Health Policy and Legislation Alert

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The Drug Pricing Drumbeat Continues: IRA Update and Key Areas to Watch in 2023

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The Biden-Harris administration and Congress appear poised to continue focusing on drug pricing issues this year, most notably with the Centers for Medicare & Medicaid Services moving forward with implementation of the drug pricing provisions included in the Inflation Reduction Act. This alert highlights key drug pricing areas to watch in 2023.

IRA Implementation

The Inflation Reduction Act (IRA), P.L. 117-169, which became law in August 2022, included some of the most consequential prescription drug pricing reforms ever enacted. The Department of Health and Human Services (HHS) and the Centers for Medicaid & Medicaid Services (CMS) are moving forward with implementation of the mandatory drug price control provisions included in the IRA. As part of this effort, CMS continues to staff up the new Medicare Drug Rebate and Negotiations Group, which was established last year within the Center for Medicare to implement the Drug Price Negotiation Program ("Negotiation Program") and the Inflation Rebate Program. HHS recently provided notice in the *Federal Register* regarding a delegation of authorities for implementation of the IRA to the Administrator of CMS. Under the notice, the CMS Administrator is further empowered to re-delegate the authorities of the Secretary in the implementation of the IRA. This is a notable development given the breadth and scope of the IRA's drug pricing provisions and another specific area of implementation that is likely to be closely watched by Congress and stakeholders alike.

Our previous alert outlined key statutory implementation dates for the IRA's drug pricing reforms. On January 11, CMS released a memorandum that offers further detail on the agency's plan for implementing the Negotiation Program. This development sets the stage for further implementation actions and more specifics around the timing for these actions. In particular, stakeholders following IRA implementation may want to monitor closely the forthcoming guidance and data collection documents the agency outlines in its memorandum.

In the January 11 memo, CMS outlines its plan to issue draft guidance for implementation of the Negotiation Program for initial price applicability year 2026 and voluntarily solicit comments from the public for 30 days on certain topics in Spring

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2023. CMS also makes clear that it will provide additional information in the future related to any program guidance or rulemaking for initial price applicability years 2027 and beyond, as well as topics that are not relevant to the initial Negotiation Program for 2026, such as subsequent renegotiation procedures. The memo identifies a number of elements of the program guidance for the Negotiation Program on which CMS will request comment, including:

- Terms and conditions contained in the manufacturer agreement, including the manufacturer's and Secretary's responsibilities
- Approach for considering the manufacturer-reported data elements and evidence about alternative treatments
- Process for the offer and counteroffer exchange between the Secretary and manufacturers
- Content of an explanation for the maximum fair price
- Method for applying the maximum fair price across different dosage forms and strengths of a selected drug
- Dispute resolution process for specific issues that are not exempt from administrative and judicial review under the IRA
- Process for compliance monitoring and imposition of civil monetary penalties for violations.

CMS is also proposing three new information collection requests (ICRs) related to the Negotiation Program: 1) Small Biotech Exception ICR; 2) Negotiation Data Elements ICR; and 3) Offer and Counteroffer Exchange ICR. CMS's memo lays out the process for each ICR; in the spring of this year, CMS intends to publish a notice with a 60-day comment period in the *Federal Register* to announce the proposed ICR and solicit comments. CMS's memo further sets forth that following the consideration of the comments received, CMS intends to publish a notice with a 30-day comment period to announce the submission of the ICR to the Office of Management and Budget (OMB) in the upcoming summer.

While CMS's latest memorandum provides additional insights into how extensive the agency's implementation efforts will be, and generally how the agency intends to approach certain aspects of the drug pricing provisions under the IRA, uncertainty persists. Stakeholders will continue to closely watch for forthcoming details and developments to see how unanswered questions regarding program implementation may be addressed.

Innovation Center Drug Pricing Report

IRA implementation is not the only area of drug pricing focus for the Biden-Harris administration. On October 14, 2022, President Biden signed Executive Order (EO) 14087 on "Lowering Prescription Drug Costs for Americans." The EO calls for additional actions to "complement the IRA" in lowering drug costs and directs the Center for Medicare and Medicaid Innovation (CMMI) within CMS to submit a report to The White House on potential payment and delivery models that would lower drug costs and promote access to innovative drugs within 90 days. The EO specifically requests CMMI to consider "models that may lead to lower cost-sharing for commonly

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used drugs and support value-based payment that promotes high-quality care." The 90-day deadline date has passed, and stakeholders continue to eagerly watch to see how this report may further inform the Biden-Harris administration's work on their drug pricing priorities.

Congressional Committee Activity

Drug pricing issues are not only an area of focus for the Biden-Harris administration—these issues are also anticipated to be an area of focus for the 118th Congress. Sen. Bernie Sanders (I-VT) is set to lead the Senate Health, Education, Labor and Pensions (HELP) Committee, while Sen. Bill Cassidy (R-LA) will serve as Ranking Member. Sen. Sanders has long been a vocal advocate of aggressive drug pricing reforms over the years and stakeholders are watching to see how he approaches these issues as Chairman, such as revisiting proposals related to importation of prescription drugs. Sen. Sanders recently signed onto a letter led by Sens. Elizabeth Warren (D-MA), Angus King (I-ME) and Rep. Lloyd Doggett (D-TX) that urged HHS to exercise "march-in" rights under the Bayh-Dole Act.

While Sen. Cassidy is on record as opposing the IRA's price control provisions, the Ranking Member has worked with Democratic lawmakers in recent years on various bipartisan drug pricing bills, including proposals to promote generic competition and lower Part D out-of-pocket costs for beneficiaries. Stakeholders will be closely watching to see how the new Senate HELP Committee leadership approaches the Committee's work, including with respect to drug pricing related legislation.

Meanwhile, House Republicans, who are now in the majority, are expected to pursue a robust oversight agenda and have already staked out IRA implementation as part of their oversight focus. Last August, then Republican leaders of the House Energy and Commerce and Ways and Means Committees sent an oversight letter to HHS Secretary Xavier Becerra, seeking information on implementation of the IRA and requesting monthly briefings from the department on the law. IRA implementation is expected to continue to be an area of focus for these committees.

PBM Oversight

Pharmacy benefit manager (PBM) reform is a priority for some Republicans, and will be a focus for several congressional committees. Rep. Buddy Carter (R-GA), a pharmacist who sits on the Energy and Commerce Committee, will likely continue his efforts to increase transparency into PBM practices. Rep. James Comer (R-KY), who will chair the House Oversight Committee, also has stated that Congress must "take on PBMs to implement transparency and restore competition." And Senate Finance Committee Chairman Ron Wyden (D-OR) has indicated that he is "deeply concerned with PBM behavior" and is "committed to taking on all the drivers of high drug prices."

The focus on PBMs is not limited to Congress—the Federal Trade Commission (FTC) announced on June 7, 2022 its concern with the vertical integration of PBMs and insurers and their "enormous influence" on prescriptions and patient costs. As a result, the FTC commenced an investigation into the practices of the PBM industry, issuing Compulsory Orders to the six largest PBMs seeking information on their operations, pharmacy networks, reimbursement data and financial arrangements with all retail, chain, independent, specialty and mail-order pharmacies and pharmacy services

administrative organizations. The congressional committees of jurisdiction are likely to seek to explore similar issues in 2023.

State-Level Scrutiny

State governments also continue to be interested in drug pricing, resulting in new legislative efforts as well as increased regulatory and enforcement activity.

Over the last several years, States have passed new laws targeting PBMs. As preemption challenges to those laws make their way through the federal courts, a bipartisan group of nearly three dozen States has joined in an amicus effort to defend broad state jurisdiction to regulate PBMs.

In addition, last week, the California Attorney General sued three insulin manufacturers and three PBMs alleging illegal and deceptive practices in violation of the State's unfair competition law.

Conclusion

The drug pricing drumbeat does not appear to be abating in 2023 as the 118th Congress gets underway and the Biden-Harris administration presses forward with their drug pricing priorities. In particular, stakeholders will continue to closely watch for further developments related to IRA implementation and how key committees, members of Congress and the administration engage on these issues. Stakeholders will also want to watch for developments beyond the Beltway as various states continue to engage on drug pricing related fronts.

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