COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

Inflation Reduction Act and Prescription Drug Reforms

What does it mean and what will happen next?

Your Presenters

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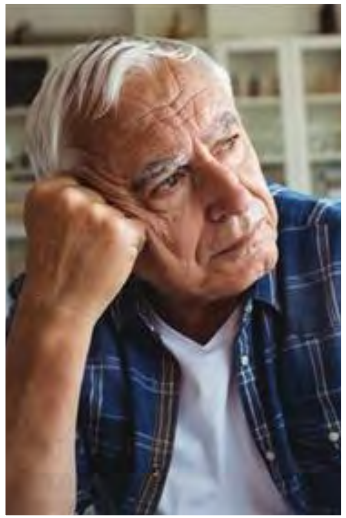
A Bit of History

- **Medicare Part D was enacted in 2003**
  - Plans negotiate drug price concessions with manufacturers and reimbursement with pharmacies
  - HHS was prohibited from interfering in these negotiations
- **Part D is a well-liked, successful program**
  - Stable, low premiums
  - Robust plan choices
  - Wide access to therapies
  - Less costly to taxpayers than expected
- **The IRA takes a different approach where market forces are significantly eroded**
  - The “negotiation” process is heavily weighted to government
  - Large penalties apply to manufacturers who refuse the maximum fair price
  - Option to avoid MFP by opting out of the Medicare program, harming markets and access
- **The IRA will lead to higher Part D premiums, fewer products, more utilization controls, less access to community-based providers**

Overview – Inflation Reduction Act Health Provisions



Medicare

- Imposes price caps on Part B and D drugs
- Reforms Part D benefit and caps out of pocket costs
- Imposes rebates on price increases greater than inflation
- Limits beneficiary out-of-pocket costs for insulin
- New add-on payment for biosimilars in Part B
- Eliminates cost sharing on some vaccines in Medicare

Rebates

- Nullifies Trump-era rule requiring plans to pass rebates on to patients at the pharmacy counter until 2032

ACA

- Extends ACA subsidies for higher income, while making more generous subsidies for lower income

Timeline for Prescription Drugs Provisions in Inflation Reduction Act

2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029

Limits Part D Premium Growth to 6 Percent Annually (2024-29)

Prohibits Implementation of Trump Rebate Rule Prior to January 1, 2032

Drug Pricing Negotiation/Caps Imposed

- •10 Medicare Part D drugs
- •15 Medicare Part D drugs
- •15 Medicare Part B and Part D drugs
- •20 Medicare Part B and Part D drugs

Drugs included in price caps are cumulative - by 2029 there will be 60 drugs subject to controls.

Medicare will pay ASP+8 percent for certain biosimilars

Requires drug companies to pay rebates if Medicare drug prices rise faster than inflation

Eliminates beneficiary cost-sharing for Part D catastrophic coverage

Adds $2,000 OOP cap in Part D

Shifts risks between plans and taxpayers

Eliminates cost sharing for vaccines covered under Part D and caps insulin costs to $35/month

Expands income eligibility to 150% FPL for full Low-Income Subsidies

Allows beneficiaries to "smooth" cost-sharing throughout the year

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Drug Price Negotiation – Drug Selection Process

First Step: Establish List of Qualifying Drugs

- Identify all drugs with Medicare sales in excess of $200 million/year in the reference period plus all insulins
  - Small Molecule w/o Generic Competition: FDA approved more than 7 years ago
  - Biologics w/o Biosimilar Competition: FDA licensed more than 11 years ago
- Exclude drugs and biologics that are exempt (see list)*

Second Step: Establish List of Negotiation Eligible Drugs

- Exclude drugs previously selected and "Small biotech drugs" for 2026, 2027, and 2028 and
  - order rank from highest to lowest spend the 50 Qualifying Part D drugs.
  - order rank from highest to lowest spend the 50 Qualifying Part B drugs
- Combine lists and re-rank from highest to lowest spend
- Select drugs starting at highest spend drug up to the maximum number of drugs for the year (i.e. 20 for 2029), or all drugs if not a sufficient listed number for the year.
- If the Secretary determines that the selected drug has a generic or biosimilar that is marketed, then the selected drug will exit the selected-drug status beginning with the year that begins at least nine months after the determination.

*The law excludes the following products from price negotiation:

(1) Orphan drugs (designated as a drug for only one rare disease or condition and for which the only approved indication is for that disease or condition);

(2) "low spend Medicare drugs" <$200 million;

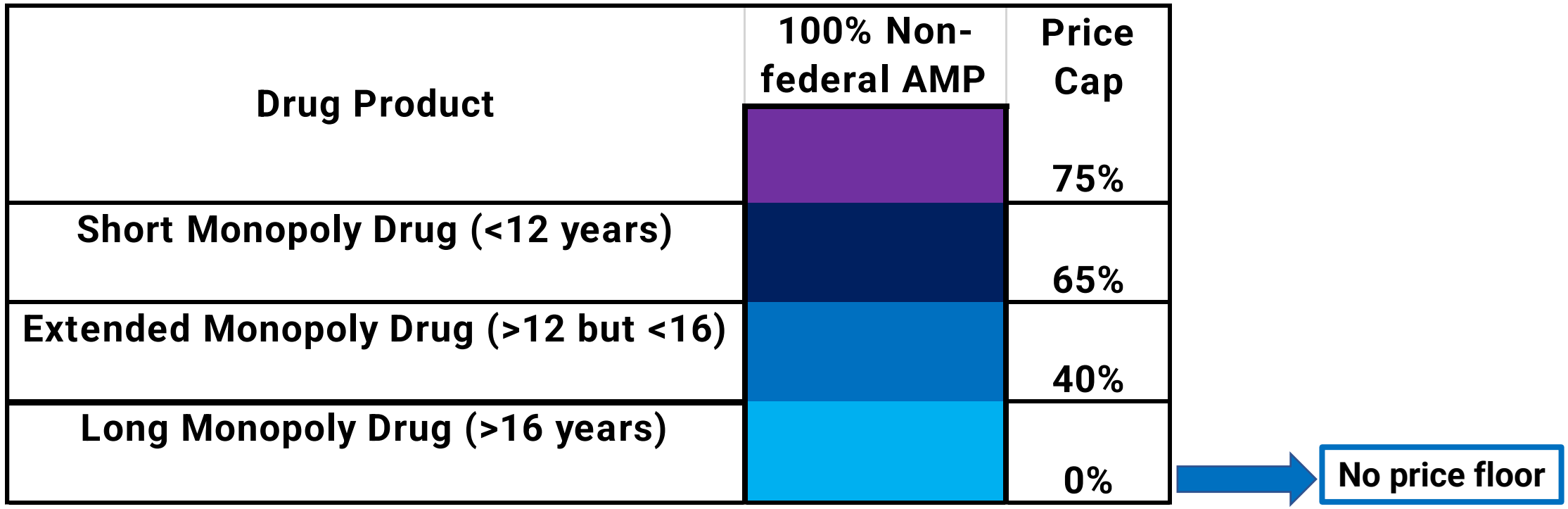
(3) plasma-derived products;

(4) biologicals where a biosimilar market entry "imminent"; and

(5) for 2026 through 2028, "**small biotech drugs**," which refer to drugs with total 2021 Part B or Part D expenditures that constitute (1) no more than 1% of the total 2021 expenditures for drugs of all manufacturers and (2) at least 80% of total 2021 expenditures for all drugs of the manufacturer, with some exceptions.

Maximum Price Cap Guides Price Setting

- The law imposes specific price controls that must be applied for drugs based on length of time on market
- While there is a price ceiling, there is no minimum price required
- The only way to come off the price control list is if there is a generic competitor
- Law ignores therapeutic competition when defining “monopoly”
- CBO estimates $98.5 billion in Medicare savings over 10 years (2022-2031)



Percentage is against the historic Spending based on the Part D enrollment-weighted negotiated price net of price concessions or the Part B average sales price for the year prior to the publication date, OR the Applicable Percentage of 2021 non-federal average manufacturer price increased by inflation

Drug Price Negotiation – Process and Compliance

Process

- Within the maximum price cap, the law provides significant discretion to conduct negotiations with biopharmaceutical manufacturers. HHS is required to ***consider*** certain factors in negotiation, including:
  - R&D and production costs
  - Federal support for drug discovery, such as through the NIH
  - Patent term and revenue
  - Whether the drug constitutes a therapeutic advance
  - Impact on patient populations or those with unmet medical needs
- Beginning in 2028, HHS is required to re-negotiate prices for any products that transition into a new category (extended to long monopoly drugs, for example), or if there is a new indication or other factors that may change MFP

Compliance

- **Excise Tax:** A manufacturer that is not in compliance with the negotiation process (for a variety of reasons, including failure to provide access to MFP pricing) is assessed an escalating noncompliance fee beginning at 65 percent of the sales of the drug, increasing to 95 percent once the manufacturer is out of compliance for more than 270 days
- **Market Exit:** Alternatively, the manufacturer may choose to withdraw their products from Medicare and Medicaid, instead of engaging in negotiations
- **Civil monetary penalties:** Penalties apply for not offering negotiated price of up to 10x difference between price charged and negotiated price, $1 million per day to fail to negotiate or provide information, and $100 million CMP for each item of false information with respect to the small biotech exemption

Part B and D Highest Spend Drugs

- In 2020, the top 10 drugs accounted for 40% ($15.6 billion) of Part B drug spending and 21% ($42.5 billion) of Part D spending before rebates

- Drugs with competition are excluded from MFP
- The average length of time before entry of generic or biosimilar competition has historically exceeded 14 years

Drug (Brand Name)	2020 Medicare Gross Spending ($, millions)	Years Since Approval	Estimated Year Eligible for MFP
Part D			
Apixaban (Eliquis)	$9,936	10	2026
Lenalidomide (Revlimid)	5,356	17	N/A[1]
Rivaroxaban (Xarelto)	4,701	11	2026
Adalimumab (Humira)[2]	4,167	20	2026
Sitagliptin (Januvia)	3,565	16	2026
Insulin Glargine (Lantus)	3,719	22	N/A[1]
Dulugluide (Trulicity)	3,285	8	2026
Ibrutinib (Imbruvica)	2,963	9	2026
Empagliflozin (Jardiance)	2,376	8	2026
Palbociclib (Ibrance)	2,109	8	2026
Part B			
Pembrolizumab (Keytruda)	$3,558	8	2028
Afilbercept (Eylea)	3,039	11	2028
Denosumab (Prolia)	1,996	12	2028
Nivolumab (Opdivo)	1,624	8	2028
Abatacept (Orencia)	1,435	17	2028
Rituximab (Rituxan)	1,351	25	N/A[1]
Ranibizumab (Lucentis)	1,116	16	N/A[1]
Pegfilgrastim (Neulasta)	941	20	N/A[1]
Daratumumab (Darzalex)	858	7	2029
Bevacizumab (Avastin)	700	18	N/A[1]

[1]Drug already has a marketed generic or biosimilar competitor
[2]Expected biosimilar competition before 2026

Source: JAMA, Medicare Drug Dashboard, Amerisource Bergen Biosimilar Pipeline Report, FDA

Timeline for Drug Price Negotiation Process

For 2026	Negotiation Action	For 2027 and subsequent years
Sept. 1, 2023	HHS must publish list of selected drugs subject to negotiation	February 1, 2025
October 1, 2023	HHS and manufacturer enter an agreement on negotiation process	February 28, 2025
October 2, 2023	Manufacturer submits information to HHS necessary for the negotiation, including pricing	March 1, 2025
February 1, 2024	HHS sends maximum fair price offer to manufacturers	June 1, 2025
March 2, 2024	Manufacturer accepts or counteroffers	July 1, 2025
August 1, 2024	Parties must conclude negotiations	November 1, 2025
September 1, 2024	HHS publishes maximum fair price	November 30, 2025
March 1, 2025	HHS publishes explanation of maximum fair price for each drug	March 1, 2026
January 1, 2026	Maximum fair price for drug in effect	January 1, 2027

Inflation Rebates

- Requires manufacturers to pay a rebate on all non-Medicaid sales for drugs covered by Medicare Parts B and D whose ASP or AMP (respectively) in a given year is greater than its ASP or AMP in 2021, adjusted for inflation as measured by the CPI-U

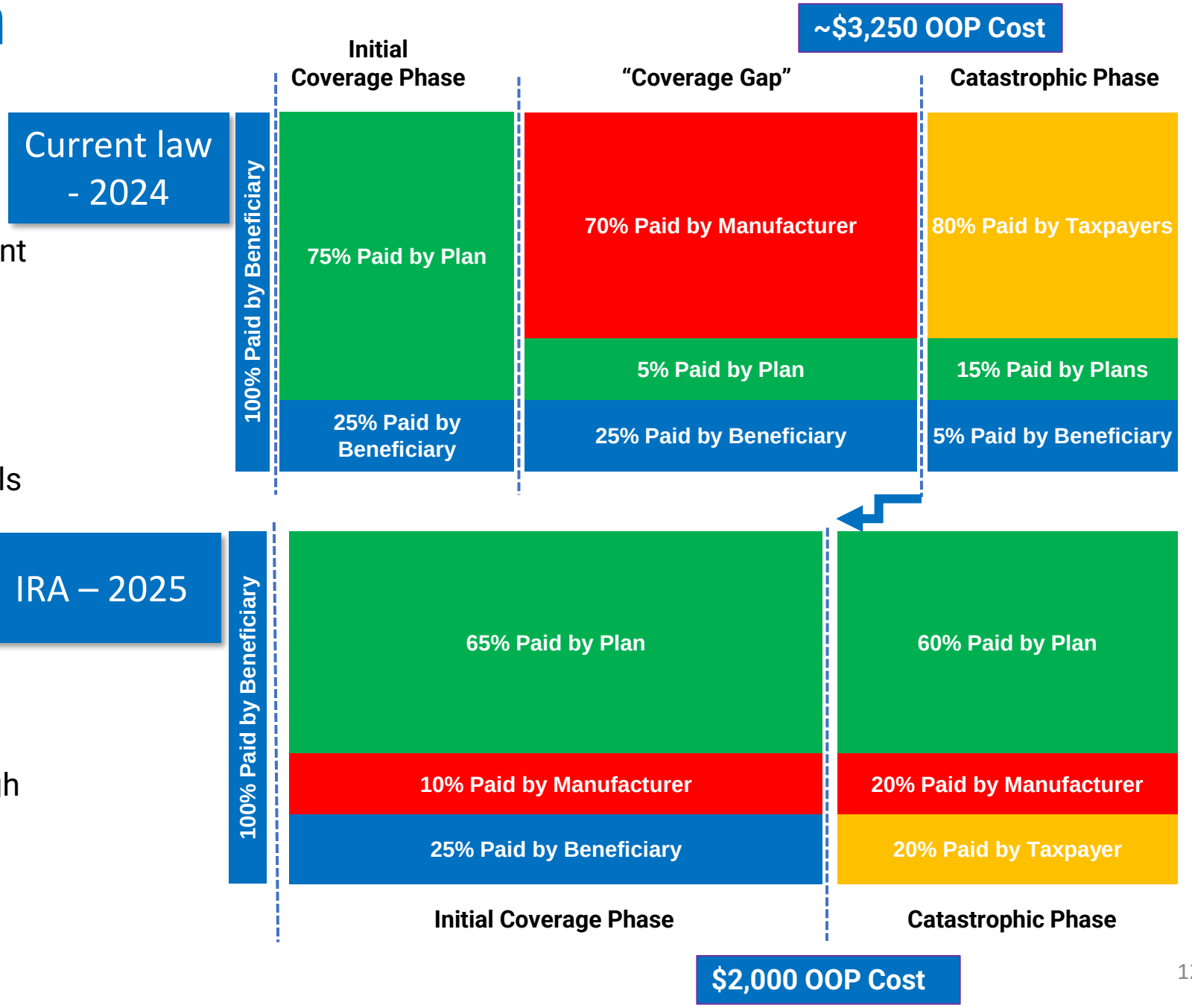
- Starts in October 2022 for Part B drugs and April 2023 for Part D Drugs. Rebate is 125% of amount owed

- CBO estimates this provision would generate $63.2 billion over 10 years

Category	Part B	Part D
Drugs	Single source drugs and biologics excluding vaccines and those less than $100 per year	All part D drugs, including line extensions
Cost Basis	106% of ASP for the quarter six months before the current quarter	Weighted average AMP by units for each quarter
Benchmark Year	Q3 2021 or 3rd full quarter post launch	2021 AMP or first calendar year post launch
Inflation Adjustment	September 2021 CPI-U, or first quarter post-launch	September 2021 CPI-U or January post launch to January current year
When does the this apply?	Q3 2023 or six full quarters post-launch	2023 or first full calendar year post launch

Part D Redesign

- Reduce OOP Cost to $2,000 hard cap
- Creates new manufacturer discount program for innovator drugs (10% initial phase and 20% in catastrophic phase)
- Increases eligibility threshold for low-income subsidies to individuals below 150% FPL
- Shifts liability to plans
- Allows beneficiaries to “smooth” cost-sharing throughout the year
- Caps premiums at 6%/year through new subsidy



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Biosimilars

- Updates the add-on payment for biosimilars from 6% to 8% of the reference product average sales price for 2022 to 2027

Vaccines

- Requires zero coinsurance for vaccines recommended by the Advisory Committee on Immunization Practices under Medicare Part D
- Requires coverage of certain adult vaccinations under Medicaid while also eliminating some cost-sharing
- Increases by 1% the Federal Medical Assistance Percentage (FMAP) for adult vaccines and administration
- Requires the coverage and eliminates cost-sharing of recommended adult vaccines or individuals ages 19 and older under CHIP

Insulin

- In Medicare Part B and D Insulin OOP costs are capped:
  - $35 per month from 2023 through 2025
  - Beginning in 2026, insulin is capped at the lowest of:
    - $35 per month;
    - 25% of the established maximum fair price; or
    - 25% of the negotiated price.
- Deductible does not apply
- Effective Jan. 1, 2023, creates a safe harbor that allows employers with an HSA qualified health plan to cover any insulin dosage of any type before the individual meets the plan's deductible.

Implementation

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Regulatory Implementation

- **Unprecedented implementation of a major program:**
  - Limits on administrative and judicial review
  - Many initial provisions to be implemented by sub-regulatory guidance, eliminating a formal process for input into rulemaking
  - Increased uncertainty as rules can be changed overnight
  - Limited transparency as notice and comment process not required

- **New and significant regulatory and compliance regime for manufacturers, and others in the supply chain, that dwarfs Medicaid Best price data submission**
  - Significant, unclear data submission
  - Unprecedented regulator view into cost and profit structures of the supply chain
  - Messy roll out of data with lots of 'retroactivity' is likely

Provision	Exempt from Administrative or Judicial Review	Implemented by Sub-regulatory Guidance
Drug price negotiation program – 2026 through 2028		✓
Unit determinations	✓	
Drug selection	✓	
MFP determination	✓	
Inflation rebate (determination of units, rebate amount, coinsurance, calculation of Part B payment)	✓	✓
Part D manufacturer discount program		✓

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IRA Implementation

- New, government-run PBM
- $3 billion in new funding
- Hundreds of new bureaucrats
- Duplicating effort of private sector

Proposed
 # FTEs: 95
 # Vacancies: 95

Medicare Drug Rebate and Negotiations Group (Admin Code TBD) 7 FTEs
1 Director, ES-0340-00 1 Deputy Director (Policy), GS-0107-15 1 Deputy Director (Operations), GS-0107-15
1 Pharmacist, GS-0660-15 1 HIS (TA), GS-0107-15 1 Operations Spec, GS-0301-09 1 HIS (SA), GS-0107-14

Division of Contract Support (Admin Code TBD) 12 FTEs	Division of Manufacturer Compliance and Oversight (Admin Code TBD) 13 FTEs	Division of Manufacturer Data (Admin 15
1 Director (Supv. HIS), GS-0107-15 1 Deputy Director (Supv. HIS), GS-0107-14	1 Director (Supv. HIS), GS-0107-15 1 Deputy Director (Supv. HIS), GS-0107-14	1 Director (Supv 1 Deputy Director (S
3 Contracting Officer Rep, GS-1101-12/13 2 HIS (Program Contractor Mgmt), GS-0107-12/13 1 Budget Analyst, GS-0560-12/13 2 Financial Mgmt Analyst, GS-0501-12/13 2 Mgmt & Prog Analyst, GS-0343-12/13	1 HIS (Program Contractor Mgmt), GS-0107-12/13 4 HIS (Program Policy), GS-0107-12/13 4 HIS (Program Oversight), GS-0107-12/13 2 Mgmt & Prog Analyst, GS-0343-12/13	1 HIS (TA), 2 HIS (Program Contract 4 HIS (Program Po 2 Mgmt & Prog An 3 IT Spec (Data Mg 1 Pharmacist,

* FTEs displayed are vacant

KEY:
New Group/Division

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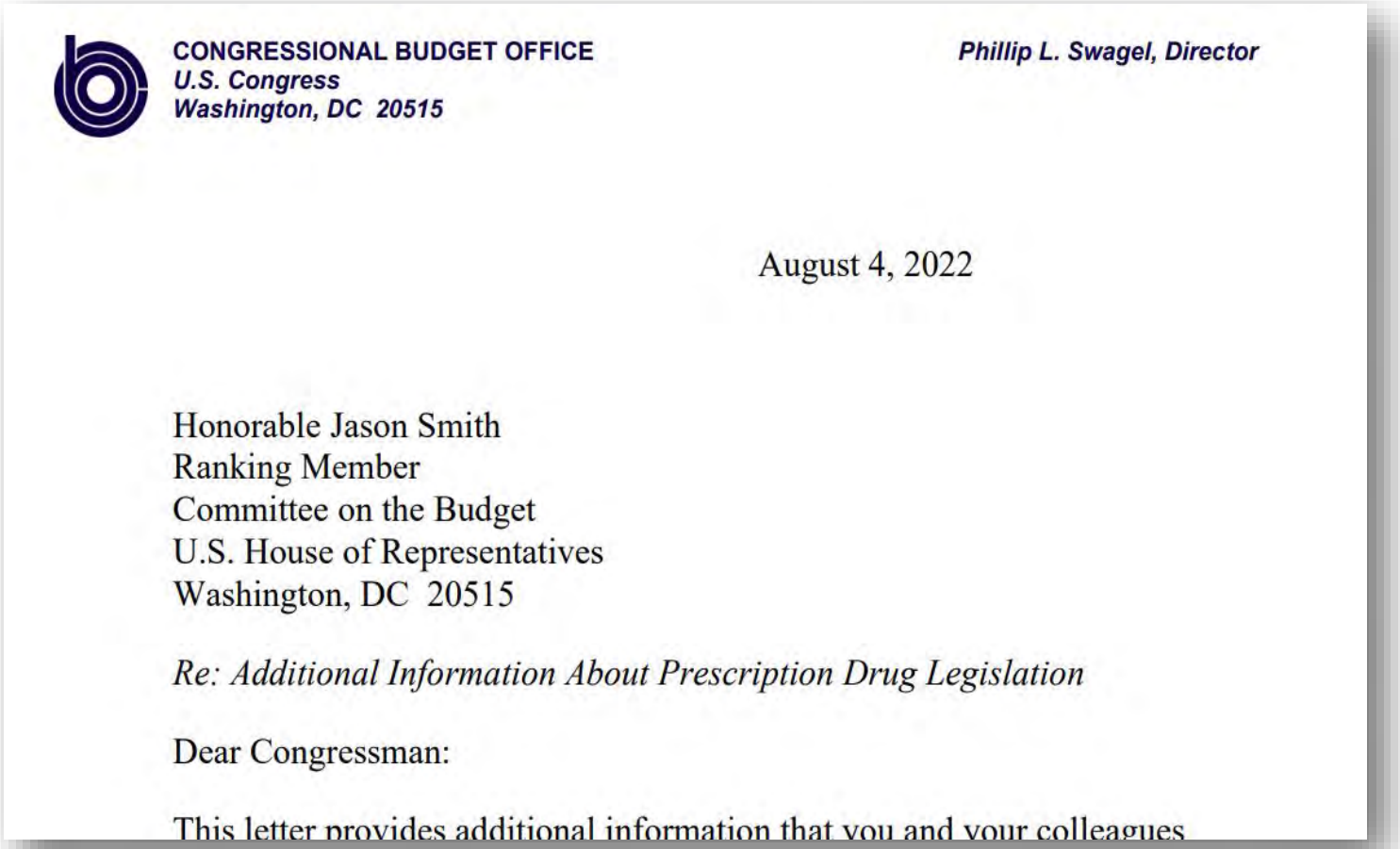
Impact

Implications: Higher Launch Prices



CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Phillip L. Swagel, Director

August 4, 2022

Honorable Jason Smith
Ranking Member
Committee on the Budget
U.S. House of Representatives
Washington, DC 20515

Re: Additional Information About Prescription Drug Legislation

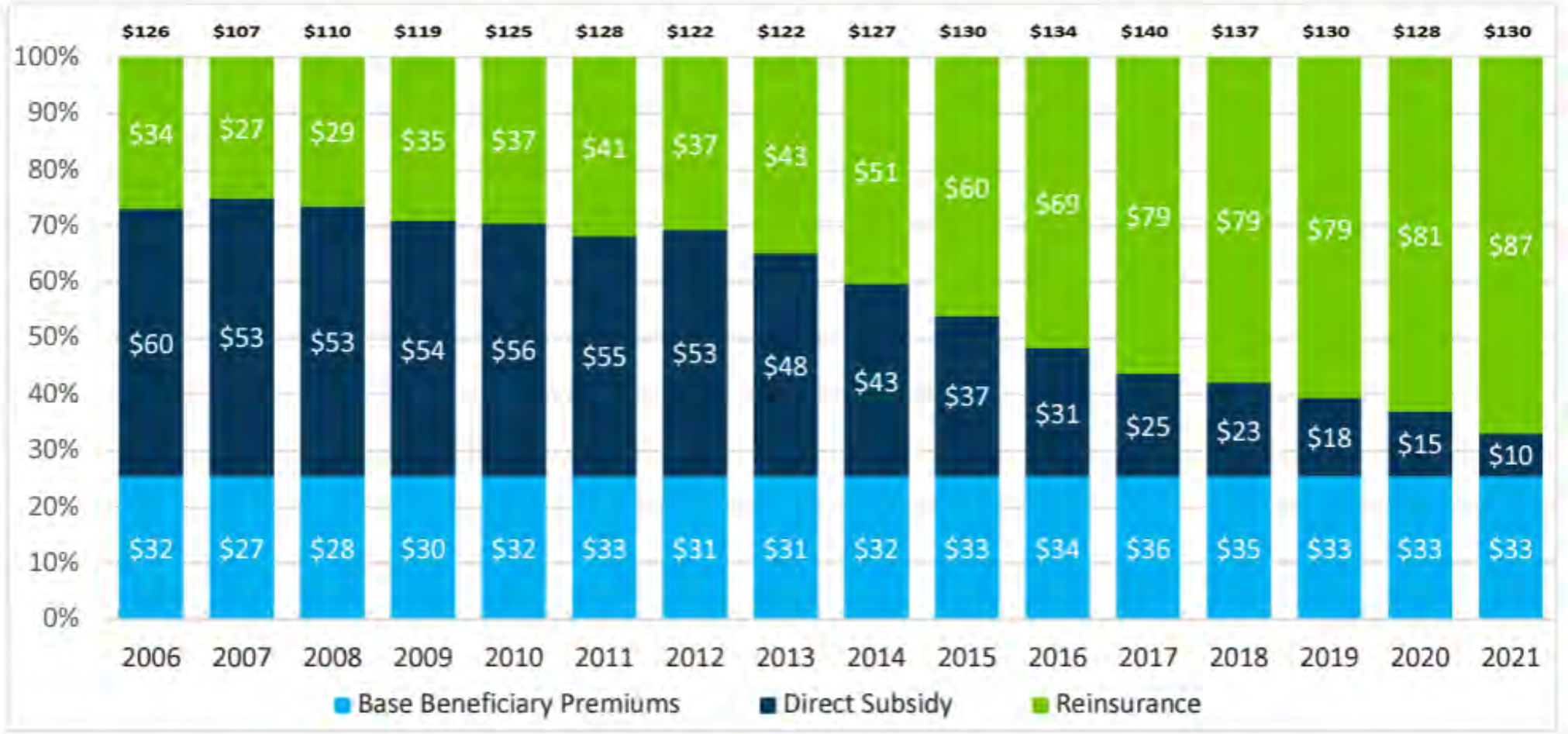
Dear Congressman:

This letter provides additional information that you and your colleagues

"The Congressional Budget Office projects that the inflation-rebate and negotiation provisions would increase the launch prices for drugs that are not yet on the market relative to what such prices would be otherwise …manufacturers would have an incentive to launch new drugs at a higher price to offset slower growth in prices over time."

Implications: Higher Premiums

Trends in Part D Bids and Payments, Per Member Per Month Costs, 2006–2021



Source: Analysis of CMS annual release of the Part D National Average Bid Amount and other Part C & D bid information, 2006–2021. Avalere, 2021

Implications: Fewer Treatments, Less Access

Less Innovation: $663 billion reduction in R&D through 2039

Fewer Treatments:
- 135 fewer new drugs will be developed

Sicker patients, more death: Loss of more than 331 million life years over the next two decades

Changed Incentives:
- Fewer small molecule (oral meds) versus biologics (9 versus 13 years)
- Less follow on indications (cancer), fewer products to treat rare conditions

Worse Access:
- Fewer community-based doctors, clinics due to Part B cuts
- More expensive treatments in more expensive settings

From Academic to Real World

CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

August 6, 2

Honorable Chuck Schumer
Majority Leader
United States Senate
Washington, DC 20510

Re: Information About H.R. 5376, the Inflation Reduction Act of 2022

Dear Mr. Leader:

This letter provides information about the budgetary effects 6,
the Inflation Reduction Act of 2022, as amended in the natu

IRA Effect: Alnylam Acting 'Rationally' In Halting Second Orphan Indication For Amvuttra – Analysts

07 Nov 2022 | **ANALYSIS**

"…the most damaging thing about [the Inflation Reduction Act] is that it sends a signal to investors and capital allocators …that small molecules...are worth a lot less"

— Eli Lilly's CEO, David Ricks

Next Steps

1. **Promote Implementation Transparency and Accountability** – program should be implemented through the regular rule-making process

2. **Promote Competition** – products with therapeutic competition are not monopolies and should not be subject to price controls

3. **Expand Innovation** – secondary indications should not subject products to price controls

4. **Fix Small Molecule Penalty** – equalize length of time on market before price controls are effective