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Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations

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Hannah-Alise Rogers
Legislative Attorney

Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations

This report discusses P.L. 117-169, a budget reconciliation measure often referred to as the Inflation Reduction Act (IRA), and its creation of the Medicare Drug Price Negotiation Program (the Program). The Program is to allow the Secretary of Health and Human Services (HHS), through the Centers for Medicare and Medicaid Services (CMS), to negotiate the prices of certain Medicare drugs directly with drug manufacturers for the first time.

On March 15, 2023, CMS issued guidance regarding the initial implementation of the Program, specifically with respect to the identification and selection of drugs for negotiation. CMS is to first identify qualifying single source drugs, as defined in the statute. CMS is to next identify negotiation-eligible drugs from the list of qualifying single source drugs, excluding small biotech drugs in price applicability years 2026-2028. The agency is to then rank the top 50 highest-spend negotiation-eligible drugs for price applicability year 2026 using Medicare claims data, and may delay price negotiation for certain biological products for up to two years, in accordance with the statute. The 10 drugs with the highest Medicare expenditures are to then be selected for price negotiation in 2026. In addition to providing more information about the selection of drugs, CMS's initial guidance also presents details about the process for negotiating the market fair price (MFP) of selected drugs, the calculation of the MFP, and CMS's planned enforcement of the MFP.

A significant question about CMS's implementation of the Program may be the extent to which it is subject to judicial review. The Program's authorizing statute precludes administrative and judicial review of certain aspects of CMS's rollout of the Program, including (1) the determination of drug units; (2) certain aspects of the identification, determination, and selection of drugs; (3) the determination of the MFP; and (4) the determination of renegotiation-eligible drugs. The statute's preclusion of judicial review of certain aspects of CMS's implementation of the Program provides limited clarity on the types of lawsuits that might be prohibited. The report explores the extent to which the statute may bar such legal challenges in light of previous Supreme Court decisions regarding preclusion, as well as arguments that both CMS and manufacturers might make about preclusion.

In addition to the specific provisions of the IRA, the Medicare statute as a whole contains several provisions that limit judicial review of different aspects of CMS's administration of the Medicare program, and the Supreme Court has discussed the statute's limitations on judicial review on several occasions. The Court's decisions in *Bowen v. Michigan Academy of Family Physicians*, *American Hospital Association v. Becerra*, and *Heckler v. Rinker* offer insight into how the Court generally looks at statutory provisions limiting judicial review, and each case describes the strong presumption in favor of judicial review. If a federal court is asked to review a challenge to CMS's implementation of the Medicare Drug Price Negotiation Program, the Court's decisions in these cases could affect the outcome.

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Introduction

P.L. 117-169, a budget reconciliation measure often referred to as the Inflation Reduction Act of 2022 (IRA), became law on August 16, 2022. As described in other CRS publications, the IRA created the Medicare Drug Price Negotiation Program (the Program), which allows the Secretary of Health and Human Services (HHS)¹ to negotiate drug prices directly with manufacturers for certain drugs dispensed to Medicare drug prices with manufacturers for the first time.²

The IRA requires HHS to publish a list of selected drugs, enter into agreements with manufacturers of drugs selected for negotiation, negotiate a maximum fair price (MFP) for those drugs with manufacturers, and monitor manufacturer compliance with Program requirements.³ The Congressional Budget Office (CBO) estimated that the Program will contribute a \$25 billion reduction to the deficit.⁴ CBO further estimated that in 2031, Part D drug prices will be 8% lower, and Part B drug prices will be 9% lower, as a result of the price negotiations.⁵ The Program's generation of significant savings is expected to help fund other parts of the IRA, including a provision capping Medicare beneficiaries' out-of-pocket spending for prescription drugs at \$2,000 per year starting in 2025.⁶

The Centers for Medicare and Medicaid Services (CMS) has since begun implementing the IRA's changes to various aspects of the Medicare Program.⁷ Under the authority in § 11001 and § 11002 of the IRA, CMS has accomplished much of the Program's initial rollout via agency guidance, published on March 15, 2023.⁸ The guidance describes how CMS is to select the first 10 drugs subject to price negotiation for price applicability year 2026,⁹ and it identifies several categories of drugs excepted from price negotiation.¹⁰ The guidance also reviews the factors by which CMS is to determine a "Starting Point" for its initial offer for the MFP to the manufacturer.¹¹ The guidance further explains CMS's role in ensuring manufacturer compliance with the terms of the

¹ References to the "Secretary," "CMS," and "the agency" are used interchangeably in this report to generally refer to actions taken by HHS.

² For a complete summary of the IRA's changes to Medicare, Medicaid, and private insurance, see CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*, coordinated by Katherine M. Kehres. For a brief overview of the IRA's changes to the Medicare Program, including an overview of the Medicare Prescription Drug Price Negotiation Program and other changes to Medicare Parts B and D, see CRS In Focus IF12203, *Selected Health Provisions of the Inflation Reduction Act*, by Suzanne M. Kirchoff.

³ 42 U.S.C. § 1320f(a)(1)-(4).

⁴ HOW CBO ESTIMATED THE BUDGETARY IMPACT OF KEY PRESCRIPTION DRUG PROVISIONS IN THE 2022 RECONCILIATION ACT at 5, 19, CONGRESSIONAL BUDGET OFFICE (Feb. 2023), <https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf> [hereinafter CBO REPORT]. See also Michael Erman et al., *Bristol Myers, Pfizer, AbbVie Drugs Likely to Face U.S. Price Negotiation*, REUTERS (Mar. 13, 2023), <https://www.reuters.com/business/healthcare-pharmaceuticals/bristol-myers-pfizer-abbvie-drugs-likely-face-us-price-negotiation-2023-03-13/>.

⁵ CBO REPORT, *supra* note 4, at 12. For more information about Medicare drug coverage under Parts B and D, see CRS Report R40425, *Medicare Primer*, coordinated by Patricia A. Davis.

⁶ Erman et al., *supra* note 4; see 42 U.S.C. §§ 1395w-102(b), 1395w-115(b).

⁷ See Social Security Act, 42 U.S.C. § 301 *et seq.*, amended by Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001-02, 136 Stat. 1818 (codified at 42 U.S.C. §§ 1320f-1320f-7).

⁸ CENTERS FOR MEDICARE AND MEDICAID, 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 (Mar. 15, 2023), <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf> [hereinafter CMS GUIDANCE].

⁹ Only Part D drugs are initially eligible for selection for price applicability years 2026 and 2027. Medicare Part B drugs will become eligible for selection beginning in price year 2028. See 42 U.S.C. § 1320f-1(d)(1)(A).

¹⁰ CMS GUIDANCE, *supra* note 8, at 7-25.

¹¹ *Id.* at 47-53.

Program and describes civil monetary penalties (CMPs) for manufacturers that provide false information to CMS or otherwise fail to comply with the terms of the Program.¹²

This report discusses several aspects of the CMS guidance, the pharmaceutical industry's response to the guidance, and the limitations the statute places on administrative and judicial review. The report concludes by reviewing how the Supreme Court has previously interpreted other provisions precluding judicial review in the Medicare statute and offers a few considerations for the 118th Congress.

CMS Initial Program Guidance for the Medicare Drug Price Negotiation Program

Selection of Drugs for the Initial Price Applicability Year 2026

To carry out the Program, the statute requires CMS to first identify and publish a list of qualifying single source, negotiation-eligible, selected drugs for price year 2026.¹³ Section 1320f-1 of the Medicare statute and the CMS guidance lay out the process for selection. According to the statute, the Secretary is required to select and publish a list of 10 drugs for price applicability year 2026, 15 for price applicability years 2027 and 2028, and 20 drugs for price applicability year 2029 and thereafter.¹⁴

Identification of Qualifying Single Source Drugs

The statute's definition of "qualifying single source drug" distinguishes drug products and biological products, and each is discussed in turn below.¹⁵ For a drug product to be a qualifying single source drug, the drug must be a covered Part B or Part D drug and (1) be approved by the U.S. Food and Drug Administration (FDA) and be marketed pursuant to such approval; (2) at least seven years must have passed since the initial approval; and (3) the drug cannot be the listed drug for any approved and marketed generic drug.¹⁶ CMS guidance provides that CMS will consider "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs."¹⁷ This definition includes repackaged and relabeled products, authorized

¹² *Id.* at 63–70.

¹³ 42 U.S.C. § 1320f-1(a)(1). CMS guidance explains that to select a drug for negotiation, the agency will first identify "qualifying single source drugs," excluding orphan drugs, low spend Medicare drugs, and plasma derived products. CMS GUIDANCE, *supra* note 8, at 5; 42 U.S.C. § 1320f-1(e). From there, for price applicability year 2026, CMS will identify "negotiation-eligible drugs" by selecting the 50 qualifying single source drugs with the highest total expenditures under Part D using PDE and other data. CMS GUIDANCE, *supra* note 8, at 6; 42 U.S.C. § 1320f-1(d)(1)(A). For price applicability years 2026–2028, CMS will exclude small biotech drugs, a term described in more detail below, from negotiation-eligible drugs. 42 U.S.C. § 1320f-1(d)(2). CMS will select the top 10 highest-spending negotiation-eligible drugs for price negotiation, excluding any biologic that meets the criteria for a one-year delay as the result of a high likelihood of a biosimilar market entry; these are known as "selected drug[s]." CMS GUIDANCE, *supra* note 8, at 6; 42 U.S.C. § 1320f-1(c).

¹⁴ 42 U.S.C. § 1320f-1(a)(1)-(4). For price applicability years 2026 and 2027, only Part D drugs will be eligible for selection. *Id.* § 1320f-1(a)(1)-(2). Beginning in 2028 and thereafter, both Part B and Part D drugs will be eligible for selection. *Id.* § 1320f-1(a)(3).

¹⁵ *Id.* § 1320f-1(e)(1)(A)-(B).

¹⁶ *Id.* § 1320f-1(e)(1)(A)(i)-(iii).

¹⁷ CMS GUIDANCE, *supra* note 8, at 8 (footnote omitted). For more information about FDA regulations concerning (continued...)

generic drugs, and multimarket approval products (MMAs).¹⁸ Through this guidance, CMS attempts to target drugs without meaningful market competition, and attempts to prevent manufacturers from taking relatively simple steps to avoid negotiation by changing product labels or packaging, releasing a new dosage level, or authorizing a generic.¹⁹ For fixed combination drugs (i.e., those with two or more active ingredients), the guidance provides that the “single combination” of ingredients will be considered as one for purposes of identifying a single source drug.²⁰ As defined in the statute and elaborated in the guidance, CMS’s definition of a single source drug for purposes of the Program is broad, such that the identification of a single “drug” or “biologic” could lead to the price negotiation of many different products.²¹

For a biological product to meet the definition of qualifying single source drug, the statute requires the covered Part B or Part D biological product (1) to be licensed under § 351 of the Public Health Service Act (PHSA), 42 U.S.C. § 201 *et seq.*, and be marketed under the license; (2) to have been marketed for at least 11 years from the date of initial licensure; and (3) not to be the reference product for any other licensed and marketed biosimilar.²² Similar to its guidance with respect to qualifying single source drugs, CMS states that “all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application” will be considered as negotiation-eligible, including repackaged and relabeled products, authorized biologics, and MMAs.²³

Exceptions to Qualifying Single Source Drugs

The statute and CMS guidance also specify certain drugs and biologics that are to be excluded from the definition of qualifying single source drug, including orphan drugs, “low-spend” Medicare drugs, and plasma-derived products.²⁴ To be considered an orphan drug for purposes of the exclusion, the statute requires that the drug or biologic be designated as a drug used to treat only one rare disease or condition and approved by the FDA for that purpose.²⁵ All dosage forms and strengths of the drug must meet the definition, as stated in the guidance.²⁶ Additionally, in accordance with the statute, CMS is to exclude “low-spend” drugs, which the statute defines as

active ingredients and active moieties, see CRS Report R46110, *Defining Active Ingredient: The U.S. Food and Drug Administration’s Legal Interpretation of Regulatory Exclusivities*, by Erin H. Ward.

¹⁸ *Id.*

¹⁹ An authorized generic drug is not the same as a generic drug. According to the FDA, an authorized generic “is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label.” Authorized generics are not true generic competition, as they are typically marketed by the same brand name manufacturer, or with that manufacturer’s permission. For more information about authorized generics, see FOOD AND DRUG ADMIN., *FDA List of Authorized Generic Drugs* (Mar. 2021), <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs>.

²⁰ CMS GUIDANCE, *supra* note 8 at 9. For a definition of fixed combination drugs, see 21 C.F.R. § 300.50.

²¹ 42 U.S.C. § 1320f-1(e); CMS GUIDANCE, *supra* note 8, at 7–8.

²² 42 U.S.C. § 1320f-1(e)(1)(B)(i)–(iii).

²³ CMS GUIDANCE, *supra* note 8, at 8.

²⁴ *Id.* at 10–11; 42 U.S.C. § 1320f-1(e)(3)(A)–(C).

²⁵ 42 U.S.C. § 1320f-1(e)(3)(A). In the Guidance, CMS elaborates that to meet the definition of orphan drug for purposes of exclusion as a qualifying single source drug, a drug must (1) be designated under Section 526 of the Food, Drug, and Cosmetics Act as a drug used to treat only one rare disease or condition; and (2) be FDA-approved to treat only one or more indications associated with that condition. CMS GUIDANCE, *supra* note 8, at 10–11. An FDA-designated orphan drug either (1) treats a disease or condition that affects fewer than 200,000 people in the United States; or (2) affects more than 200,000 people in the United States, but there is no reasonable expectation that the cost of developing and making the drug would be recovered. U.S. Food & Drug Admin., *Rare Diseases at FDA* (Dec. 13, 2022), <https://www.fda.gov/patients/rare-diseases-fda>.

²⁶ CMS GUIDANCE, *supra* note 8, at 11.

those that make up less than \$200 million in combined Medicare Parts B and D expenditures.²⁷ The statute also excludes biologics that are derived from plasma or human whole blood.²⁸

Identification of Negotiation-Eligible Drugs

Once the qualifying single source drugs are identified, CMS is to next identify 50 negotiation-eligible drugs from that set.²⁹ For each qualifying single source drug in price applicability year 2026, CMS is to look at Part D prescription drug cost and payment (PDE) data between June 1, 2022, and May 31, 2023, which it is to use to calculate the Medicare Program's total expenditures for each drug.³⁰ CMS is to remove drugs that qualify for the small biotech exception, which is discussed further below, and is to then rank the qualifying single source drugs according to their highest total expenditures in the most recent 12-month period prior to the drug publication date.³¹ The top 50 highest-spend drugs are to be considered negotiation-eligible drugs.³²

CMS does not seek comment on the parts of its initial guidance explaining how the agency is to identify negotiation-eligible drugs, although it requests feedback on other aspects of the guidance.³³ The agency states that the initial guidance with respect to price year 2026 is final, “[i]n order to facilitate the timely implementation of the . . . Program in accordance with statutory deadlines.”³⁴ CMS also states that it may make changes to any aspect of the guidance in the future.³⁵

The Small Biotech Exception

For price years 2026-2028, the statute contains an exception for “small biotech drugs,” the effect of which is to remove them from consideration as negotiation-eligible drugs.³⁶ CMS guidance states that to identify small biotech drugs, it will consider whether the Part D total expenditures for the drug in calendar year (CY) 2021 were (1) equal to or less than 1% of the total expenditures for all Part D drugs; and (2) were equal to at least 80% of the total Part D expenditures for all Part D drugs that were covered under the manufacturer's Medicare Coverage Gap Discount Program (CGDP) agreement.³⁷ The effect of these two conditions is to identify drugs that make up a relatively small part of the Part D program's expenditures and are also a

²⁷ 42 U.S.C. § 1320f-1(e)(3)(B).

²⁸ *Id.* § 1320f-1(e)(3)(C).

²⁹ *Id.* § 1320f-1(b)(1)(A); CMS GUIDANCE, *supra* note 8, at 5–6.

³⁰ CMS GUIDANCE, *supra* note 8, at 12. For more information about PDE data, see CNTRS. FOR MEDICARE & MEDICAID SERVS., QUESTIONS AND ANSWERS ON OBTAINING PRESCRIPTION DRUG EVENT (PDE) DATA, <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/downloads/partdclaimsdataqa.pdf> (last visited May 5, 2023).

³¹ CMS GUIDANCE, *supra* note 8, at 5-6.

³² *Id.* at 15.

³³ *Id.* at 5.

³⁴ *Id.*

³⁵ *Id.* at 2.

³⁶ 42 U.S.C. § 1320f-1(d)(2)(A).

³⁷ CMS GUIDANCE, *supra* note 8, at 13. The Medicare Coverage Gap Discount Program (MCGDP) makes drug manufacturer discounts available to eligible Medicare beneficiaries who receive applicable, covered Part D drugs while in the Part D coverage gap. To participate in the program, the manufacturers must sign an agreement with the Secretary to provide discounts on all applicable part D drugs, which include drugs that are licensed or approved as a new drug or biologic. For more information about the MCGDP, see Ctrs. for Medicare & Medicaid Servs., *Part D Information for Pharmaceutical Manufacturers* (Mar. 30, 2023), <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/pharma>.

particular manufacturer's most significant product. Drug manufacturers that apply for the small biotech exemption and that meet the stated criteria are not to be included on the list of negotiation-eligible drugs for the specified price applicability year.³⁸

On January 24, 2023, CMS released an Information Collection Request seeking public comment on the small biotech exception generally and the specific data that are to be used to implement it; comments were due on March 27, 2023.³⁹ The information request, as well as the initial guidance, state that, given the statute's tight implementation timeline, manufacturers that wish to apply for the exception must do so prior to the date that CMS publishes the negotiation-eligible drug list for price year 2026.⁴⁰ CMS anticipates that this deadline will be in June 2023, but CMS says it will provide the exact date in additional guidance.⁴¹ CMS's initial guidance also notes that its approval of an exception will last for one year, so manufacturers must resubmit exception requests for subsequent years.⁴²

Identification of Selected Drugs and the Biosimilar Delay

After excluding small biotech drugs and ranking the negotiation-eligible drugs, CMS is to publish the top 10 highest-spend Medicare drugs, which are known as selected drugs.⁴³ These selected drugs are to be subject to price negotiation for the initial price applicability year 2026.⁴⁴

The statute also creates a delay for the selection of certain qualifying biological products, which is explained in further detail below.⁴⁵ A biologic whose status as a selected drug is delayed is to still be considered a negotiation-eligible drug for purposes of the previous step of CMS's analysis, but cannot be selected for negotiation in the current year.⁴⁶

The Secretary may delay a qualifying biological product from selection for up to two years if certain requirements are met.⁴⁷ In order to qualify for a delay as a selected drug, the biological product must meet the definition of an extended monopoly drug, as defined in the statute.⁴⁸ To qualify as an extended monopoly drug, the biologic must have been FDA-approved or licensed at least 12 years but fewer than 16 years before the applicable pricing year.⁴⁹

As noted above, a biologic may be eligible for price negotiation only if it is not listed as the reference product for any licensed or marketed biosimilar. The biosimilar delay provision

³⁸ CMS GUIDANCE, *supra* note 8, at 14–15.

³⁹ LETTER FROM CHIQUITA BROOKS-LASURE, ADMINISTRATOR, CMS, TO INTERESTED PARTIES (Jan. 11, 2023), <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf>.

⁴⁰ *Id.*; CMS GUIDANCE, *supra* note 8, at 14.

⁴¹ CMS GUIDANCE, *supra* note 8, at 14.

⁴² *Id.* at 15.

⁴³ 42 U.S.C. § 1320f-1(c)(1); *id.* § 1320f-1(a)(1); CMS GUIDANCE, *supra* note 8, at 6.

⁴⁴ 42 U.S.C. § 1320f-1(a)(1).

⁴⁵ *Id.* § 1320f-1(b)(1)(C). This section provides a general overview of the delay process. For more detailed information, see CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*, coordinated by Katherine M. Kehres.

⁴⁶ 42 U.S.C. § 1320f-1(b)(1)(C).

⁴⁷ *See generally id.* § 1320f-1(f)(2).

⁴⁸ *Id.* § 1320f-1(f)(1)(A).

⁴⁹ *Id.* § 1320f-3(c)(4). The statute excludes from the definition vaccines licensed and marketed under § 351 of the PHSA, as well as drugs for which the manufacturer has an MFP agreement with the Secretary for a pricing year prior to 2030. *Id.* CMS notes that for the Initial Delay Requests submitted for price year 2026, in order to qualify as an extended-monopoly drug, the biologic must have received its initial licensure between January 1, 2010, and January 1, 2014. CMS GUIDANCE, *supra* note 8, at 17.

attempts to protect from negotiation biologics that may soon no longer qualify as a qualifying single source drug by looking ahead at whether that biologic is likely to *become* the reference biologic for a biosimilar in the near future.

Therefore, a biosimilar manufacturer may submit a request to the Secretary to delay price negotiation of the reference biologic for one year (Initial Delay Request).⁵⁰ The statute states that only the manufacturer of the biosimilar may make an Initial Delay Request, and the request must be made prior to the publication of the selected drug list for the price applicability year.⁵¹ The statute gives the Secretary the discretion to specify any relevant information that must be included in a manufacturer's request for a delay.⁵²

If, based on that information, the Secretary finds that there is a "high likelihood" that a biosimilar that would list the negotiation-eligible biologic as its reference product will be licensed by the FDA and marketed within two years of the date of publication of the selected drug, the Secretary must grant the request and delay price negotiation of the biologic for one year.⁵³ If the biosimilar is not licensed and marketed during the initial one-year delay period, a biosimilar manufacturer may make an "Additional Delay Request" for the Secretary to reevaluate the determination of high likelihood for delaying the inclusion of the reference biologic on the selected drug list for a second year.⁵⁴ In addition to the high likelihood determination, as described for the Initial Delay Request, when determining whether a reference biologic qualifies for a second year delay, the statute requires the Secretary to evaluate whether the manufacturer has demonstrated "clear and convincing evidence" that the competing manufacturer has "made a significant amount of progress" toward licensing and marketing the biosimilar.⁵⁵

At the end of year of the Initial Delay Request, if the Secretary determines that there is no longer a high likelihood that the biosimilar will be licensed and marketed, or that significant progress has not been made toward licensure and marketing, the reference biologic would not qualify for an Additional Delay Request and is to be included on the selected drug list for the next price applicability year.⁵⁶ The manufacturer must also pay a rebate, in an amount determined by a formula in the statute, for the year that the manufacturer would have been required to sell the reference biologic at the MFP but did not because of the initial delay.⁵⁷ If the Secretary determines that the biosimilar is not licensed and marketed after the second year, a similar

⁵⁰ *Id.* at 16.

⁵¹ 42 U.S.C. § 1320f-1(f)(1)(B)(i)(I). Section 30.3.1.2 of the CMS Guidance states that "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." See CMS GUIDANCE, *supra* note 8, at 23.

⁵² 42 U.S.C. § 1320f-1(f)(1)(B)(ii). The statute specifies that the request must include all agreements related to the biosimilar product filed with the Federal Trade Commission or the assistant attorney general pursuant to subsections (a) and (c) of § 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. See Pub. L. No. 108-173, 117 Stat. 2066.

⁵³ See 42 U.S.C. § 1320f-1(f)(1)(A). According to the statute, a high likelihood will be said to exist when the Secretary finds that another manufacturer has filed an application to license a biosimilar product and the FDA has either accepted or approved the application. *Id.* § 1320f-1(f)(3)(A). The statute also requires the determination of high likelihood to include consideration of (1) any agreements filed with the Federal Trade Commission or Attorney General; (2) the biosimilar's manufacturing schedule, as submitted to the FDA; and (3) any required disclosures that pertain to marketing under relevant sections of the Securities Exchange Act of 1934. *Id.* § 1320f-1(f)(3)(B); see also CMS GUIDANCE, *supra* note 8, at 16, 20.

⁵⁴ See CMS GUIDANCE, *supra* note 8, at 16.

⁵⁵ 42 U.S.C. § 1320f-1(f)(2)(B)(i)(I)-(II).

⁵⁶ *Id.* § 1320f-1(f)(2)(B)(ii)(I).

⁵⁷ *Id.* § 1320f-1(f)(2)(B)(ii)(II). The rebate amount is outlined in § 1320f-1(f)(4).

process occurs.⁵⁸ The reference biologic is included on the selected drug list, and the manufacturer is required to pay a rebate to Medicare.⁵⁹

To submit an Initial Delay Request for price year 2026, CMS guidance instructs manufacturers to notify CMS of their intention to submit a request via email no later than May 10, 2023.⁶⁰ CMS is to provide manufacturers with a template request form, which the manufacturer should complete no later than May 22, 2023.⁶¹ CMS is to then have until June 20, 2023, to request additional information, and the manufacturer is to have until July 3, 2023, to submit any additional information.⁶² CMS is to notify each manufacturer that submits an Initial Delay Request of its decision of whether or not to delay price negotiation in September 2023.⁶³ If CMS accepts the request for delay, the reference biologic is not to appear on the selected drug list.⁶⁴ In its initial guidance, CMS discusses only Initial Delay Requests, stating that further details about the Additional Delay Request will be provided in future guidance.⁶⁵

Negotiation Process and Development of MFP

After CMS identifies the selected drugs for price negotiation in 2026, the statute directs the Secretary to “enter into agreements” with the manufacturers of the selected drugs and to negotiate an MFP.⁶⁶ According to the statute, the agreement will require the manufacturers to submit certain pricing data, including the nonfederal average manufacturer price (non-FAMP),⁶⁷ as well as other information the Secretary requires to carry out the negotiation process.⁶⁸ CMS is to use this information to develop an initial offer price as a starting point for the MFP negotiation.

The Creation of the Initial Offer

The statute authorizes the Secretary to develop a methodology for the negotiation process, and CMS seeks comments on the following approach, which it describes in the guidance.⁶⁹ In summary, CMS states that to determine an initial offer for the MFP, it will (1) identify any therapeutic alternatives for the drug; (2) use either the Part D net price for the therapeutic alternative of a Part D drug, or the Part B average sales price for Part B drugs to determine a starting point for the initial offer; (3) evaluate the selected drug’s clinical benefits (including by

⁵⁸ *Id.* § 1320f-1(f)(2)(C).

⁵⁹ *Id.* § 1320f-1(f)(2)(C)(i)-(ii).

⁶⁰ CMS GUIDANCE, *supra* note 8, at 21, 24.

⁶¹ *Id.* at 24.

⁶² *Id.*

⁶³ *Id.* at 23.

⁶⁴ *Id.*

⁶⁵ *Id.* at 16.

⁶⁶ 42 U.S.C. § 1320f-2(a).

⁶⁷ Non-FAMP is defined as “the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account . . . any prices paid by the Federal Government; or . . . any prices found by the Secretary to be merely nominal in amount.” 38 U.S.C. § 8126(h)(5)(A)-(B). The CMS guidance advises that CMS will consider non-FAMP information as proprietary for purposes of negotiation year 2026, and the agency seeks stakeholder comments on its proposed confidentiality policy, as outlined in the guidance. *See* CMS GUIDANCE, *supra* note 8, at 28–29.

⁶⁸ 42 U.S.C. § 1320f-2(a)(4)(A)-(B).

⁶⁹ *Id.* § 1320f-3(b)(1); CMS GUIDANCE, *supra* note 8, at 38, 47.

comparing it to its therapeutic alternatives); and (4) use the negotiation factors listed in § 1320f-3(e) to further adjust the price as needed.⁷⁰

The Secretary is to use the data submitted by manufacturers, other stakeholders, and the public to develop an initial written offer for the price of the negotiated drug.⁷¹ CMS intends to identify a single proposed MFP, based on a 30-day equivalent supply of the drug, for purposes of the negotiation.⁷² CMS explains that such methods will “allow for a more direct comparison with therapeutic alternatives, which might have different dosage forms, strengths, and frequency of use.”⁷³ Once finalized, CMS is to then “translate” the single price back to a per unit price for the drug in its various strengths and dosage forms.⁷⁴

The statute lists two main categories of negotiation factors that the Secretary is to consider when negotiating the MFP: manufacturer data and alternative treatments.⁷⁵ First, the statute directs the Secretary to consider manufacturer-specific data (submitted by both manufacturers and the public) regarding (1) research and development costs and the extent to which the manufacturer has recouped those costs; (2) the unit cost of production and distribution; (3) prior federal financial support received for novel therapeutic discovery and development of the drug; (4) data regarding pending or approved patent applications and existing or pending exclusivity of the drug; and (5) market data, including revenue and sales volume data.⁷⁶ With respect to alternative treatments, the Secretary must consider evidence including (1) whether the drug constitutes a therapeutic advance as compared to existing therapeutic alternatives, and the cost of those alternatives; (2) FDA-approved prescribing information for the drug and existing therapeutic alternatives; (3) the comparative effectiveness of the drug and its therapeutic alternatives (including effects of the drug and its alternatives on specific populations, including elderly individuals and the terminally ill); and (4) whether the drug addresses current unmet medical need for a condition for which a treatment or diagnosis is not addressed adequately by available therapy.⁷⁷ The statute also creates a ceiling for the MFP and states that the Secretary may not negotiate an MFP above that ceiling price.⁷⁸

CMS guidance indicates that to inform the price negotiation process, the agency intends to do its own research on “existing literature and real-world evidence,” and it permits both manufacturers

⁷⁰ *Id.* at 47.

⁷¹ CMS GUIDANCE, *supra* note 8, at 35-37, 47.

⁷² *Id.* at 38. CMS’s initial guidance explains that, in accordance with the definition of MFP found in § 1320f(c)(3), the MFP is the price negotiated in accordance with § 1320f-3 and updated in subsequent years, as applicable, in accordance with § 1320f-4(b). CMS states that it “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 [guidance].” *Id.*

⁷³ *Id.* at 38.

⁷⁴ *Id.* at 38–39.

⁷⁵ 42 U.S.C. § 1320f-3(e)(1), (2). The Guidance also states that if a selected drug has no therapeutic alternative, “CMS intends to adjust the starting point for the initial offer based on the extent to which the drug fills an unmet medical need.” CMS GUIDANCE, *supra* note 8, at 52.

⁷⁶ 42 U.S.C. § 1320f-3(e)(1)(A)-(E); *see* CMS GUIDANCE, *supra* note 8, at 35.

⁷⁷ 42 U.S.C. § 1320f-3(e)(2)(A)-(D).

⁷⁸ *Id.* § 1320f-3(b)(2)(F)(i)-(ii), (c)(1)(A). The statute also describes a temporary floor for small biotech drugs in § 1320f-3(d), which is not discussed here or in the CMS Guidance, as it does not take effect until 2029. *See* 42 U.S.C. § 1320f-3(d). For more information regarding the determination of the ceiling for the MFP, *see* CMS GUIDANCE, *supra* note 8, at 39-40. For more information regarding both the ceiling and the temporary floor for small biotech drugs in 2029-2030, *see* CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*, coordinated by Katherine M. Kehres, at 19-21.

and the public to submit information on therapeutic alternatives.⁷⁹ The statute does not limit CMS to using only data submitted by the manufacturer for information regarding the negotiation factors described above. Presumably, the Secretary has the discretion to weigh the negotiation factors as appropriate, as the statute does not specify whether the Secretary should equally weigh each factor. The statute also does not expressly address whether the Secretary could consider additional factors outside of those listed in the statute.

Responses to the Initial Offer

In accordance with the statute, CMS must present the manufacturers of the selected drugs for price applicability year 2026 with an initial offer no later than February 1, 2024.⁸⁰ The initial offer will also include a written explanation of CMS's justification of the offered price, including a list of the factors used in developing the offer.⁸¹ The statute provides the manufacturer with 30 days to respond to CMS's initial offer, once it is received, either by accepting the offer or proposing a counteroffer.⁸² The Secretary is required to respond to the manufacturer's counteroffer in writing, but the statute does not provide a timeline for that response.⁸³ The negotiation process for price applicability year 2026 must end by August 1, 2024.⁸⁴ As noted above, in accordance with the statute, the Secretary is limited by the ceiling price and may not accept an offer for MFP above that price.⁸⁵

The CMS guidance provides that if CMS rejects the manufacturer's counteroffer for the MFP, the agency is to then invite the manufacturer to either an in person or virtual negotiation meeting, which is to occur within 30 days of the agency's receipt of the counteroffer.⁸⁶ Each party may then request an additional meeting, for a total of no more than three meetings.⁸⁷ For the initial price year 2026, CMS states that it intends for all negotiation meetings to end no later than June 30, 2024, so as to allow the agency time to prepare a final offer, which CMS intends to submit to the manufacturer no later than July 15, 2024.⁸⁸ The manufacturer is to have until July 31, 2024, to consider the final offer and respond to CMS in writing.⁸⁹ The agency is to then publish the MFP and its explanation in accordance with § 1320f-4.

The agency's guidance seeks stakeholder comments on this proposed negotiation process and its advantages and disadvantages.⁹⁰

⁷⁹ CMS GUIDANCE, *supra* note 8, at 37.

⁸⁰ 42 U.S.C. § 1320f-3(b)(2)(B); CMS GUIDANCE, *supra* note 8, at 54.

⁸¹ CMS GUIDANCE, *supra* note 8, at 54.

⁸² 42 U.S.C. § 1320f-3(b)(2)(C). The statute further requires the counteroffer to be submitted in writing; manufacturers must also use the negotiation factors described above, as listed in § 1320f-3(e), to justify their counteroffer price. *Id.* § 1320f-3(b)(2)(C)(i)-(ii).

⁸³ *Id.* § 1320f-3(b)(2)(D).

⁸⁴ CMS GUIDANCE, *supra* note 8, at 55.

⁸⁵ Section 1320f-3(b)(2)(F) prohibits the Secretary from accepting an offer for the MFP at a price above the statutory ceiling. For more information on how CMS intends to calculate the ceiling price, see CMS GUIDANCE, *supra* note 8, at 39–42.

⁸⁶ CMS GUIDANCE, *supra* note 8, at 55.

⁸⁷ *Id.* at 55–56.

⁸⁸ *Id.* at 56. CMS titles this final offer as a “Notification of Final Maximum Fair Price Offer.” *Id.* at 57.

⁸⁹ *Id.* at 56. The statute prescribes that, with respect to initial price year 2026, negotiations must end by August 1, 2024. See 42 U.S.C. § 1320f(d)(2)(B); *id.* § 1320f-3(b)(2)(E).

⁹⁰ CMS GUIDANCE, *supra* note 8, at 56.

CMS Oversight and Civil Monetary Penalties

The statute requires the Secretary to monitor drug manufacturers to ensure their compliance with the MFP under the terms of the negotiation agreements and directs the Secretary to establish a process for the reporting of violations.⁹¹ The statute does not establish how CMS should carry out the necessary compliance monitoring and program oversight. CMS guidance advises that it plans to establish a process by which Medicare beneficiaries, pharmacies and other providers, suppliers, and dispensaries may report being unable to access the MFP or other violations.⁹² It also creates several CMPs for noncompliant manufacturers and manufacturers that knowingly furnish false information to CMS.⁹³ In addition, CMS is to expect manufacturers to report dispensers that do not extend the MFP to eligible individuals, noting that the statute makes it the ultimate responsibility of manufacturers to ensure access to the MFP.⁹⁴

IRA Limitations on Judicial Review and Potential for Legal Challenges

Section 1320f-7's Limitation on Review

The IRA limits administrative and judicial review of some of CMS's determinations for purposes of carrying out the Program in several areas: (1) the determination of drug units; (2) certain aspects of the determination of whether the drug is a qualifying single source drug, whether it is a negotiation-eligible drug, and the selection of drugs published as selected drugs; (3) the determination of the MFP; and (4) the determination of renegotiation-eligible drugs.⁹⁵ The statute outlines each of these areas, which are explored in detail below, but there remain some ambiguities in the types of lawsuits that might be prohibited.

First, the IRA bars administrative and legal challenges related to CMS's identification of a drug "unit."⁹⁶ A drug unit is defined as the "lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed."⁹⁷ Drug units are discussed in two main sections of the statute. Section 1320f-3(e) references the "unit costs of production and distribution" as one of the negotiation factors in the computation of the MFP, and § 1320f-6 mentions drug units in the context of the computation of penalties a manufacturer will owe for failure to sell or ensure that drugs are dispensed at or below the MFP.⁹⁸

⁹¹ 42 U.S.C. § 1320f-5(b).

⁹² CMS GUIDANCE, *supra* note 8, at 64–67.

⁹³ 42 U.S.C. § 1320f-6(a).

⁹⁴ *Id.* § 1320f-2(a)(3). Section 11003 of the IRA amends the internal revenue code to establish an excise tax on drug sales by manufacturers and others during certain noncompliance periods. The excise tax increases the longer the duration of noncompliance. For more information about the excise tax, see CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*, coordinated by Katherine M. Kehres.

⁹⁵ See generally 42 U.S.C. § 1320f-7. This report covers the first three limitations in depth, but it does not provide a similarly detailed discussion of the fourth limitation, as CMS has not yet issued guidance on the renegotiation of drugs under § 1320f-3(f). The agency has stated that such a process will be detailed in future guidance. See CMS GUIDANCE, *supra* note 8, at 31.

⁹⁶ 42 U.S.C. § 1320f-7(1).

⁹⁷ Drug "unit[s]" are defined in § 1320f(c)(6).

⁹⁸ *Id.* §§ 1320f-3(e)(1)(B), 1320f-6(a). This section describes that manufacturers that do not provide drugs at or below (continued...)

CMS has not yet explained how it will calculate the “lowest identifiable amount” of a drug for purposes of identifying a drug unit, which could have major financial consequences for manufacturers whose drugs are subject to negotiation. A court could read the limitation on judicial review as not only preventing a manufacturer from challenging CMS’s identification of a drug unit, but also as preventing any challenges based on the consequences stemming from it. For example, with respect to the MFP negotiation factors, if a manufacturer disagrees with CMS about the per-unit cost of the drug and challenges CMS’s calculation of that overall cost, CMS could argue that its finding with respect to the per-unit cost is not subject to judicial review. On its face, the statute limits review of the “identification” of a drug unit, but it is unclear whether this would prevent challenges related to the financial impact as a result of that determination.

Second, the law limits review of CMS’s determination of qualifying single source drugs, negotiation-eligible drugs, and the identification of selected drugs under § 1320f-1(b), (d), and (e), respectively.⁹⁹ Section 1320f-1(b) authorizes the Secretary to rank negotiation-eligible drugs and, for price year 2026, to select the 10 drugs with the highest total Medicare expenditures.¹⁰⁰ Section 1320f-1(d) defines “negotiation-eligible drug,” as well as “Part D High Spend Drugs,” and “Part B High Spend Drugs” for purposes of the Program.¹⁰¹ Section 1320f-1(d)(2) also contains the small biotech exception, outlining which Parts B and D drugs qualify for the exception.¹⁰² The definition of qualifying single source drugs and biologics is contained in § 1320f-1(e)(1), authorized generics are defined in § 1320f-1(e)(2), and the exceptions for orphan drugs, low-spend drugs, and plasma-derived products is contained in § 1320f-1(e)(3).

Although some kinds of challenges to CMS’s determinations are plainly precluded under § 1320f-7(2), the availability of other claims will likely depend on how narrowly the courts interpret the limitations set forth in § 1320f-7. For example, it is unclear whether lawsuits regarding CMS’s determination of eligibility for the small biotech exception will be subject to judicial review. Section 1320f-7(2) bars “the determination of negotiation-eligible drugs under section 1192(d).”¹⁰³ That prohibition could be interpreted to apply only to a determination that CMS makes under § 1320f-1(d)(1), which generally defines negotiation-eligible drugs, or it may also preclude challenges brought under the small biotech exception of § 1320f-1(d)(2). Thus, if a manufacturer were to claim that its drug or biologic meets the qualifications for the small biotech exception, but CMS disagrees and, as a result, the drug is included as a negotiation-eligible drug, the reviewing court would have to decide whether the statute allows it to consider the applicability of the small biotech exception.

Third, § 1320f-7(3) bars administrative and judicial review of CMS’s “determination” of the MFP under § 1320f-3(b) and (f).¹⁰⁴ These sections seem more clearly tied to the negotiation process involved in reaching an MFP, however, rather than the MFP calculation itself. Section 1320f-3(b)(1) authorizes the Secretary to develop and use a methodology to “achieve” the MFP.¹⁰⁵ Several provisions within subsection § 1320f-3(b)(2) provide specific timelines for CMS to

the MFP to eligible individuals and providers “shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished . . . and the difference between the price for such drug made available . . . and the maximum fair price.”

⁹⁹ 42 U.S.C. § 1320f-7(2).

¹⁰⁰ *Id.* § 1320f-1(b)(1).

¹⁰¹ *Id.* § 1320f-1(d)(1)(A)-(B).

¹⁰² *See generally Id.* § 1320f-1(d)(2)(A)-(B).

¹⁰³ *Id.* § 1320f-7(2).

¹⁰⁴ *Id.* § 1320f-7(3).

¹⁰⁵ *Id.* § 1320f-3(b)(1).

implement the Program, including dates for drug manufacturers to submit information to CMS, for CMS to make an initial offer, for manufacturers to make a counteroffer, and for CMS to respond.¹⁰⁶ This subsection also prohibits the Secretary from both making an offer that exceeds the ceiling price, as described in § 1320f-3(c), and from offering a price below the floor described in § 1320f-3(d), if applicable.¹⁰⁷ Section 1320f-3(f) describes the renegotiation process, to begin in 2028, of negotiation-eligible drugs.¹⁰⁸

Because the provisions listed in § 1320f-7(3) relate primarily to the negotiation process, it is unclear whether that section bars judicial review of CMS's calculation of the final MFP itself on *any* grounds, or only on grounds related to the negotiation process. A plain reading of § 1320f-7(3) and its references to § 1320f-3(b) would seem to preclude manufacturers or other interested parties from challenging the implementation timeline as set forth in the statute and CMS guidance. But other potential situations and claims may not be covered by the statute's plain language. For example, CMS guidance invokes the Secretary's authority in § 1320f-3(b) when describing various aspects of the negotiation process, including the potential for three meetings to happen between the manufacturer and CMS, while the parties are engaged in active negotiation of the MFP of a drug.¹⁰⁹ If a manufacturer cannot reach an agreement with CMS after three such meetings and requests another meeting, a manufacturer might attempt to challenge CMS's decision on the basis that insufficient time was given for the negotiation process. A reading of § 1320f-7(3) on its face would also not seem to preclude a suit challenging some aspect of how CMS calculated the MFP, which is arguably done via the authorities in § 1320f-3(c) (the determination of the ceiling price), § 1320f-3(d) (the determination of a temporary floor for small biotech drugs), and § 1320f-3(e) (prescribing factors that the Secretary must consider when negotiating the MFP).

Finally, § 1320f-7(4) precludes challenges of CMS's decisions to reselect a drug for negotiation in subsequent years and renegotiate its MFP. In accordance with the statute, the renegotiation process does not begin until 2028, and CMS has not yet provided guidance on this process.¹¹⁰ As such, it is not discussed further here.

The Supreme Court's Interpretation of the Medicare Statute's Limits on Administrative and Judicial Review

At the time of this writing, no litigants have challenged the provisions of the IRA that created the Program, or CMS's guidance seeking to implement it. As discussed above, if a challenge were to be brought against the guidance implementing the statute or a particular decision that HHS makes, HHS could try to argue that § 1320f-7 precludes judicial review.

Courts considering the scope of § 1320f-7 might draw upon cases that have applied other provisions of the Medicare statute that preclude judicial review of certain aspects of the

¹⁰⁶ *Id.* § 1320f-3(b)(2)(A)-(E).

¹⁰⁷ *Id.* § 1320f-3(b)(2)(F)(i)-(ii).

¹⁰⁸ *Id.* § 1320f-3(f). The CMS Guidance does not cover the renegotiation of drugs under § 1320f-3(f). CMS states that further information about the renegotiation process of drugs, which will begin in 2028, will be provided in future guidance. CMS GUIDANCE, *supra* note 8, at 5, 31.

¹⁰⁹ *See, e.g., id.* at 37, 55.

¹¹⁰ CMS states, "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." *Id.* at 5.

Secretary’s administration of the Medicare program.¹¹¹ Similar to § 1320f-7(1)-(4), these provisions limiting review often make specific references to the Secretary’s actions in other parts of the statute and can be complicated to understand or interpret.

Questions about the scope of judicial review of agency action appear often in litigation, and CMS’s administration of the Medicare statute is no exception.¹¹² The U.S. Supreme Court has made clear that there is a “strong presumption” in favor of judicial review of a federal agency’s final action.¹¹³ The Court has observed, however, that this presumption “is just that—a presumption,” and as such, it “may be overcome by specific language or specific legislative history” indicating congressional intent to forgo review.¹¹⁴ When determining whether a statute precludes judicial review, the Court has assessed several factors, including the express language of the statute; the statutory scheme, structure, and objectives; the legislative history; and the “nature of the administrative action involved.”¹¹⁵ The government bears the burden of rebutting the presumption in favor of judicial review.¹¹⁶

Cases Finding the Medicare Statute’s Limitation on Judicial Review Inapplicable

Historically, and consistent with the presumption in favor of review, the Supreme Court has trended toward a narrow reading of the Medicare statute’s preclusions of administrative and judicial review. For example, in *Bowen v. Michigan Academy of Family Physicians*, a unanimous Court held that Congress did not bar judicial review of CMS regulations related to the calculation of physician reimbursement payments under Medicare Part B.¹¹⁷ Several participant providers challenged those regulations, which authorized different payment amounts for Part B physician services.¹¹⁸ When the lower courts held that the regulations were invalid,¹¹⁹ CMS argued that the Medicare statute precluded administrative or judicial review of the Part B payment calculation altogether.¹²⁰

¹¹¹ See, e.g., 42 U.S.C. § 1395l(t)(12) (precluding judicial review of certain aspects of Part B benefit determinations); *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667 (1986) (finding that Congress did not intend to bar judicial review of CMS regulations regarding the calculation methodology of physician reimbursement under Part B).

¹¹² See, e.g., *Am. Hosp. Ass’n v. Becerra*, 142 S. Ct. 1896 (2022); *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019); *Bowen*, 476 U.S. at 672; *Heckler v. Ringer*, 466 U.S. 602 (1984).

¹¹³ *Am. Hosp. Ass’n*, 142 S. Ct. at 1902 (quoting *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 489 (2015)).

¹¹⁴ *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984).

¹¹⁵ *Id.* at 345 (citing *S. Ry. Co. v. Seaboard Allied Milling Corp.*, 422 U.S. 444, 454 (1979); *Morris v. Gressette*, 432 U.S. 491, 499 (1977)).

¹¹⁶ *Bowen*, 476 U.S. at 672.

¹¹⁷ *Id.* at 667 (Rehnquist, J. did not participate in the decision). At the time the Court decided *Bowen*, judicial review was available for claims related to benefit amounts under Part A, but not Part B. A person wishing to dispute a Part B payment amount was entitled only to a hearing and did not have access to judicial review, per the Supreme Court’s holding in an earlier case, *United States v. Erika, Inc.*, 456 U.S. 201, 207–08 (1982). In *Illinois Insurance Guaranty Fund v. Becerra*, 33 F. 4th 916, 924 (7th Cir. 2022), the Seventh Circuit explained that the “amount/methodology dichotomy” that the Court set up in *Bowen* was made irrelevant by Congress in 1986, when Congress amended the Medicare statute to provide for administrative and judicial review for claims under both Part A and Part B. (See Pub. L. No. 99-509, § 9341(a), 100 Stat. 1874, 2037–38).

¹¹⁸ *Bowen*, 476 U.S. at 668.

¹¹⁹ *Mich. Acad. of Family Physicians v. Blue Cross & Blue Shield*, 502 F. Supp. 751, 755 (E.D. Mich. 1980); *Mich. Acad. of Family Physicians v. Blue Cross & Blue Shield*, 728 F.2d 326 (6th Cir. 1984), *vacated sub nom. Heckler v. Mich. Acad. of Family Physicians*, 469 U.S. 807 (1984).

¹²⁰ 476 U.S. at 669.

The Supreme Court disagreed, observing that judicial review is not precluded “unless there is a persuasive reason to believe that such was the purpose of Congress.”¹²¹ The Court read the judicial review provisions of the Medicare statute in the context of the greater statutory scheme. It also distinguished the facts of *Bowen* from its earlier decision in *United States v. Erika, Inc.*, where it held that Congress “deliberately intended to foreclose further review” of amount determinations for Part B awards.¹²² The *Bowen* Court found that the statutory scheme of Part B “simply does not speak to challenges mounted against the *method* by which such amounts are to be determined.”¹²³ In other words, the Court reasoned that although the statute prohibited judicial review of the payment amount itself, a regulation describing the method CMS used to calculate that payment amount could be challenged.¹²⁴

HHS’s most recent argument that a particular provision of the Medicare statute was not subject to judicial review also failed.¹²⁵ In *American Hospital Association v. Becerra*, the Secretary argued that a provider group could not challenge a CMS regulation calculating payments for specified covered outpatient drugs (SCODs) under Medicare Part B because § 1395l(t)(12)(A) and (C) of the statute precluded judicial review of such actions.¹²⁶ The Court concluded that those provisions related to HHS’s “general payment methodology” for calculating Medicare reimbursement rates for services rendered, rather than the specific SCODs reimbursement rates at issue in *American Hospital Association*.¹²⁷ The statute did not expressly preclude judicial review of the calculation of the reimbursement rates, and in the Court’s view, the existence of a “detailed statutory formula” for that calculation suggested that HHS’s implementation of that formula was subject to review.¹²⁸ According to the Court, “HHS’s arguments against judicial review cannot override the text of the statute and the traditional presumption in favor of judicial review of administrative action.”¹²⁹ Here again, therefore, the Court drew a distinction between the process by which HHS made its determination and the substance of that final determination, and read the statute’s limit on judicial review to apply narrowly only to one of those elements.

Cases Upholding the Medicare Statute’s Limitation on Judicial Review

Although the Supreme Court has narrowly interpreted the Medicare statute’s restrictions on administrative and judicial review, it has upheld the statute’s limitations on federal court jurisdiction over Medicare claims under certain circumstances. For example, in *Heckler v. Ringer*, the Supreme Court upheld the statute’s mechanism for adjudicating Medicare claim benefit denials, including its requirement that administrative exhaustion precede judicial review.¹³⁰ In *Heckler*, several Medicare beneficiaries brought a variety of constitutional and other statutory challenges to Medicare Part A’s denial of coverage for a surgery, but the district court dismissed the case in its entirety, holding that the Medicare statute limited judicial review to only instances

¹²¹ *Id.* at 670, 672.

¹²² 456 U.S. 201, 208 (1982).

¹²³ *Bowen*, 476 U.S. at 675.

¹²⁴ *Id.*

¹²⁵ *Am. Hosp. Ass’n*, 142 S. Ct. at 1902. The case interpreted the Medicare statute’s preclusion on judicial review found in 42 U.S.C. § 1395l(t)(12)(A) and (C). For more information on the Supreme Court’s decision in the case, see CRS Legal Sidebar LSB10821, *Supreme Court Overturns HHS Regulation Reducing the Medicare Outpatient Drug Reimbursement Rate for 340B Hospitals*, by Edward C. Liu and Hannah-Alise Rogers.

¹²⁶ *Am. Hosp. Ass’n*, 142 S. Ct. at 1902.

¹²⁷ *Id.* at 1897.

¹²⁸ *Id.* at 1902.

¹²⁹ *Id.*

¹³⁰ 466 U.S. 602 (1984).

in which the Secretary had issued a final decision.¹³¹ The Supreme Court agreed, holding that “[i]n the best of all worlds, immediate judicial access . . . might be desirable. But Congress . . . struck a different balance . . . requiring that administrative remedies be exhausted before judicial review of the Secretary’s decisions takes place. . . . If the balance is to be struck anew, the decision must come from Congress and not from this Court.”¹³²

Potential Challenges to the Program and § 1320f-7

In light of this background, it is possible that the scope of judicial review available under § 1320f-7 could become the subject of similar litigation. That statutory section may help insulate the agency from challenges to its implementation of the Program, but litigants are likely to test how much protection § 1320f-7 provides. For example, if a manufacturer were to challenge some aspect of the MFP negotiation process, the agency could argue that such challenges are prohibited by § 1320f-7(3), which states that “the determination of a[n] [MFP]” under § 1320f-3(b) is exempt from administrative or judicial review.¹³³ Similar to the holding of *Bowen*, a manufacturer might respond that a court should not interpret § 1320f-7(3) to prohibit a challenge to the *method* of computing the MFP, but only a challenge to the final *amount*.¹³⁴ Alternatively, relying on the Court’s decision in *American Hospital Association*, manufacturers might argue that a court reviewing its challenge to the MFP should distinguish between the “general methodology” of the MFP and the specific calculation of it.¹³⁵

To avoid litigation over whether the courts have jurisdiction over such challenges, Congress may further clarify which sections of the statute are judicially reviewable. For example, after the Court’s decision in *Bowen*, Congress amended the Medicare statute to alter the Court’s holding on the judicial reviewability of payment amounts under Part B.¹³⁶

¹³¹ *Heckler*, 466 U.S. at 611.

¹³² *Id.* at 627. The Court further explained, “[h]ere respondents clearly have an adequate remedy in § 405(g) [of the Medicare statute] for challenging all aspects of the Secretary’s denial of their claims. . . . Thus § 405(g) is the *only* avenue for judicial review of respondents’ . . . claims for benefits, and, when their claim was filed in District Court, each had failed to satisfy the exhaustion requirement that is a prerequisite to jurisdiction under that provision.” *Id.* at 617 (emphasis added).

¹³³ *See* 42 U.S.C. § 1320f-7.

¹³⁴ *See Bowen*, 476 U.S. at 675.

¹³⁵ *See Am. Hosp. Ass’n*, 142 S. Ct. at 1897. The legislative history of the IRA, which some courts might use to evaluate its judicial review provisions, provides little guidance. During floor debates about the IRA, Congress did not discuss § 1320f-7 at length, but Sen. Michael Crapo mentioned its limitation on judicial review in a floor statement opposing the bill. In his characterization, the provision established “permanent prohibitions on even judicial and administrative review and with initial implementation shielded from basic notice-and-comment rulemaking requirements.” 168 CONG. REC. S4155–56 (daily ed. Aug. 6, 2022) (statement of Sen. Michael Crapo).

¹³⁶ As discussed *supra* note 117, in 1986, the year that *Bowen* was decided, Congress amended the Medicare statute to provide for administrative and judicial review for claims under both Part A and Part B, thus eliminating the “amount/methodology dichotomy” that the *Bowen* Court created. (*See* § 9341(a), 100 Stat. at 2037–38).

Considerations for Congress

Since the IRA became law in August 2022, the Medicare Drug Price Negotiation Program has received mixed responses from stakeholders. Some have expressed skepticism, arguing that the legislation will discourage innovation and increase drug list prices, while others praise the Program as a response to the need for more affordable Medicare prescription drugs.¹³⁷ Many stakeholders are also skeptical of the short implementation timeline and the limited, 30-day window for stakeholders to provide feedback to CMS on its initial guidance, anticipating that this will make litigation more likely.¹³⁸ Although no cases challenging the Program have been filed, many stakeholders see litigation as inevitable, given the high stakes.¹³⁹ Legal commentators have speculated on the types of challenges that manufacturers might bring against the law, including the Due Process Clause, the Fifth Amendment takings clause, or even under the nondelegation doctrine.¹⁴⁰

Assuming a legal challenge arises, a court may need to consider whether and to what extent the statute's provisions on preclusion of judicial review limit manufacturers' ability to bring cases. The courts' primary resource in interpreting those provisions is likely to be the statutory text. The most effective way that Congress could influence the scope of judicial review of the Program would therefore be to amend the statute to clarify further the types of legal challenges it intends to prohibit.

Author Information

Hannah-Alise Rogers
Legislative Attorney

¹³⁷ Compare AARP, *Senate Vote is Historic Step Toward Real Relief on Prescription Drug Pricing* (Aug. 7, 2022), <https://press.aarp.org/2022-8-AARP-Senate-Vote-Historic-Step-Toward-Real-Relief-Prescription-Drug-Pricing>; with Caleb Watney & Heidi Williams, *Drug Pricing Reforms Can Hurt Innovation. Here Are Three Ways To Prevent That*, WASH. POST (Aug. 22, 2022), <https://www.washingtonpost.com/opinions/2022/08/22/medicare-drug-prices-negotiation-innovation/>.

¹³⁸ Celine Castronuovo, *Drug Price Negotiation Deadlines Expose Medicare to Litigation*, BLOOMBERG LAW (Feb. 22, 2023), <https://news.bloomberglaw.com/health-law-and-business/drug-price-negotiation-deadlines-expose-medicare-to-litigation>.

¹³⁹ Kaustuv Basu, *Drug Price Law to Spur Creative Claims as Industry Readies Fight*, BLOOMBERG LAW (Sept. 29, 2022), <https://news.bloomberglaw.com/health-law-and-business/drug-price-law-to-spur-creative-claims-as-industry-readies-fight>.

¹⁴⁰ *Id.*

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