” is calculated based on a “payment amount benchmark period” for each Part D rebatable drug (established at section 1860D-14B(g)(3) for drugs first approved or licensed on or before October 1, 2021 and at section 1860D-14B(b)(5)(A) for drugs first approved or licensed after October 1, 2021), and a “benchmark period CPI-U”³⁸ for each Part D rebatable drug (established at section 1860D-14B(g)(4) for drugs first approved or licensed on or before October 1, 2021 and section 1860D-14B(b)(5)(A) for drugs first approved or licensed after October 1, 2021). The

³⁷ CMS published initial guidance on both Part B and Part D inflation rebates on February 9, 2023, which includes more specific details on the operation of the Part B and Part D inflation rebate programs. See:

<https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf> and <https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf>.

³⁸ CPI-U refers to the Consumer Price Index for all urban consumers (United States city average).

payment amount benchmark period is the basis for the calculation of the benchmark period manufacturer price.

For the period of time before a Part D rebatable drug is a selected drug, and during the time it is a selected drug, CMS will calculate the Part D inflation rebate amount, if applicable, based on the Part D rebatable drug's applicable payment amount benchmark period and benchmark period CPI-U, which is determined based on when the drug is first approved or licensed, as noted above. However, the statute at section 1860D-14B(b)(5)(C) specifies a different "payment amount benchmark period" and a "benchmark period CPI-U" for each Part D rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period is reset as the last year that begins during such price applicability period for such selected drug, and the benchmark period CPI-U is established as the January of the last year beginning during such price applicability period.

Cited in Boehringer Ingelheim Pharmaceuticals, Inc.
v. Dep't of Health & Hum. Servs., No. 24-2092,
archived on 8/7/2025

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Appendix A: Email Template for Biosimilar Manufacturer to Indicate Intent to Submit an Initial Delay Request for Initial Price Applicability Year 2026

Email subject line:

Biosimilar Delay: Notice of Intent to Submit Initial Delay Request for Initial Price Applicability Year 2026

Body of email:

Dear CMS,

I, an authorized representative of [insert manufacturer name], am notifying CMS that my company is the manufacturer of a biosimilar biological product and we anticipate the reference product for our biosimilar biological product will be included in a negotiation-eligible drug with respect to initial price applicability year 2026 for the Medicare Drug Price Negotiation Program. My company reasonably believes the market entry of our biosimilar biological product meets the criteria for the special rule to delay selection and negotiation of the negotiation-eligible drug, described in section 1192(f) of the Social Security Act. Therefore, I am notifying CMS of my company's intent to request that CMS delay the inclusion of the negotiation-eligible drug that includes the reference product for our biosimilar biological product on the selected drug list for initial price applicability year 2026.

As part of this notification, I am providing the following information:

My job title:	[insert]
My email address:	[insert]
My phone number:	[insert]
My company's mailing address:	[insert]
My company's biosimilar biological product name:	[insert]
Product name of the reference product for my company's biosimilar biological product	[insert]

Signed,

[Insert name of authorized representative]

Appendix B: Template for the Initial Delay Request Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act), to negotiate maximum fair prices (MFPs)³⁹ for selected drugs. Under section 1192(f) of the Act (the “Biosimilar Delay”), the manufacturer of a biosimilar biological product (“Biosimilar Manufacturer” of a “Biosimilar”) may submit a request, prior to the selected drug publication date, for CMS’ consideration to delay the inclusion of a negotiation-eligible drug (as defined in section 1192(d) of the Act) that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a “Reference Drug”) on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA for the Biosimilar that has been submitted for review by FDA.

Please refer to the memo titled “Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments” (Initial Negotiation Program Guidance) for additional details regarding the implementation of the Biosimilar Delay for initial price applicability year 2026. This form serves as the template that a Biosimilar Manufacturer may complete to submit an Initial Delay Request with respect to initial price applicability year 2026.

Submission of the email described in that memo indicating the Biosimilar Manufacturer’s intention to submit an Initial Delay Request for initial price applicability year 2026 and receipt of the fillable Initial Delay Request form template and request-specific Box folder should occur prior to completing this form.

Instructions

- Initial Delay Requests that are incomplete or not timely submitted will not be accepted. For an Initial Delay Request to be timely for initial price applicability year 2026, the Biosimilar Manufacturer must submit a complete Initial Delay Request to CMS no later than 11:59 pm PT on May 22, 2023. CMS will deem an Initial Delay Request to be complete if it includes a complete Initial Delay Request form using this fillable template and the following documentation.
 - All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

³⁹ In accordance with section 1191(c)(3) of the Social Security Act, (“the Act”), maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

- The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act, to the extent available; and
- Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.
- The data entry component of this submission should be completed by an individual authorized by the Biosimilar Manufacturer.
- The certification of the Initial Delay Request should be executed by (1) the chief executive officer (CEO) of the Biosimilar Manufacturer, (2) the chief financial officer (CFO) of the Biosimilar Manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

CMS is relying on the fullness, accuracy, and completeness of the Biosimilar Manufacturer's submission to determine whether to approve the Initial Delay Request for initial price applicability year 2026. If the Biosimilar Manufacturer submits an Initial Delay Request that is not timely, complete, and accurate, the submission may adversely affect the Negotiation Program, including the process for selecting drugs for negotiation for initial price applicability year 2026.

Section 1: Identifying information

Identifying information for Biosimilar Manufacturer

Q1. Complete the following table with identifying information for the Biosimilar Manufacturer.

Field	Response
Entity Type	<input type="checkbox"/> Biosimilar Manufacturer
Entity name	Text
Employer Identification Number (EIN(s))	Text
Address	Text
Unique Identifier Assigned by CMS (P-number)	Text
Labeler Code(s)	Text

Identifying information on Biosimilar

Q2. Complete the following table with identifying information for the Biosimilar.

Field	Response
Product Name	Text
Active Ingredient	Text
NDC-9(s) (if applicable)	[optional, only if available]

Q3. List all applications for licensure for the Biosimilar under 351(k) of the Public Health Service (PHS) Act regardless of status (i.e., including applications that are approved, accepted for review, and submitted but not yet accepted for review). Leave approval date blank if license has not been approved.

Add additional rows for each application

Application Number	Submission Number	Application status	Approval Date [if licensed]	Indication	Dosage Form and Strength	Licensure planned before September 1, 2025?	Marketing planned before September 1, 2025?
nnnnnn	nnn	[Approved, Accepted for Review, Submitted]	MM/DD/YYYY	Text	Text	[Yes/No]	[Yes/No]

Identifying information on Reference Product

Q4. Complete the following table with identifying information for the reference product for the Biosimilar.

Field	Response
Product Name	Text
Active Ingredient	Text
NDC-9(s)	Text

Q5. List the Biologic License Application (BLA) approved by the Food and Drug Administration (FDA) under section 351(a) of the PHS Act for the reference product for the Biosimilar.

Application Number	Submission Number	Approval Date	Indication	Dosage Form and Strength	Sponsor
nnnnnn	nnn	MM/DD/YYYY	Text	Text	Text

Identifying information on Reference Manufacturer

Q6. Complete the following table with identifying information for the Reference Manufacturer.

Field	Response
Entity Type	<input type="checkbox"/> Reference Manufacturer
Entity name	Text
Employer Identification Number (EIN)	[Optional, only if known]
Address	[Optional, only if known]
Unique Identifier Assigned by CMS (P-number)	[Optional, only if known]
Labeler Code(s)	[Optional, only if known]

Section 2: Attestations to Requirements for Granting an Initial Delay Request

In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not delay inclusion of a biological product on the list of selected drugs if the Biosimilar Manufacturer meets any of the statutory criteria for an excluded manufacturer. Questions 7 through 9 address whether the Biosimilar Manufacturer is an excluded manufacturer.

Q7. Relationship between Biosimilar Manufacturer and Reference Manufacturer: In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not approve an Initial Delay Request if the Biosimilar Manufacturer is the same as the Reference Manufacturer or is treated as being the same as the Reference Manufacturer based on the aggregation rule in section 1192(f)(1)(C) of the Act. This aggregation rule provides, “all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer” for purposes of the Biosimilar Delay. Further, section 1192(f)(1)(C) of the Act establishes that “the term ‘partnership’ means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on” by two or more parties for the purposes of the Biosimilar Delay.

Read the following statement and check the box if accurate:

I confirm consistent with sections 1192(f)(1)(C) and 1192(f)(2)(D)(iv) of the Act that the Biosimilar Manufacturer submitting this request is not the same or is not treated as being the same as the Reference Manufacturer.	<input type="checkbox"/>
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Q8. Incentives: In accordance with section 1192(f)(2)(D)(iv)(II)(aa) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(aa) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that requires or incentivizes the Biosimilar Manufacturer to submit this or any other Initial Delay Request.	<input type="checkbox"/>
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Q9. Quantity Restriction: In accordance with section 1192(f)(2)(D)(iv)(II)(bb) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that restricts the quantity, either

directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(bb) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that restricts the quantity, either directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.	<input type="checkbox"/>
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In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025. Questions 10 and 11 are relevant for this determination.

Q10. Licensure: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be licensed before September 1, 2025. For the purposes of this Initial Delay Request, 'licensed' means approved by the FDA under section 351(k) of the PHS Act.

Select the following option that best describes the current licensure status of the Biosimilar as of the submission of this Initial Delay Request:

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and the Biosimilar has been licensed.	<input type="checkbox"/>
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and the FDA has accepted such application for review.	<input type="checkbox"/>
(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and has not received a determination from FDA that such application has been accepted for review.	<input type="checkbox"/>
(D) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has not submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act.	<input type="checkbox"/>

Q11. Marketing: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be marketed before September 1, 2025.

Select the following option that best describes the current marketing status of the Biosimilar as of the submission of this Initial Delay Request:

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar is currently marketed.	<input type="checkbox"/>
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar has not yet been marketed but the Biosimilar Manufacturer expects it to be marketed by September 1, 2025.	<input type="checkbox"/>
(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar has not yet been marketed and the Biosimilar Manufacturer does not expect it to be marketed by September 1, 2025.	<input type="checkbox"/>

Section 3: Supporting Documentation

Q12. Manufacturing schedule: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, the manufacturing schedule for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation - Manufacturing schedule' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload the manufacturing schedule(s) for the Biosimilar submitted to the FDA for each application listed in Q3.

Read the following statements and check the boxes if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that the manufacturing schedule(s) for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure is available for submission.	<input type="checkbox"/>
I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS the manufacturing schedule(s) for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure.	<input type="checkbox"/>

Q13. Disclosures: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the Biosimilar Manufacturer that are typical of the normal course of business before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation – Disclosures' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload all such disclosures.

Read the following statements and check the boxes if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the Biosimilar Manufacturer that are typical of the normal course of business before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, are available for submission.	<input type="checkbox"/>
I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS all such disclosures.	<input type="checkbox"/>

Q14. Agreements:

In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation – Agreements' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload all such agreements.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.	<input type="checkbox"/>
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Section 4: Certification

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including to determine whether CMS should delay the selection of a biological product that would, absent this request, be included on the selected drug list for initial price applicability year 2026, as described in section 1192(f) of the Social Security Act. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes ☐

No ☐

Contact Information

Field	Response
Name of the Person Responsible for the Submission	Text
Title	Text
Telephone	Text
Email	Text
Signature	Text
Date	Text

Cited in Boehringer Ingelheim Pharms., Inc.
v. Dep't of Health & Hum. Servs.,
no. 24-2092,
archived on 8/7/2025

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Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data

For the purposes of describing the data at sections 1194(e)(1) and 1193(a)(4)(A) of the Act to be collected for use in the Negotiation Program, as described in section 50.1 of this memorandum, CMS intends to adopt the following definitions as described in this Appendix C. CMS is seeking comment on this Appendix C.

General

- “Marketing” is defined as the introduction or delivery for introduction into interstate commerce of a drug product.
- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment. If a Primary Manufacturer uses a cost of capital below 8.1 percent, that amount should be used.

Non-FAMP

For the purposes of collecting the data described in section 1193(a)(4)(A) of the Act for use in the Negotiation Program, as described in section 50.1.1 of this memorandum, CMS intends to adopt the following definitions:

- Non-FAMP price: Section 1194(c)(6) of the Act defines “average non-Federal average manufacturer price” as the average of the non-FAMP (as defined in section 8126(h)(5) of title 38 of the U.S. Code) for the four calendar quarters of the year involved.
- Non-FAMP unit. Non-FAMP unit is the package unit as described in section 8126(h)(6) of title 38 of the U.S. Code.

Research & Development (R&D) Costs

For the purposes of describing R&D costs of the Primary Manufacturer to be collected for use in the Negotiation Program for the selected drug and the extent to which the Primary Manufacturer has recouped those costs, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

CMS is considering R&D costs to mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications of a drug falling into the following categories, and excluding Federal funding, acquisition costs, and costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

1. R&D: Basic Pre-Clinical Research Costs
2. R&D: Post-Investigational New Drug (IND) Application Costs
3. R&D: Completed U.S. Food and Drug Administration (FDA)-Required Phase IV Trials
4. R&D: Post-Marketing Trials
5. R&D: Abandoned and Failed Drug Costs
6. R&D: All Other R&D Costs

CMS is calculating recoupment of R&D costs using the global, total lifetime net revenue for the selected drug:

7. Recoupment: Global, Total Lifetime Net Revenue for the Selected Drug.

The definitions and associated time periods for these terms are included below.

Definitions for 1. R&D: Basic Pre-Clinical Research Costs:

- Basic pre-clinical research is defined as all discovery and preclinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and is the sum of (1) direct research expenses and (2) a proportion of indirect research expenses.
- The basic pre-clinical research period is defined as the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA/BLA(s) or NDA/BLA(s) of the future selected drug (whichever is earlier) to the day before the last IND application for the selected drug went into effect.^{40, 41} This may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. For example, if the selected drug had five IND applications approved, use the date of the first IND application that went into effect as the end date for the 52-month period.⁴²
- Direct research expenses are costs that can be specifically attributed to the discovery and preclinical development of the selected drug. Direct research expenses could include personnel (compensation for investigators and staff) researching the selected drug, materials for conducting basic preclinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect research expenses and relevant general and administrative expenses are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biologics. To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.⁴³ For example, if the *direct* costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs, then

⁴⁰ CMS acknowledges that the exact date of initial discovery might not be known, but manufacturers should use their best estimate.

⁴¹ For the purposes of identifying the date the Primary Manufacturer acquired the right to hold the NDA(s)/BLA(s) of the selected drug, use the earliest date of acquisition for any NDA/BLA of the selected drug.

⁴² DiMasi, J, Hansen, R, Grabowski, H. The price of innovation: new estimates of drug development costs. *Journal of Health Economics*. <https://fds.duke.edu/db?attachment-25--1301-view-168>. CMS believes that 52 months represents an average across studies. For example, the Congressional Budget Office (CBO) estimated that the preclinical phase can take anywhere from 31 months to 84 months in this report: <https://www.cbo.gov/publication/57126>.

⁴³ Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*. 2020;323(9):844-853. doi:10.1001/jama.2020.1166; Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press; 2005, [https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition\(e43f24cd-099a-4d56-97e6-6524afaa37d1\)/export.html](https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html).

indirect costs should be allocated proportionally, thus for the selected drug they should be 10 percent of the total spending on *indirect* costs during that time period.

Definitions for 2. Post-Investigational New Drug (IND) Application Costs

- Post-IND costs are defined as all direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication.
- Direct costs for post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period.
- The post-IND period is defined as the day the IND went into effect for the first FDA-approved indication for the selected drug through the date the most recent NDA/BLA was approved for the selected drug.

Definitions for 3. R&D: Completed U.S. Food and Drug Administration (FDA)-Required Phase IV Trials

- Post-marketing trials are defined as studies conducted after the FDA has approved a product for marketing, including studies required of or agreed to by a manufacturer.
- Direct costs for completed Phase IV studies include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed Phase IV study.

Definitions for 4. R&D: Post-Marketing Trials

- Post-marketing trials are defined as studies conducted after the FDA has approved a product for marketing, including studies required of or agreed to by a manufacturer.
- The post-marketing trial costs should include the direct cost for FDA-required Phase IV trials that were not completed and the direct cost for post-marketing trials conducted for the purposes of marketing claims.
- Direct costs include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the incomplete Phase IV trial or the post-marketing trial.

Definitions for 5. R&D: Abandoned and Failed Drug Costs

- Failed or abandoned product costs include a sum of the portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
- Failed or abandoned products costs include a portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials.
 - Direct research expenses are costs that can specifically be attributed to the discovery and preclinical development of the drug.

- Direct research expenses include personnel (compensation for investigators and staff) researching the drug, materials for conducting basic preclinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned products costs include a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
 - Direct post-IND costs are costs that can specifically be attributed to the dosing and clinical trials for the drug.
 - Direct post-IND costs include Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting dosing and clinical trials for the drug.

Definitions for 6. R&D: All Other R&D Costs

- No additional definitions adopted.

Definitions for 7. Global, Total Lifetime Manufacturer Net Revenue for the Selected Drug

- CMS will use the Primary Manufacturer's global, total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug.
- Global, total lifetime net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.
- Global, total lifetime net revenue period is defined as the date the drug or biologic was first sold anywhere globally through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If global, total lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.

Current Unit Costs of Production and Distribution

For the purposes of describing current unit costs of production and distribution to be collected for use in the Negotiation Program for the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- In accordance with section 1191(c)(6) of the Act, the term 'unit' means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

- Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)⁴⁴: each (EA), milliliter (ML), or gram (GM). The unit reported must be specified for each of the NDC-9s included in the selected drug. Selections of EA, ML or GM must be made as follows:
 - “EA” is used when the product is dispensed in discrete units. These products are not measured by volume or weight. The Billing Unit of “EA” is also used to address exceptions where “GM” and “ML” are not applicable. Examples of products defined as “EA” include, but are not limited to:
 - Tablets;
 - Capsules;
 - Suppositories;
 - Transdermal patches;
 - Non-filled syringes;
 - Tapes;
 - Devices/Digital Therapies;
 - Blister packs;
 - Oral powder packets;
 - Powder filled vials for injection;
 - Kits; and
 - Unit-of-use packages of products other than injectables with a quantity less than one milliliter or gram should be billed as “one each,” for example, ointment in packets of less than 1 gram or eye drops in dropperettes that contain less than 1 mL.
 - “ML” is used when a product is measured by its liquid volume. Examples of products defined as “ML” include, but are not limited to:
 - Liquid non-injectable products of 1 mL or greater;
 - Liquid injectable products in vials/ampules/syringes;
 - Reconstitutable non-injectable products at the final volume after reconstitution except when they are in powder packets; and
 - Inhalers (when labeled as milliliters on the product).
 - “GM” is used when a product is measured by its weight. Examples of products defined as “GM” include, but are not limited to:
 - Creams (of 1 GM or greater);
 - Ointments (of 1 GM or greater); and
 - Inhalers (when labeled as GM on the product)⁴⁵.
- Costs of production are defined as all (direct and allocation of indirect) costs related to:
 - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
 - Formulation and preparation of the finished drug product;

⁴⁴ <https://standards.ncdpd.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22>

⁴⁵ https://standards.ncdpd.org/Standards/media/pdf/BUS_fact_sheet.pdf. Permission is hereby granted to any organization to copy and distribute this material as long as this copyright statement is included, the contents are not changed, and the copies are not sold.

- Quality control and testing of the drug; and
- Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug;
- Costs of distribution are defined as all (direct and allocation of indirect) costs related to:
 - Packaging and packaging materials;
 - Labeling;
 - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
 - Operating costs for facilities, transportation, and other expenses related to packaging, labelling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer;
- Current unit costs of production and distribution of the selected drug are defined to include:
 - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
 - Average unit costs during the 12-month period ending May 31, 2023 (for selected drugs for initial price applicability year);
 - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.; and
 - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third parties (e.g., contractors) performing activities that qualify as production or distribution, as specified above.
 - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-9 based on unit volume.
- Current unit costs of production and distribution of the selected drug are defined not to include:
 - R&D costs; and
 - Marketing costs.

Prior Federal Financial Support

For the purposes of describing prior federal financial support for novel therapeutic discovery and development to be collected for use in the Negotiation Program with respect to the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- “Federal financial support for novel therapeutic discovery and development” refers to tax credits, direct financial support, grants or contracts, and any other funds provided by the

federal government that support discovery, research, and/or development related to the selected drug.

- “*Prior Federal financial support*” refers to Federal financial support for novel therapeutic discovery and development (as defined above) issued during the time period from when initial research began (as defined above in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, to the day through the date the most recent NDA/BLA was approved for the selected drug.

Patents, Exclusivities, and Approvals

For the purposes of describing patents, exclusivities, and approvals to be collected for use in the Negotiation Program for the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- CMS considers patents relevant to this data to include:
 - all pending and approved patent applications, including expired and non-expired approved patents, submitted, sponsored, licensed, and/or acquired by the Primary Manufacturer relating to the selected drug as of September 1, 2023;
 - patents linked to the selected drug where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product); and
 - all patent applications, pending and approved, for which a claim of patent infringement could reasonably be, or has been, asserted against a person engaged in the unlicensed manufacture, use, or sale of the selected drug in any form.
- A pending patent application is any provisional or nonprovisional patent application submitted to the United States Patent and Trademark Office for which a patent number(s) has not been issued.
- An approved patent application is any patent application submitted to the United States Patent and Trademark Office for which a patent number(s) has been issued.
- An expired patent is any patent application approved by the United States Patent and Trademark Office for which a patent number(s) was issued and that has now expired.
- Exclusivity periods recognized by FDA refer to certain delays and prohibitions on the approval of competitor drugs that attach upon approval of a drug. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met.⁴⁶ Exclusivities include:
 - Orphan Drug Exclusivity (ODE);⁴⁷
 - New Chemical Entity Exclusivity (NCE);⁴⁸
 - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);⁴⁹

⁴⁶ <https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity>

⁴⁷ 21 C.F.R. 316.31, 316.34

⁴⁸ 21 C.F.R. 314.108

⁴⁹ Section 505E of the Federal Food, Drug, and Cosmetic Act

- New Clinical Investigation Exclusivity (NCI);⁵⁰
- Pediatric Exclusivity (PED);⁵¹ and
- Reference Product Exclusivity for Biological Products.⁵²
- Active and pending FDA applications and approvals includes:
 - all applications for approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or sections 351(a) of the Public Health Service Act, including those not yet decided; and
 - all applications for which the Primary Manufacturer is directly or indirectly involved in the production, preparation, propagation, compounding, conversion, processing, packaging, repackaging, labeling, relabeling, or distribution (not just those applications the Primary Manufacturer has submitted or sponsored).

Market Data and Revenue and Sales Volume Data

For the purposes of describing market data and revenue and sales volume data to be collected for use in the Negotiation Program for the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- Wholesale acquisition cost (WAC) unit price: The manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price would be reported at the NDC-9 level.
- National Council of Prescription Drug Programs Billing Unit Standards: The three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)⁵³ are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS to facilitate comparison with the amounts in the quantity dispensed field found in PDE data that also uses the NCPDP BUS.
- 340B ceiling price: The 340B ceiling price is defined in section 340B(a)(1) of the PHS Act and in 42 CFR §10.3 and §10.10(a). The 340B ceiling price would be reported at the NDC-11 level.
- Medicaid best price: The Medicaid best price is defined in 42 CFR §447.505(a). The Medicaid best price would be reported at the NDC-9 level.
- Average manufacturer price (AMP) unit: The type of unit used to report AMP (42 CFR §447.504) and best price (42 CFR §447.505) to Medicaid: injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie.

⁵⁰ 21 C.F.R. 314.108

⁵¹ Section 505A of the Federal Food, Drug, and Cosmetic Act

⁵² Section 351(a) of the PHS Act

⁵³ <https://standards.ncdpd.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22>

- 340B prime vendor program (PVP) price: The price offered under the 340B PVP established by section 340B(a)(8) of the PHS Act. The 340B PVP price would be reported at the NDC-11 level.
- Federal supply schedule (FSS) price: The price offered by the Department of Veterans Affairs (VA) in its FSS program, by delegated authority of the General Services Administration.⁵⁴ The FSS price would be reported at the NDC-11 level.
- Big Four price: The Big Four price is described in section 8126 of title 38, U. S. C. The Big Four price would be reported at the NDC-11 level.
- U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid Managed Care. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price would be reported at the NDC-9 level.
- U.S. commercial average net unit price— without patient assistant program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the U.S. commercial average net unit price net of coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price— without patient assistant program would be reported at the NDC-9 level.
- U.S. commercial average net unit price— best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price— best would be reported at the NDC-9 level.
- Manufacturer average net unit price to Part D Plan sponsors: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for Part D plan sponsors. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The manufacturer average net unit price to Part D Plan sponsors would be reported at the NDC-9 level.

⁵⁴ <https://www.fss.va.gov/index.asp>

- Manufacturer average net unit price to Part D Plan sponsors— without patient assistant program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer average net unit price to Part D Plan sponsors net of coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The manufacturer average net unit price to Part D Plan sponsors— without patient assistant program would be reported at the NDC-9 level.
- Manufacturer average net unit price to Part D Plan sponsors— best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest manufacturer average net unit price to Part D Plan sponsors offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any Part D plan sponsor. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The manufacturer average net unit price to Part D Plan sponsors— best would be reported at the NDC-9 level.
- Covered entity: Covered entity is defined in 42 CFR §10.3.
- Acquisition: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the Primary Manufacturer purchase of the rights to hold previously approved or future NDA(s)/BLA(s) of the future selected drug from another manufacturer.
- Gross revenue: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the Primary Manufacturer and all Secondary Manufacturer(s) total sales to all purchasers in the U.S. Gross revenue would be reported at the NDC-9 level.
- Net revenue: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, gross revenue minus discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers in the U.S. Net revenue would be reported at the NDC-9 level.
- Net revenue— without patient assistance programs: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, net revenue further net coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). Net revenue— without patient assistance programs would be reported at the NDC-9 level.
- Quarterly total U.S. unit volume: The total number of units (using NCPDP BUS) of the selected drug sold to any purchaser during the quarter. Quarterly total U.S. unit volume would be reported at the NDC-9 level.

Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026



CENTERS FOR MEDICARE & MEDICAID SERVICES

In August 2022, President Biden signed the Inflation Reduction Act of 2022 (P.L. 117-169) into law. The new law makes improvements to Medicare by expanding benefits, lowering drug costs, and improving the sustainability of the Medicare program for generations to come. The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare, both now and in the long run.

For the first time, the law provides Medicare the ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition. On August 29, 2023, the Centers for Medicare & Medicaid Services (CMS) announced the [10 drugs](#) covered under Medicare Part D selected for the first cycle of negotiations.

October 1, 2023 was the statutory deadline for drug companies that manufacture the drugs selected for the Negotiation Program for 2026 to choose to sign agreements to participate in the Negotiation Program. The below list indicates that drug companies that manufacture all 10 drugs selected for the Medicare Drug Price Negotiation Program for the first cycle have chosen to participate in the Negotiation Program.

Drug Name	Participating Manufacturer
Eliquis	Bristol Myers Squibb
Jardiance	Boehringer Ingelheim
Xarelto	Janssen Pharms
Januvia	Merck Sharp Dohme
Farxiga	AstraZeneca AB
Entresto	Novartis Pharms Corp
Enbrel	Immunex Corporation
Imbruvica	Pharmacyclics LLC
Stelara	Janssen Biotech, Inc.
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc.

Key Milestones to Date

- On March 15, 2023, CMS issued initial guidance for the Medicare Drug Price Negotiation Program, including requests for public comment on key elements.
- On June 30, 2023, CMS issued [revised guidance](#) detailing the requirements and parameters of the Medicare Drug Price Negotiation Program for the first round of negotiations, which will occur during 2023 and 2024. Any negotiated prices will be effective beginning in 2026.
- On August 29, 2023, CMS announced the 10 drugs covered under Medicare Part D selected for the first cycle of negotiations. For a list of these drugs, please click [here](#).
- On October 3, 2023, CMS announced that drug companies that manufacture the first 10 drugs selected for the Negotiation Program have chosen to participate in the program.

Q: How is CMS structuring the negotiation process with the drug companies of selected drugs?

- CMS is approaching implementation of the new drug law, including the Medicare Drug Price Negotiation Program, with the goal of promoting transparency and engagement. As discussed in detail in the revised guidance, CMS has set out a [process](#) for the first round of negotiations that engages drug companies and the public throughout. The process includes several steps, such as:
 - Participating drug companies with a selected drug for the Negotiation Program and the public had an opportunity to submit data and information on the selected drugs and their therapeutic alternatives to CMS no later than October 2, 2023.
 - During the Fall 2023, CMS will invite each participating drug company with a selected drug to engage in a meeting on its data submission. CMS will also hold a public patient-focused listening session for each selected drug with patients and other interested parties. The patient-focused listening sessions will be held between October 30, 2023 and November 15, 2023. The listening sessions are subject to change, including postponement and/or cancellation.
 - CMS will send an initial offer for each selected drug for which the drug company is participating in the Negotiation Program with CMS' proposal for the maximum fair price and a concise justification no later than February 1, 2024, and the drug company will have 30 days to respond to the initial offer by accepting the offer or providing a counteroffer, if desired. In developing an initial offer, CMS will consider evidence related to therapeutic alternatives as well as other factors, such as costs of research and development, and production and distribution of the selected drug.
 - If agreement on a maximum fair price is not reached through the initial offer or counteroffer, CMS will invite each participating drug company for up to three negotiation meetings during Spring and Summer 2024 before the negotiation period ends on August 1, 2024.

For more information on the Medicare Drug Price Negotiation Program, including the revised guidance and the negotiation process, please click [here](#).