CMS Announces First 10 Medicare Part D Drugs Subject to Price Negotiations

October 6, 2023

The Inflation Reduction Act ("IRA") established a new program authorizing the Department of Health and Human Services ("HHS") to negotiate the price of certain high-spend Medicare Part B and/or Part D drugs and biologics with manufacturers—albeit with provisions that enable HHS to compel a significant reduction in the amount it pays in reimbursement for these drugs. As we discuss in our previous article, these provisions represent a radical shift in HHS's role in Medicare drug pricing. Previously, Part B drugs were reimbursed according to a statutory formula, and Part D sponsors negotiated prices with the manufacturers. Recently, the Center for Medicare & Medicaid Services ("CMS") announced the first 10 Medicare Part D drugs subject to negotiations, with negotiated prices set to take effect in 2026.

Below, we review the IRA's negotiation requirements and recent legal challenges and discuss key takeaways for industry stakeholders and investors.

Background

Medicare beneficiaries typically obtain necessary medications through either Medicare Part B or Part D. Medicare Part B covers certain prescription medications administered on an outpatient basis that are not self-administered (i.e., they are given by physicians as part of delivering medical services to patients). Drugs covered under Medicare Part B have historically been reimbursed at a rate of 104% of the drug's "Average Sales Price." Medicare Part D, on the other hand, is a voluntary prescription drug benefit for Medicare beneficiaries administered by private plans (Medicare Prescription Drug Plans) that provides broad coverage for outpatient prescription drugs. Part D drug prices are directly negotiated between the drug manufacturer and pharmacies; HHS historically has been precluded from interfering with these negotiations. The IRA disrupted these pricing schemes by specifically allowing HHS to directly negotiate prices of certain drugs with manufacturers.

Under the IRA, HHS is tasked with selecting high-spend Medicare Part B and/or Part D drugs, which will then be subject to negotiations to determine a so-called "maximum

fair price" ("MFP"), equal to or less than a statutorily defined ceiling price. HHS was required to pick 10 drugs for negotiated pricing to take effect in 2026, and is slated to pick 15 additional drugs for 2027, 15 additional drugs for 2028, 20 additional drugs for 2029 and 20 additional drugs each subsequent year. Unless subject to one of the limited exceptions provided in the IRA, the drugs selected for each round of negotiations are chosen from a list of the 50 drugs with the highest Medicare Part D or Part B spending; only those drugs not subject to "generic competition" can be selected for negotiations. Further, small molecule drugs are provided a nine-year period of immunity from negotiations and the application of MFPs; biologics (large molecules) have 13 years of immunity.

Each manufacturer of the selected drugs is required to enter into negotiations with HHS or withdraw all of their prescription drugs from Medicare and Medicaid coverage. Failure to cooperate with negotiations can result in a punishing excise tax starting at 65% of the drug's U.S. sales, increasing each quarter to as high as 95% of U.S. sales. The selected drug's initial MFP is set at the lower of (i) the amount at which the drug would have been reimbursed under Medicare Part B or Part D under the old regime and (ii) the average non-federal average manufacturer price in 2021 (adjusted for inflation). There is, however, no statutory minimum fair price. The MFP applies to Medicare Part B and Part D beneficiaries and must be applied before coverage or other financial assistance is applied.

During negotiations, the HHS Secretary will base HHS's offer on a number of factors, including manufacturer-specific data (e.g., R&D costs, production and distribution costs, market data, revenue, sales volume), evidence of alternative treatments, the comparative effectiveness of the drug and therapeutic alternatives and the unmet medical needs that the drug addresses. A negotiated drug's MFP will apply until a generic or biosimilar drug is launched.

CMS Selects 10 Initial Drugs for Negotiations

On August 29, 2023, CMS announced the selection of 10 Medicare Part D drugs for negotiations which are used to treat a wide range of conditions, including rheumatoid arthritis, heart failure, chronic kidney disease and diabetes:

Manufacturer	Drug	Category	Medicare Spend in Billions[1]
Bristol Myers Squibb Partner: Pfizer	Eliquis	Blood Clotting	$16.5B
Boehringer Ingelheim Partner: Eli Lilly	Jardiance	Diabetes; Heart Failure	$7.1B
Janssen Pharmaceuticals (Johnson & Johnson)	Xarelto	Blood Clotting	$6B
Merck Sharp Dohme	Januvia	Diabetes	$4.1B
AstraZeneca AB	Farxiga	Diabetes; Heart Failure; Chronic Kidney Disease	$3.3B
Novartis Pharmaceuticals Corp	Enestro	Heart Failure	$2.9B
Immunex Corp (Amgen)	Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic Arthritis	$2.8B
Pharmacyclics LLC (Abbvie)	Imbruvica	Blood Cancers	$2.7B
Janssen Biotech, Inc. (Johnson & Johnson)	Stelara	Psoriasis; Psoriatic Arthritis; Crohn's Disease; Ulcerative Colitis	$2.6B
Novo Nordisk	Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill (Insulin)	Diabetes	$2.6B

The White House stated that 9 million Medicare Part D enrollees use these 10 drugs, paying over $3.4 billion in out-of-pocket costs in 2022 alone.[2] Of note, CMS selected an entire class of insulin drugs produced by Novo Nordisk as a "single drug" subject to negotiations: CMS released a guidance document in June of 2023 clarifying that the IRA allows CMS to aggregate dosage forms and strengths of a drug, and the MFP is to be applied across all strengths and dosage forms of a negotiation-eligible drug.

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1 Medicare spend data is for the period June 2022 to May 2023.

2 *See* FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation (Aug. 29, 2023), available here.

Recent Legal Challenges to the IRA

In recent months, pharmaceutical companies and other stakeholders have sued HHS, challenging the legal viability of the negotiation provisions under a range of theories, as well as the implementation of such provisions through agency guidance (as opposed to formal notice and comment rulemaking procedures). Eight lawsuits have been filed by a combination of pharmaceutical manufacturers and trade groups. The plaintiffs have argued that the IRA is unconstitutional because the drug price negotiation program:

- violates the First Amendment by requiring the plaintiffs to communicate that they have agreed to a fair price;
- constitutes uncompensated takings in violation of the Fifth Amendment by requisitioning the plaintiffs' patented products and transferring them to Medicare beneficiaries through forced sales;
- violates the Due Process clause of the Fifth Amendment by depriving the plaintiffs of their property interests without providing a meaningful opportunity to be heard by a neutral decision-maker;
- implements a punishing "excise tax" on manufacturers to coerce compliance with the negotiations program in violation of the Eighth Amendment;
- conditions participation in Medicare and Medicaid on the relinquishing of First and Fifth Amendment rights;
- violates the Administrative Procedures Act on both procedural (failure to implement the program via notice-and-comment rulemaking) and substantive grounds;
- violates the non-delegation doctrine as Congress did not provide CMS with an "intelligible principle" pursuant to which it may carry out the mandates required by the IRA; and
- implements an excise tax that exceeds the legislative authority of Congress under the Commerce Clause and Taxing Clause of Article I.

These matters are ongoing. The arguments made by plaintiffs, while novel, will be carefully considered by the courts and provide potential bases that could be used to invalidate the challenged IRA drug pricing provisions.

Takeaways for Industry Stakeholders and Investors

At least one federal judge has rejected a bid for a preliminary injunction to pause negotiations, allowing the process to continue as originally planned. If the IRA's drug price negotiation program ultimately survives its various legal challenges, the first round of formal negotiations is slated to begin February 1, 2024, and will end August 1, 2024. Prior to February 1, 2024, CMS will meet with each participating drug manufacturer, giving the manufacturer an opportunity to provide additional context to their data submission ahead of the negotiation process. The negotiated MFP for the initial 10 Part D drugs would be listed by September 1, 2024, and take effect January 1, 2026. Despite the ongoing lawsuits, the manufacturers for all 10 selected drugs have communicated their intent to reluctantly participate in the negotiation process.

The IRA's negotiation provisions are likely to inflict significant harm on the pharmaceutical industry as reduced government reimbursement will translate into correspondingly lower revenue and profits. As a result, innovator pharmaceutical manufacturers are likely to decrease investment in small molecules that may someday result in drugs that are subjected to the IRA negotiation provisions and may reduce efforts to find new indications for drugs already on the market for the same reason. Generic competition may also be negatively impacted, as generic drugs generate much of their value from being priced well below brand name prices in order to capture a significant amount of the market; because the IRA's MFP will drive down the price of brand name products, generic manufacturers have a decreased incentive to enter the market. Further, while the IRA is limited to Medicare drugs and the MFP must only be offered to Medicare beneficiaries, there is likely to be a spillover into the private market. Commercial insurers, for instance, may use the negotiation process as a basis for reducing the amount they pay for certain products.

Given that the number of drugs subject to the IRA is set to increase every year, investors should:

- carefully consider the impacts of the IRA's drug price negotiation program and whether a target's portfolio includes drugs with high aggregate Medicare spending likely to be subject to future negotiations;

- be mindful of how the IRA will impact the future flow of capital, as the IRA disincentivizes investment in small molecules (which have only a nine-year protection period from negotiations, as compared to 13 years for biologics/large molecules);

- inquire into a target company's plans that may mitigate the impacts of the IRA; and

- remain aware of ongoing litigation developments that may alter how the IRA is implemented and corresponding obligations of portfolio or target companies.

In a recent announcement, CMS outlined upcoming opportunities to receive public input regarding the negotiation program. Individual dates will be scheduled for each of the 10 selected drugs and interested parties and stakeholders will have the opportunity to share input relevant to the drugs for the first cycle of negotiations.[3] While a temporary funding bill has postponed concerns over a government shutdown until November 17, 2023, any future shutdown of the federal government could significantly reduce CMS staffing and potentially impact negotiation timelines.

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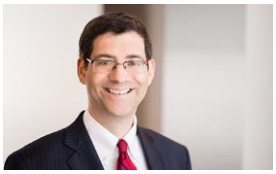
We will continue to monitor the status of the IRA and related legal challenges. Please do not hesitate to contact us with any questions.



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[3] The dates for the 10 listening sessions are available here.

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