What a Difference a Year Makes: IRA's Drug Pricing Provisions Turn One

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This week marks the one-year anniversary since the enactment of the Inflation Reduction Act (IRA), which included **sweeping reforms** empowering the Secretary of Health and Human Services (HHS) to set prices for certain pharmaceuticals in the Medicare program. Since enactment last year, the Biden-Harris administration has repeatedly made it clear that they are full-steam ahead with implementing the law's drug pricing provisions and have even proposed doubling down on them in their Fiscal Year 2024 Budget Proposal with plans to increase the scope of the program. As the IRA marks its one-year anniversary and stakeholders prepare for key implementation milestones in the weeks and months ahead, this client alert identifies key dates and complex and controversial aspects of IRA implementation and emerging litigation that stakeholders should continue to closely watch as they navigate an actively evolving IRA landscape.

Key Implementation Dates for Medicare Drug Negotiation Program

The IRA requires the Centers for Medicare & Medicaid Services (CMS) to publish a list of 10 Part D selected drugs for negotiation for 2026 on September 1, 2023. This pivotal implementation date is quickly followed by two additional key implementation dates in early October. Under the IRA, October 1, 2023, is the deadline for sponsors of drugs selected for the Medicare Drug Negotiation Program ("Negotiation Program") to sign a required and proscribed template contract in order to participate in the negotiation process for 2026. In reality, manufacturers of selected drugs do not have a choice of whether to sign the Agreement or not: It is required by law and IRA imposes significant penalties on any firm that does not execute the Agreement. The following day, October 2, marks the deadline for Sponsors of drugs selected for the Negotiation Program to submit manufacturer specific data to CMS to consider in setting the "Maximum Fair Price" (MFP) under the IRA and CMS's guidance documents. However, manufacturers of these selected drugs are expected to act well before October 1.

In preparation for these upcoming deadlines, in July, CMS posted the Medicare Drug Price Negotiation Agreement template and corresponding memorandum setting forth related instructions for completing the agreement on its website. Notably, in this memorandum, CMS requests that, within five days following the publication of the list of selected drugs for the initial price applicability year, manufacturers submit to the agency "all names, titles, and contact information for representatives authorized to execute the Agreement, inclusive of Addenda," and further stipulates that a manufacturer's authorized representative or representatives "must be legally authorized to bind the Manufacturer to the terms and contained in the Agreement, including any Addenda."

Looking further ahead, the next wave of key implementation dates for the Negotiation Program will come early next year when the negotiation periods are expected to kick in. Under the IRA statute, CMS is to send initial offers of an MFP with a justification to the manufacturers of the 10 selected Part D drugs, after which manufacturers will only have 30 days to counteroffer. However, despite this so-called negotiation process, ultimately, the IRA empowers CMS to reject any counteroffer and set the prices for the selected drugs. The IRA statute further lays out that CMS is to publish the maximum fair prices for drugs selected for negotiation for 2026

on September 1, 2024. Absent any change to the IRA's current implementation trajectory, the prices set by the Secretary would go into effect on January 1, 2026.

Bona Fide Biosimilar and Generic Entry

In its revised guidance **memorandum** issued on June 30, 2023, CMS confirmed the process it will use to determine whether there is *bona fide* marketing of a generic or biosimilar, which would result in an otherwise qualifying drug being ineligible for participation in the Negotiation Program or ceasing to be subject to an MFP. CMS made clear that "token" or "de minimis" availability of generic or biosimilar products in the marketplace will be insufficient to establish *bona fide* marketing, but declined to set a specific numeric threshold such as market share that will satisfy the requirement. Instead, CMS elucidated that it will determine whether there is *bona fide* marketing in view of the totality-of-the-circumstances, and after that determination is made, CMS will keep monitoring and assessing whether meaningful competition continues to exist.

CMS emphasized that no single source of data is necessarily dispositive to CMS's totality-of-the-circumstances inquiry. Rather, CMS intends to review the evidence holistically, starting with Prescription Drug Event (PDE) and Average Manufacturer Price (AMP) data from the most recent 12-month period available. Additionally, CMS explained that whether the applicable generic or biosimilar product is consistently available to be purchased via the pharmaceutical supply chain and the extent to which there are any agreements that limit the drug's availability or distribution are relevant considerations to its inquiry. To that end, CMS has encouraged drug manufacturers to submit evidence regarding generic or biosimilar market competition to help inform its determination whether a generic or biosimilar is being marketed on a *bona fide* basis. CMS will also monitor these factors on an ongoing basis to confirm that the generic or biosimilar is still being marketed on a *bona fide* basis over time, as defined.

With this new sub-regulatory guidance, CMS has made clear that the mere launch of a product by a generic or biosimilar, even if *bona fide* from other legal perspectives, will be subject to a new and unique standard of review. It is thus possible that realistically, all drugs will continue to be subject to an MFP for some amount of time after a generic or biosimilar launch, while CMS gathers its data and performs an analysis to confirm the *bona fide* nature of the competitor launch under the new standard. How long will it take? Will CMS request additional information? CMS has set no deadline or goal for itself in the guidance for when it will make the determination on a *bona fide* launch.

Further, CMS has made clear that depending on when it makes the *bona fide* determination will have a significant impact on the applicability of the MFP. CMS has stated that if it makes the determination that a *bona fide* generic or biologic launch has occurred before the MFP would apply, but after August 2 of the Negotiation Period year, the selected drug "remains a selected drug and MFP applies for [the] initial price applicability year…[the] selected drug ceases to be a selected drug [in the subsequent year]." In other words, a drug that would otherwise be exempt from MFP may be subject to MFP for an entire calendar year merely because of CMS's delay in confirming a *bona fide* launch. *See* CMS Guidance, at section 70, p. 165-66.

The possibility of those unknown gaps in timing could create substantial uncertainty for various stakeholders in the pharmaceutical supply chain as well as for investors.

In the revised guidance document, CMS disclosed that "many" commenters argued that CMS lacked statutory authority to determine the meaning of "marketed" under section 1192 of the IRA as "*bona fide*" or anything but the first market date consistent with other Food and Drug Administration (FDA) and CMS precedent (including CMS' own original guidance document on the subject which defined it as the mere "introduction or delivery for introduction into interstate commerce of a drug product"). CMS now argues in the revised guidance commentary that the statute contemplates that CMS "would consider whether meaningful competition exists on an ongoing

basis" in determining whether a generic or biosimilar "is marketed" under the statute. Stakeholders should watch closely for developments on the *bona fide* marketing issue, including the potential for Administrative Procedure Act (APA) litigation to challenge CMS's sub-regulatory guidance.

CMS Guidance on Formulation, Unmet Needs and QALY Data

MS's revised guidance addresses a host of substantive scientific and regulatory issues affecting the drug price negotiation program that have, until now, been in the domain of the FDA to consider in drug approvals and exclusivity determinations. For example, the IRA states that HHS will "aggregate[e] across dosage forms and strengths of the drug, including new formulations of the drug" and thus combine sales of several separate NDAs or BLAs together as one drug for purposes of determining "Negotiation Eligible Drugs" under the Act. 42 USC § 1320f-1(d)(3)(B). In other words, several otherwise small drugs not hitting the top 50 list can get dragged up into the top 50 if they meet this definition. CMS's revised guidance on the issue further clarifies that it will aggregate such products of "the same holder" of an NDA, "inclusive of products that are marketed pursuant to different NDAs [or BLAs]" including authorized generics. *See* CMS Guidance at section 30.1, p. 98-100. However, fixed combination drugs are handled a bit differently: A fixed combination drug will not be aggregated together with a drug containing only one of the active moieties. Fixed combination drugs will be aggregated with each other if they have the same active moieties and are held by the same sponsor. *Id*.

Under the IRA, after the MFP ceiling has been set by CMS, it will apply a host of other factors in determining the final MFP. One such key factor is whether the drug meets an "unmet medical need." 42 USC § 1320f-3(e)(2)(D). The final CMS guidance provides that an "unmet medical need" exists only where "the drug or biological product treats a disease or condition in cases where no other treatment options exist or existing treatments do not adequately address the disease or condition", citing to a 2014 FDA guidance on "Expedited Programs for Serious Conditions". *See* CMS Guidance at section 60.3.3.1, p. 148-49. However, in the cited guidance, FDA, consistent with other usage, actually defines unmet medical need as "a condition whose treatment or diagnosis is not addressed adequately by available therapy." Thus, CMS's new definition is a new, narrower standard for NDA and BLA sponsors to take into consideration. In addition, CMS makes clear that even where a drug had been "first in class", it will look at subsequently approved drugs and determine "what the difference in clinical benefit is between the selected drug and [subsequently approved] therapeutic alternative(s)." Id.

Finally, section 1194(e) of the IRA explicitly prohibits the use of "evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." 42 USC § 1320f-3(e)(2)(D)."

CMS further clarified in the revised guidance that it specifically "will not use Quality-Adjusted Life Years (QALYs) to determine any [MFP] offer" when considering comparative effectiveness under 42 USC § 1320f-3(e)(2)(C). *See* CMS Guidance at 46. QALY is a measure widely criticized for minimizing the value of life for sick, disabled or older patients. Many comments were filed with CMS expressing the concern that despite the statutory prohibition and HHS's commitment not to use QALYs per se, that HHS would in effect be using the equivalent of QALYs because CMS has stated that it will in fact rely on portions of QALY studies that contain relevant "underlying data, results or other content." Critics maintain that such studies are irrevocably biased and should not be referenced in any way by CMS.

Other than comparative effectiveness, what will CMS be looking at? Per the revised guidance, when comparing a drug to therapeutic alternatives, CMS will look at:

- Cure, survival, progression-free survival or improved morbidity.
- Changes in symptoms or other factors that are of importance to patients and patient-reported outcomes.

- Changes to productivity, independence and quality of life if corresponding to "a direct impact" on the patient, including patient-centered outcomes when available.
- Caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug.

See CMS Guidance at 60.3.3.1, p. 148. Sponsors and other stakeholders will need to pay attention to these factors when designing clinical trials and lifecycle management plans for drugs that could come under the CMS negotiation program.

Litigation Update

In the midst of CMS's IRA implementation, several suits have been filed challenging the IRA on various Constitutional grounds. The suits all point to aspects of CMS's implementation as support for a finding that the IRA creates a process that is unconstitutional in several interlocking dimensions. To date, six separate suits have been filed in U.S. District Courts in Washington, D.C., New Jersey, Texas, Ohio and Illinois. Plaintiffs include four drug manufacturers (Merck, Bristol Myers Squibb, Astellas and Janssen), two industry associations (PhRMA and the U.S. Chamber of Commerce), and two medical and patient organizations (the National Infusion Center Association and the Global Colon Cancer Association, who are co-plaintiffs with PhRMA). Each suit contains a different array of constitutional arguments, including in summary:

- Fifth Amendment: The IRA is a "taking" without providing "just compensation" because it is designed to allow the government (and others) to pay less than fair market value for pharmaceuticals.
- Fifth Amendment: The IRA deprives manufacturers of Due Process, including challenges to the IRA's prohibitions on judicial and administrative review of pricing decisions by CMS, and lack of a formal notice-and-comment review of CMS's implementation plans.
- First Amendment: The IRA compels speech by manufacturers in violation of the right to free speech, because of the requirement to execute contracts declaring that CMS's MFP is in fact a "fair" price.
- Separation of Powers: The IRA violates the non-delegation doctrine because it does not provide procedural protections against CMS enacting in arbitrary agency action and without specifying the substantive legal standard by which CMS will set prices.
- Eighth Amendment: The IRA's excise tax violates the Excessive Fines Clause and exceeds Congress' enumerated powers.

The first of these suits were filed in June, with motions for summary judgment filed in the Merck case on July 11, a motion for a preliminary injunction filed in the Chamber case on July 12, and a motion for summary judgment was filed in the PhRMA case on August 10. In light of the impending IRA implementation timelines, including the September 1 publication of the first 10 drugs under the negotiation program by CMS, stakeholders will be watching the timing and briefing schedules of these IRA cases closely to see if there is any effect on the program and its timing.

Congress Continues to Prioritize Drug Pricing

While the Biden-Harris administration has been full steam ahead on IRA drug pricing implementation, Congress has not been idle on related **issues**. To the contrary, Congress has leaned into examining health care consolidation and transparency, including in the context of drug pricing dynamics, with drug pricing issues being front and center in the 118th Congress. In particular, the focus on pharmacy benefit managers (PBMs) has been unprecedented, with multiple Committees in the House and Senate holding hearings and marking up PBM legislation this year. In the days leading up to the August recess, the Senate Finance Committee advanced the

Modernizing and Ensuring PBM Accountability Act by a vote of 26 to 1. While it remains to be seen when and how the House and Senate will come together on PBM legislation, it is clear that interest in moving bipartisan legislation on this issue is steadily gaining momentum as Congress looks toward September and beyond.

Yet, despite the bipartisan, bicameral focus on potential PBM reforms, drug pricing issues have also continued to play out along partisan fault lines. As one example, earlier this year, the Senate Health, Education, Labor and Pensions (HELP) Committee released a bipartisan staff discussion draft of legislation to reauthorize the Pandemic and All-Hazards Preparedness Act. However, as the press release for the discussion draft noted, there was not bipartisan agreement over bracketed drug pricing language included in that draft, and which ultimately fell out of the version of the bipartisan bill to move through the Senate HELP Committee in the weeks following. Similarly, in the days leading up to the August recess, House Education and the Workforce Committee Ranking Member Robert C. "Bobby" Scott (D-VA), House Energy and Commerce Committee Ranking Member Frank Pallone, Jr. (D-NJ), and House Ways and Means Committee Ranking Member Richard E. Neal (D-MA) introduced the Lowering Drug Costs for American Families Act. Their bill would expand on the IRA's drug pricing provisions by extending IRA's drug price negotiation and inflation rebates to the private insurance market in addition to significantly increasing the number of prescription drugs subject to price setting under the negotiation program. In addition, Congress' engagement on drug pricing issues has not been limited to legislative activity. Since enactment a year ago, the IRA drug pricing provisions has been a consistent area of bicameral oversight by Congressional Republican members and this is expected to be a continued area of oversight focus as the Biden-Harris administration moves forward with implementation.

What's Next

As IRA marks its one-year anniversary and key implementation dates draw near, controversy and uncertainty continue to surround the implementation of the law as CMS and affected stakeholders navigate unprecedented drug pricing waters. The activity related to the law's drug pricing provisions continues to be an active area of developments, both in terms of implementation related developments by the Biden-Harris administration and various pending Constitutional challenges. These dynamics are playing out against a backdrop of an active Congressional focus on drug pricing issues, most notably related to PBMs, which may result in further reforms to an already actively evolving drug pricing landscape in the wake of IRA. One thing that is certain is that a wide range of stakeholders will continue to be closely watching for IRA implementation related developments, preparing for their impact and crafting new strategic approaches to drug development, investment and commercialization to fit the emerging new healthcare landscape.

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