AMCP and the Inflation Reduction Act

The Inflation Reduction Act (IRA) is a landmark piece of healthcare legislation, one that has and will continue to have important implications across the managed care pharmacy industry. To deliver the statutorily required drug prices and benefits to Medicare patients, the IRA's complex health care provisions also necessitate enhanced collaboration between industry stakeholders. Given AMCP's success in fostering collaborative conversation through Partnership Forums, Advisory Groups, and national meetings, we hosted the first of many IRA Workshop sessions on August 2. The inaugural, four-hour virtual workshop gathered 60 representatives from health plans, pharmaceutical manufacturers, PBMs, research institutes, and patient advocacy organizations to work towards a common goal:

> **To begin multistakeholder discussion and collaborative action on consensus-based recommendations for operational implementation of the IRA that can be disseminated for industry-wide use and, ultimately, elevation to CMS.**

Workshop participants received IRA implementation progress updates from John Coster and Raghav Aggarwal, Senior Advisors from CMS with the Center for Medicare, as well as an in-depth explanation of the law's Medicare Drug Price Negotiation Program from Melissa Andel, Principal of CommonHealth Solutions. Participants were divided into breakout groups to foster generative discussion around implementation strategies for the IRA's drug price negotiation and out-of-pocket "smoothing" provisions. Each session offered productive conversations, opportunities to ask questions, and several important takeaways.

IRA WORKSHOP SERIES

WORKSHOP KICKOFF | August 2, 2023

Key Takeaways

General Session: Regulatory Perspective

***Presented by: John Coster**, Senior Advisor, Center for Medicare, Medicare Drug Rebate and Negotiation Group, and **Raghav Aggarwal**, Senior Advisor, Center for Medicare, Medicare Plan Payment Group.*

- CMS is under aggressive implementation deadlines and continues to solicit stakeholder feedback through draft guidance and public comment periods. *(See: https://www.cms.gov/inflation-reduction-act-and-medicare)*
- CMS intends to release updated guidance documents on the Medicare Part B and Part D inflationary rebate provision in late 2023.
- CMS will offer education and patient outreach reflecting the new and upcoming program changes during the Medicare Open Enrollment Period this Fall. The agency will provide more information on its strategy in the coming months.
- On August 22, CMS released draft guidance for health plans on parts of the out-of-pocket smoothing program (officially titled the *Medicare Maximum Monthly Cap on Cost-Sharing Payments Program*) with plans to release additional guidance in early 2024.
- On August 29, CMS announced the list of the first 10 drugs under Medicare Part D for price negotiation as part of IRA implementation, which can be found here.

Breakout Session: Out-of-Pocket "Smoothing" (the Medicare Prescription Payment Plan)

- Workshop participants identified educational needs that require coordination and collaboration between health plans, CMS, and pharmacies, including:
  - Brochures and other member-focused resources detailing key information about the smoothing program,
  - Guidance for health plans on how to identify which members would benefit from smoothing,
  - Empowering pharmacists to counsel patients on whether smoothing is right for them, and
  - Ensuring that educational materials incorporate patient perspectives, are written in clear and common language, and are translated into as many languages as possible to promote accessibility.
- Health plans and pharmacies are concerned about the operational challenges of implementing smoothing.
  - Health plans must upgrade their systems that track and bill patients, hire additional customer service staff, produce educational materials, and collect payments if an enrollee leaves the plan mid-year. PBMs could provide solutions to some of these challenges by offering improved billing and payment options.

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AMCP thanks all IRA Workshop Kickoff participants for their expertise and engagement in the ongoing conversation around the Inflation Reduction Act. Continued stakeholder collaboration is essential to implementing this law that will provide cost savings and improve benefits for millions of Medicare patients.

Breakout Session: Out-of-Pocket "Smoothing" (the Medicare Prescription Payment Plan) *cont'd*

- Health plans and pharmacies may face cash flow issues due to the time lags created by the smoothing program. Health plans are required to pay a pharmacy the full upfront cost of a product which will not be fully recouped until the end of the year. Under prompt pay rules, pharmacies may not receive payments from a health plan until up to 14 days after a product is dispensed, whereas currently, they receive the patient's share at the point of sale.

- Health plans are concerned about the financial burdens of smoothing, which will be combined with other changes in the IRA like lowering an enrollee's maximum out-of-pocket costs to $2,000, increasing health plans' share of costs in the catastrophic phase, and capping cost-sharing for insulin and ACIP (Advisory Committee on Immunization Practices)-recommended vaccines.

- Conversely, patients who are receiving high-cost therapies, such as cancer treatment, could reach their maximum out-of-pocket limit quickly and early in the year. With the out-of-pocket smoothing provision, the potential cost burden for these patients, of continuing treatment, would be alleviated.

General Session: Drug Price Negotiation

***Presented by: Melissa Andel**, Principal, CommonHealth Solutions*

- Along with public comment periods, CMS is hosting public listening sessions to solicit feedback on the Medicare Drug Price Negotiation Program. Sessions scheduled for the remainder of this year will focus on the initial ten drugs selected for negotiation.
  - During these listening sessions, CMS is specifically looking for feedback from patients, prescribers, and clinicians about the clinical benefit of each of the ten initially selected drugs. These stakeholders have an important role in discussing the therapeutic advances that the selected drugs represent, such as patient convenience and increased adherence.

- CMS is required by statute to provide a publicly available explanation of each of the negotiated prices for the initial ten drugs by March 2025.
  - Explanations will include the factors behind each pricing decision without disclosing trade secrets or confidential information.

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Next Steps: IRA Workshop #2

With the implementation of the IRA well underway, the Drug Price Negotiation program, Part D redesign, and inflationary rebate provisions are painting an exceedingly complex landscape for pharmaceutical companies, health plans, PBMs, patients, and government stakeholders. That's why your organization will want to take advantage of an opportunity to help shape the implementation of the IRA.

Join a select group of colleagues at AMCP's second IRA Workshop Series event on Thursday, Nov. 9, 2023. Your organization's attendance grants access to a roundtable of managed care experts and thought leaders. This "surround-sound" initiative grants the opportunity to be heard, navigate the IRA and its downstream effects, and unpack the law's key provisions. These workshops offer your organization the opportunity to lend its expertise and have its voice heard in the discussion around the IRA.

Breakout Session: Drug Price Negotiation and "Template"

- AMCP's IRA template educational tool should incorporate additional guidance from CMS to meet manufacturers' needs.
- The IRA template needs to be flexible and adaptive because CMS will likely refine the information collection process in future years.
- The IRA template is understandable, but the approach to collecting data needs clarification.
- Manufacturers will likely have difficulty calculating things like R&D costs, recoupments, and prior federal financial support.
  - There may be a "square peg, round hole" problem where the data that manufacturers maintain does not enable them to separate costs for selected drugs versus other drugs that are being developed.
  - The information that CMS wants from the Primary Manufacturer of the selected drug will require many departments to share information, which will be burdensome.
- CMS must clarify whether the information to be submitted should be limited to the US or include global data.

Contact corpopportunities@amcp.org now to secure your organization's spot for the next IRA Workshop on Nov. 9.

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