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Community Health Centers and the Impact of the Inflation Reduction Act on Inventory and Cash Flow

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Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

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Pharmacist and Technician Learning Objectives

- Identify key Inflation Reduction Act (IRA) implementation steps to monitor.
- Describe manufacturer and PBM incentives under IRA and how they might affect contracting with payers.
- Outline changes that will likely occur at the purchasing and billing level.

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Overview

What is the IRA?

How does the IRA change the drug distribution landscape?

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Inflation Reduction Act of 2022

- The IRA is not just a healthcare bill – it is the culmination of President Biden's Build Back Better Plan, which sought to address a range of topics including family medical leave, climate change, and other topics.
- For our purposes, when we talk about the IRA we are primarily talking about *a framework for Medicare to negotiate Part B and Part D drug costs and penalties for manufacturers that increase drug costs faster than the rate of inflation in the form of rebates*

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Key IRA Implementation Steps to Monitor

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IRA Phases

- The IRA's drug-related components phase in between 2022 and 2029
- That long time period introduces two major unknowns:
  - Will Congress change the law prior to complete implementation?
  - How will HHS implement the law in areas where it has rulemaking authority?

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What Does It Do?

- Rebates to Medicare for increasing drug costs faster than rate of inflation
  - Reduces Part B co-insurance for affected drugs
- Limits Medicare D out-of-pocket cost for insulin to $35/month; deductibles don’t apply
- Makes ACIP-recommended adult vaccines available to Part D
- Makes ACIP-recommended adult vaccines available to Medicaid and CHIP at no cost (Oct. 1, 2023)

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What Will It Do?

- Identify Part B and D drugs for price negotiation, with "maximum fair prices" beginning to take effect in 2026
  - 10 Part D drugs identified by Sept. 2023, priced by Sept. 2024, and available at the price in 2026
  - 15 Part D drugs identified by Feb. 2025, priced by Nov. 2025, available in 2027.
  - 15 Part B and D drugs identified by Feb. 2026, priced by Nov. 2026, available in 2028
  - 20 Part B and D drugs identified by Feb. 2027, priced by Nov. 2027, available in 2029 (repeat for 2030 and 2031).
- Eliminates coinsurance and co-payments in Part D catastrophic coverage; limits year-over-year premium increases to 6% (Jan. 1, 2024)
- Changes government contribution and manufacturer "discount" in catastrophic phase (2025)

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Key Events – Price Negotiation

- **Initial Drug List**
  - The first 10 Part D drugs subject to price negotiation will be identified before September 1
  - Generally the drugs selected will be the highest-spend drugs that are not excluded from negotiation (biosimilar competition, etc.)
  - Very likely to include:
    - Eliquis
    - Imbruvica
    - Ozempic
    - Trulicity
    - Jardiance

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Pricing Cycle

Takeaway: Approximately 14 months' notice of 10-20 drugs subject to price reductions

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Key Events – Price Negotiation

Maximum Fair Price

- The first 10 Part D drugs will have a "maximum fair price" in 2026; 15 in 2027, 20 Part B/D in 2028-2031
- "Maximum fair price" affects pharmacies directly – discussed later

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Key Events – Inflation Penalties

- **Historically**
  - Manufacturers have had to pay greater Medic**aid** rebates for drugs that increased in price faster than the rate of inflation (CPI-U)
    - Sometimes a cost of doing business if penalties are offset by increased sales for other "purchasers"
- **Now**
  - Beginning in 2023 (and looking at 2022 prices compared to 2021 prices), manufacturers are exposed to potentially pay rebates to Medicare Part B and D as well

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Poll Question

When will negotiated drug prices first take effect for Medicare Part D plans?

A. 2024
B. 2025
C. 2026
D. 2027

(assuming no changes to the law or delays)

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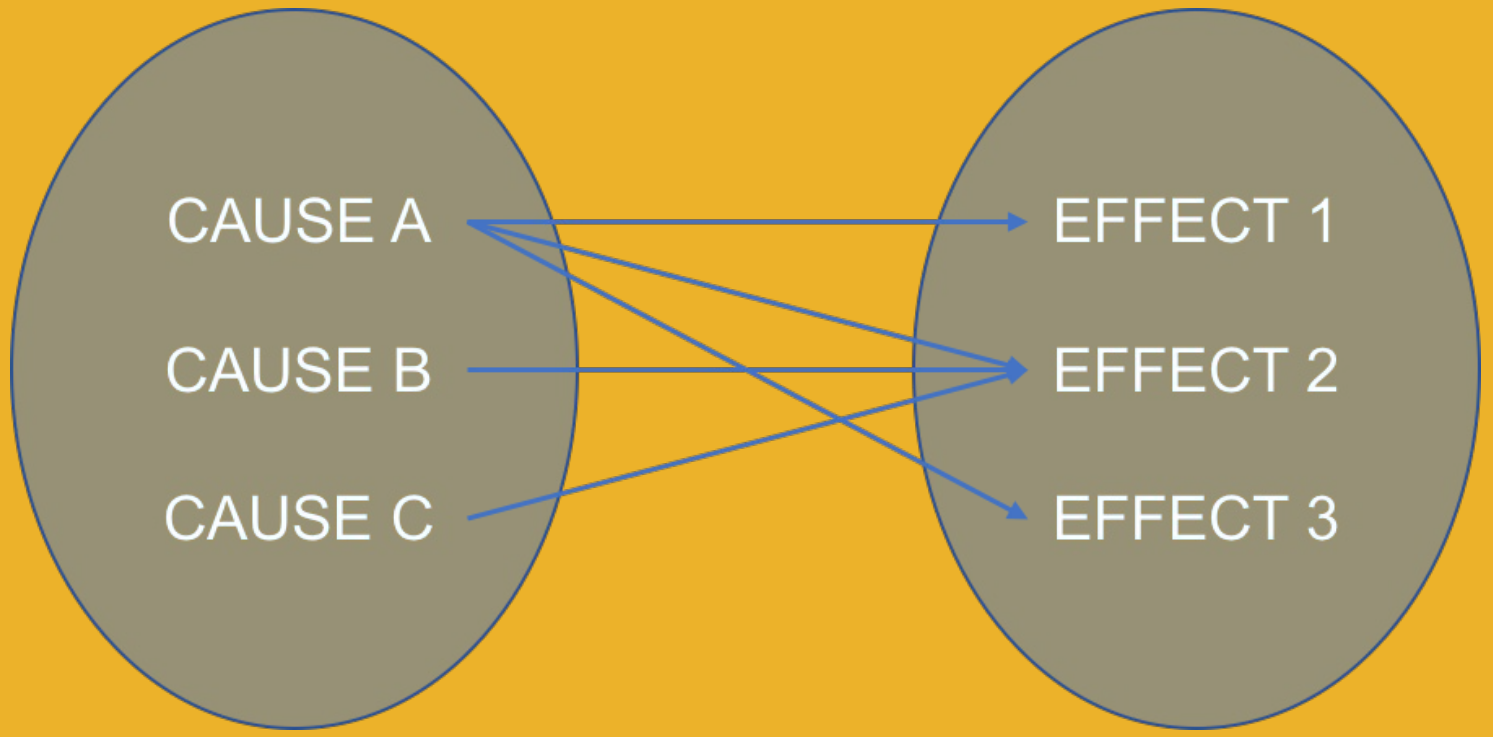
Manufacturer and PBM Incentives under the IRA

… and How They Might Affect Contracting with Payers



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Payer Incentives

- Most coverage of the IRA focuses on beneficiary out-of-pocket costs, but major changes to the Part D design, and how costs are distributed
- **Currently and in 2024**
  - Deductible: Patient pays 100% of deductible, then…
  - Coverage Phase: Patient pays 25% and a) plan pays 75% for generics or b) pays 5% for brands and mfr provides 70% discount on brands, then…
  - Donut Hole: Patient pays 25%, manufacturer pays 70%, and plan pays 5%, then
  - Catastrophic: Patient pays 5%, plan pays 15%, government pays 80% (pt 0%/plan 20% in 2024)

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Payer Incentives

- **<u>Beginning in 2025:</u>**
  - Deductible: Patient pays 100%
  - Coverage Phase: Patient pays 25%, manufacturer pays 10%, plan pays 65%
  - Catastrophic: Manufacturer pays 20%, government pays 20% (brands) or 40% (generics), plan pays 60% (brands) or 40% (generics)
  - (Patient OOP capped at $2,000 in 2025, indexed to cost)

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What Does It Mean for Payers?

- Payers have **huge exposure to catastrophic coverage** – 60% for brands and 40% for generics, up from 15%
- Patients **get to catastrophic coverage faster - $2,000** out of pocket cap

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Manufacturer Incentives

- Where do manufacturers feel pain under the IRA?
  - For the 10-20 “negotiated” price drugs, direct revenue loss. The Congressional Budget Office (CBO) projected $102B in Medicare savings over 10 years
  - For drugs that increase in price faster than the rate of inflation, direct revenue loss in the form of rebates. The CBO projects $62B in Medicare savings over 10 years.
  - That average annual $16.4B comes out of drug manufacturers with blockbuster branded drugs or branded drugs with less competition to keep prices in check

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How Will MFP Negotiations Occur?

- Drug manufacturers are rightfully concerned about Medicare Fair Price (MFP) negotiations
  - Manufacturer has very little leverage
  - Initial guidance issued March 15, 2023
  - CMS proposes to determine initial MFP based on information submitted by the manufacturer, including:

- R&D costs and recoupment
- Production costs
- Federal financial support in development
- Patent applications and other exclusivities
- Market data, including revenue and sales volume data
- Non-FAMP – non-federal average manufacturer price

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How Will MFP Negotiations Occur?

- CMS proposes to calculate an MFP based on 30-day supply, not to exceed a statutory ceiling
- Initial offer to manufacturer, which can counter, followed by up to three negotiation meetings
- Final written offer, followed by accepting or rejecting it
- **Consider**: Would a manufacturer ever reject the final offer if rejecting it means no Medicare Part D coverage?

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Poll Question

Which of the following are factors that CMS must consider in MFP negotiations?

A. Shareholder impact
B. R&D and production costs
C. 340B utilization rates
D. Advertising costs
E. All of the above

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Changes That Will Likely Occur at the Purchasing and Billing Level

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How Might Payers Respond?

- Payers are incentivized to slow progress toward the catastrophic phase and reduce spend once in it
- We might see:
  - More aggressive prior authorization, step therapy, and other utilization management techniques
  - Limitations on branded drug formularies (i.e., cover the minimum two drugs per category; avoid the most popular drugs; avoid new products)
  - Tougher payer/manufacturer negotiations
- **Pharmacies and health centers should expect more hurdles and formulary restrictions from Part D payers, especially for branded drugs**

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How Will Manufacturers React?

- Manufacturers' first line of defense is to stay off the negotiation list
  - Applies to single-source drugs
  - All dosage forms and strengths of the same active moiety/biologic, including repackaged, relabeled, and authorized generics are treated as one
  - Exclusions for some orphan drugs, low-spend Medicare drugs, plasma-derived products, small bio-tech, likelihood of biosimilar market entry

How Will Manufacturers React?

- Once on the list, very little defense
- “Negotiation” process has been described as strong-arm. CMS controls the initial offer and manufacturer has almost no leverage to reject final offer.
- Merck and Chamber of Commerce have filed suit to try to stop the negotiation process (arguing “taking” of private property without just compensation)

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What Does MFP Mean for Pharmacies and Health Centers?

- There are many decisions yet to be made.
- What we know:
  - Part C with drug/Part D enrollees will not pay more than the negotiated price for MFP drugs
  - Manufacturers must extend the MFP to pharmacies and dispensers

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Unanswered Questions

- How do pharmacies get the MFP price for drugs it dispenses to eligible Medicare patients?
  - CMS suggested a chargeback system using the wholesaler in the March 15, 2023 bulletin
    - Per-package basis? Per unit?
    - 340B replenishment model?
- How will wholesalers integrate into chargeback process?
- How will wholesalers and pharmacies be compensated for having to carry out substantial additional work for no additional reimbursement?
  - Pharmacies in particular will make almost no margin on MFP drugs

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Unanswered Questions

- How will failure to provide MFP access be penalized?
  - Manufacturers can be subjected to large penalties
  - Statute does not really address dispenser failures
- How will 340B drugs be managed?
  - Drug could be 340B, non-340B MFP, or non-340B non-MFP; could MFP be below 340B price?

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Inflation Rebates

- Manufacturer reactions to the inflationary penalties would seem more predictable
- Penalties are similar in Part B, Part D, and Medicaid (which combined are a massive payer)
- Can a manufacturer offset the penalty by increased revenue from sales to other purchasers?
  - If not, the penalty works and manufacturers will slow the increase of prices
  - If so, manufacturers might find “sweet spots” where the increased revenue from a price hike offsets the rebate exposure

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Inflation Rebate Impacts

- FQHCs and other 340B covered entities **benefit** when manufacturers increase drug costs faster than rate of inflation
  - Due to way 340B ceiling price is calculated, Medicaid inflation penalties can lower the 340B unit price of a drug to $0.01.
- If manufacturers are careful to avoid Medi**care** inflation rebates, they likely will avoid Medi**caid** inflation rebates as well
- Covered entities could see a sharp decline in “penny-priced” or otherwise sharply reduced price drugs (which decreases margin, which decreases 340B benefit)

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Poll Question

How might payers react to increased responsibility for costs during catastrophic coverage?

A. Limiting formularies
B. Increased focus on utilization management
C. Raising premiums 10% per year
D. A and B

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