The Inflation Reduction Act One Year Later
Where Are We Now? What Other Challenges are on the Horizon?
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Today’s Discussion

I. Inflation Reduction Act (IRA)
   - Latest on Medicare “Negotiation”
   - Upcoming Redesign of Medicare Part D
   - Impacts of IRA
   - Litigation

II. Broader Environment
   - Proposed Changes to Medicaid Drug Rebate Program
   - Emergence of State Prescription Drug “Affordability” Boards
   - Other Challenges
Questions Today That Aren’t Answered?

Please reach out to Crystal Kuntz

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Inflation Reduction Act (IRA)
- Latest on Medicare “Negotiation”
- Upcoming Redesign of Medicare Part D
- IRA Impacts
Recap: Drugs Subject to Medicare Negotiation

**Qualifying Single Source Drugs**
- Certain drugs/biologics approved/licensed by FDA:
  - Drugs at least 7 years post-approval by the selection date
  - Biologics at least 11 years post-licensure by the selection date
  - With no generic/biosimilar on the market (an “authorized generic drug” does not count)

**Negotiation-Eligible Drugs**
- The 50 qualifying single source drugs with highest total expenditures under Part D and the 50 qualifying single source drugs with highest total expenditures under Part B during a specified 12-month lookback period.

**Selected Drugs**
- A specified number of the highest ranked negotiation-eligible drugs, published by February 1 of the selection year, which is two years before the initial price applicability year:
  - The selection of drugs for negotiation is cumulative: The Secretary must select 10 drugs for 2026, another 15 for 2027, another 15 for 2028, and another 20 for 2029 and each year thereafter
  - Only Part D drugs may be selected for 2026 and 2027

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Key Dates – IRA Implementation

“Negotiation” Timeline for 2026

- **Sep 1, 2023**: Secretary publishes list of drugs selected for negotiation
- **Oct 1 & 2 2023**: Manufacturer enters into “agreement,” submits data
- **Feb 1, 2024**: CMS makes initial offer with “concise justification”
- **July 1, 2024**: CMS final offer to manufacturer
- **Sep 1, 2024**: CMS publishes maximum fair prices (MFPs)
- **Mar 1, 2025**: Explanation of MFPs published
- **Jan 1, 2026**: MFPs take effect

**Fall 2023 – One Meeting with Manufacturer; Patient Focused Listening Sessions**

**If counteroffer rejected, up to 3 additional meetings with manufacturer between 4/1-6/28**

The timeline for initial price applicability years after 2026: selected drugs published Feb 1; enter into agreement Feb 28; manufacturer submission Mar 1; initial offer June 1; negotiation ends Nov 1; MFP published Nov 30th.
Medicare “Negotiation” – Key Issues

✓ Drug selection process outlined by the Centers for Medicare & Medicaid Services (CMS) largely finalized without public input
  - CMS combining drugs with same active moiety/active ingredient for selection purposes (should instead be at NDA/BLA level)
  - Limited exception for orphan drugs

✓ CMS’s troubling “bona fide” marketing standard for generics and biosimilars

✓ Uncertainty and lack of transparency in how CMS will review/assess evidence in setting the maximum fair price (MFP)

✓ Uncertainty in “operationalization” of the MFP and preventing duplicate discounts

✓ Lack of clarity in how CMS will protect patient access to needed medicines in Medicare Part D
Medicare Part D – Key Changes

• **Beneficiary 5% cost sharing in catastrophic phase eliminated starting in 2024**, after beneficiaries reach the OOP threshold

• **Beneficiary OOP threshold lowered to $2,000 starting in 2025**, increased annually by an inflation factor. Beneficiaries will be able to spread these costs throughout the year through the Medicare Prescription Payment Plan or (MPPP)
  o OOP cap/payment plan (“smoothing”) longstanding BIO priority
## Overview Medicare Part D Benefit Restructure

<table>
<thead>
<tr>
<th>Current Structure (2022)</th>
<th>New Structure (2025)</th>
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<tbody>
<tr>
<td><strong>Deductible</strong></td>
<td><strong>Deductible</strong></td>
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<tr>
<td>100% beneficiary</td>
<td>100% beneficiary</td>
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<tr>
<td><strong>Initial Coverage Phase</strong></td>
<td><strong>Initial Coverage Phase</strong></td>
</tr>
<tr>
<td>25% beneficiary</td>
<td>25% beneficiary</td>
</tr>
<tr>
<td>75% plan</td>
<td>65% plan</td>
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<tr>
<td><strong>Coverage Gap</strong></td>
<td><strong>Coverage Gap</strong></td>
</tr>
<tr>
<td>25% beneficiary</td>
<td>ELIMINATED</td>
</tr>
<tr>
<td>5% plan</td>
<td></td>
</tr>
<tr>
<td>70% drug company</td>
<td></td>
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<tr>
<td><strong>Catastrophic Phase</strong></td>
<td><strong>Catastrophic Phase</strong></td>
</tr>
<tr>
<td>5% beneficiary</td>
<td>0% beneficiary</td>
</tr>
<tr>
<td>80% govt</td>
<td>20% government (or 40% where drug not subject to discount program)</td>
</tr>
<tr>
<td>15% plan</td>
<td>60% plan</td>
</tr>
<tr>
<td></td>
<td>20% drug company*</td>
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</tbody>
</table>

*Generic drugs and drugs subject to Medicare negotiation are exempt from 10%/20% obligation*
Part D Redesign—Key Issues

✓ Increased plan liability to 60% in catastrophic will result in increased use of Utilization Management - how will CMS respond and oversee?

✓ CMS has said it will intensify formulary review but there is uncertainty and lack of transparency in how CMS will actually do this.

✓ Will Medicare beneficiaries understand the new “MPPP” and take advantage of it?
Broader Environment
- Proposed Changes to Medicaid Drug Rebate Program
- Emergence of State Prescription Drug “Affordability” Boards
- Other Challenges
Challenges Extend beyond IRA

- Threats to Innovation continue to expand beyond longstanding challenges such as 340B, PBM tactics
- Coverage Limits on Accelerated Approval Drugs
- CMS Proposed Changes to Medicaid Drug Rebate Program
- State Drug Affordability Boards
Medicaid “Misclassification” Rule and BIO Strategy

Under the guise of “technical changes” CMS has proposed to upend more than 30 years of historical and legal precedent under the Medicaid Drug Rebate Program (MDRP). Specifically, CMS proposes to:

- **Materially Change the Definition of Best Price** to require aggregation (“stacking”) of discounts paid to all entities throughout the supply chain rather than the discount paid to any single entity; proposed policy would also impact the ceiling price for 340B.

- **Expand Covered Outpatient Drugs (CODs) to include bundled drugs** (if itemized), such as those delivered in the inpatient hospital setting, thereby expanding the universe of drugs subject to Medicaid rebates and also potentially expanding drugs subject to 340B discounts.

- **Subject “therapeutic vaccines” to rebates** under the MDRP (preventive vaccines would still be exempt from rebates).

- **Impose vast new reporting obligations** ("verification survey") aimed at collecting a wide range of new information that mirror the information that CMS is collecting for the new “negotiation” program in Medicare – with a specific focus on cell and gene therapies.
“Stacking” Impact

Figure 1. Illustration of Best Price Determination for a $100 Drug

Today, manufacturers report the lowest price available to a single purchaser, usually a PBM or health plan.

As proposed, manufacturers would “stack” all discounts to determine best price.

Source: Avalere July 26, 2023, “CMS Best Price Discount Stacking Proposal May Trigger AMP Cap”
Drug Pricing Legislation and the States: 25 states have passed 40 bills addressing drug pricing in 2023, ranging from launching studies, to increased transparency on pricing, to funding and empowering price review boards.
Prescription Drug Affordability Boards (PDABs)

- State created boards to address prescription drug costs by establishing an “upper payment limit” (notably, these boards do not address patient out-of-pocket costs)
- Charged with identifying high-cost therapies relative to the value – targeting some of the most innovative therapies and patients with limited treatment options
- May rely on 3rd party health-value assessment entities like ICER to determine the value of therapies – ICER advances troubling, discriminatory tools such as use of “QALYs”
- Colorado is furthest along in implementation
QUESTIONS?