

What Are the Prescription Drug Provisions in the Inflation Reduction Act?

Juliette Cubanski, Meredith Freed, and Tricia Neuman

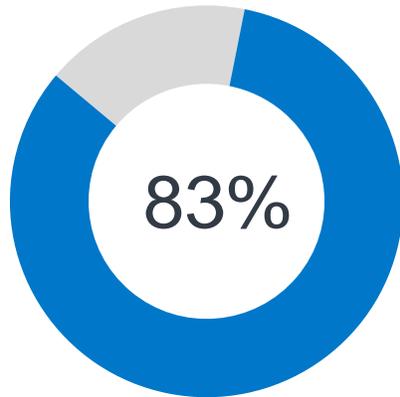
August 2022



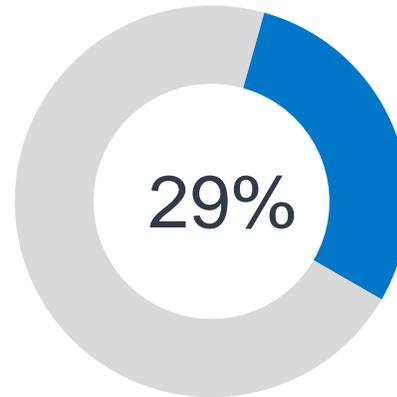
Filling the need for trusted information on national health issues.

Americans Are Concerned About the Cost of Prescription Drugs

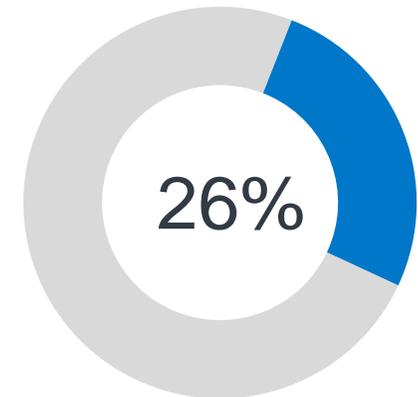
83% of adults think the cost of prescription drugs is **unreasonable**



29% say in the last year, they have **not taken prescription medicines** as directed **because of costs**



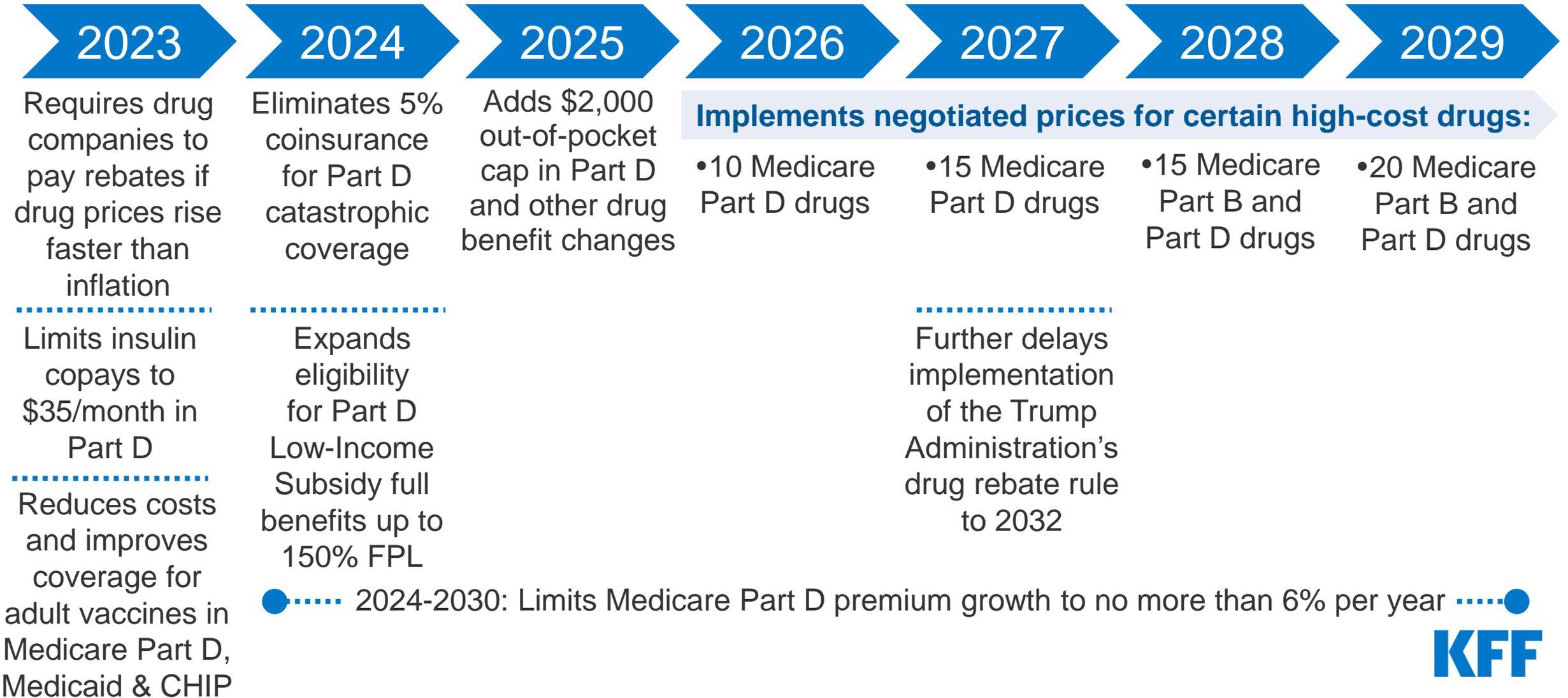
26% of adults say it is very **difficult for them to afford** to pay for their prescription drugs



Prescription Drug Provisions in the Inflation Reduction Act*

- For the first time, **requires the federal government to negotiate prices** for some top-selling drugs covered under Medicare
- Requires drug companies to pay **rebates if prices rise faster than inflation** for drugs used by Medicare beneficiaries
- **Eliminates 5% coinsurance** for catastrophic coverage in Medicare Part D in 2024, adds a **\$2,000 cap on Part D out-of-pocket spending** in 2025, and limits annual increases in Part D premiums for 2024-2030
- Limits monthly cost sharing for **insulin products to \$35** for people with Medicare
- **Expands eligibility** for **Medicare Part D Low-Income Subsidy** full benefits
- **Eliminates cost sharing for adult vaccines** covered under Medicare Part D and improves access to adult vaccines under Medicaid and CHIP
- Further **delays implementation** of the Trump Administration's **drug rebate rule**

Implementation Timeline of the Prescription Drug Provisions in the Inflation Reduction Act



Requires the Secretary of HHS to Negotiate Medicare Drug Prices

Modifies the current law “non-interference” clause to require the HHS Secretary to negotiate drug price with manufacturers for some drugs covered under Medicare Part B and Part D

Which drugs qualify for negotiation?

The Secretary selects drugs to be negotiated from the **50 “negotiation-eligible” drugs with the highest total Medicare Part D spending** and the **50 “negotiation-eligible” drugs with the highest total Medicare Part B spending**

“Negotiation eligible drugs” include **brand-name drugs or biologics** and exclude the following drugs:

- Drugs that have a generic or biosimilar available
- Drugs less than 9 years (for small-molecule drugs) or 13 years (for biological products) from their FDA-approval or licensure date
- Certain “small biotech drugs” (from 2026 to 2028)
- Drugs that account for Medicare spending of less than \$200 million in 2021
- Drugs with an orphan designation as the only FDA-approved indication

Which drugs are excluded from negotiation?

How many drugs will have negotiated prices?

Limits the total number of drugs to be negotiated to **10 Part D** drugs in **2026**, **15 Part D** drugs in **2027**, **15 Part D and Part B** drugs in **2028**, and **20 Part D and Part B** drugs in **2029 and later years**

Establishing the Negotiated “Maximum Fair Price” for Medicare

The upper limit for the negotiated price of a drug (the “maximum fair price”) is equal to *the lower of:*

- The drug’s enrollment-weighted negotiated price (net of all price concessions) for a Part D drug;
- The average sales price for a Part B drug; or
- A percentage of the non-federal average manufacturer price (i.e., the average price wholesalers pay manufacturers for drugs distributed to non-federal purchasers), depending on FDA approval date:
 - **75%** for small-molecule drugs more than 9 years but less than 12 years beyond FDA approval;
 - **65%** for drugs between 12 and 16 years beyond FDA approval; and
 - **40%** for drugs more than 16 years beyond FDA approval

Financial penalties would be imposed on drug manufacturers for non-compliance

- An excise tax would be imposed on prior year sales of a given drug for manufacturers that do not negotiate with the Secretary, starting at 65%, increasing by 10% every quarter up to 95%
 - *The excise tax would be suspended if manufacturers choose to have their drugs no longer covered by Medicare or Medicaid*
- A civil monetary penalty would be imposed on drug manufactures for not offering the agreed-upon maximum fair price of up to 10x difference between price charged and negotiated price

Requires Drug Manufacturers to Pay Rebates For Drug Price Increases Above Inflation

- **Requires drug manufacturers to pay a rebate if drug prices increase faster than the rate of inflation (CPI-U) for:**
 - Single-source drugs and biologicals covered under Medicare Part B
 - All covered drugs under Medicare Part D except those where average annual cost is <\$100
- 2021 is the base year for measuring cumulative price changes relative to inflation
- The rebate amount is based on units sold in Medicare multiplied by the amount that a drug's price in a given year exceeds the inflation-adjusted price
- Price changes are measured based on the average sales price (for Part B drugs) or the average manufacturer price (for Part D); these measures include prices charged in the commercial market
- Rebates paid by manufacturers would be deposited in the Medicare Supplementary Medical Insurance (SMI) trust fund
- Manufacturers that do not pay the required rebate would face a penalty of at least 125% of the original rebate amount

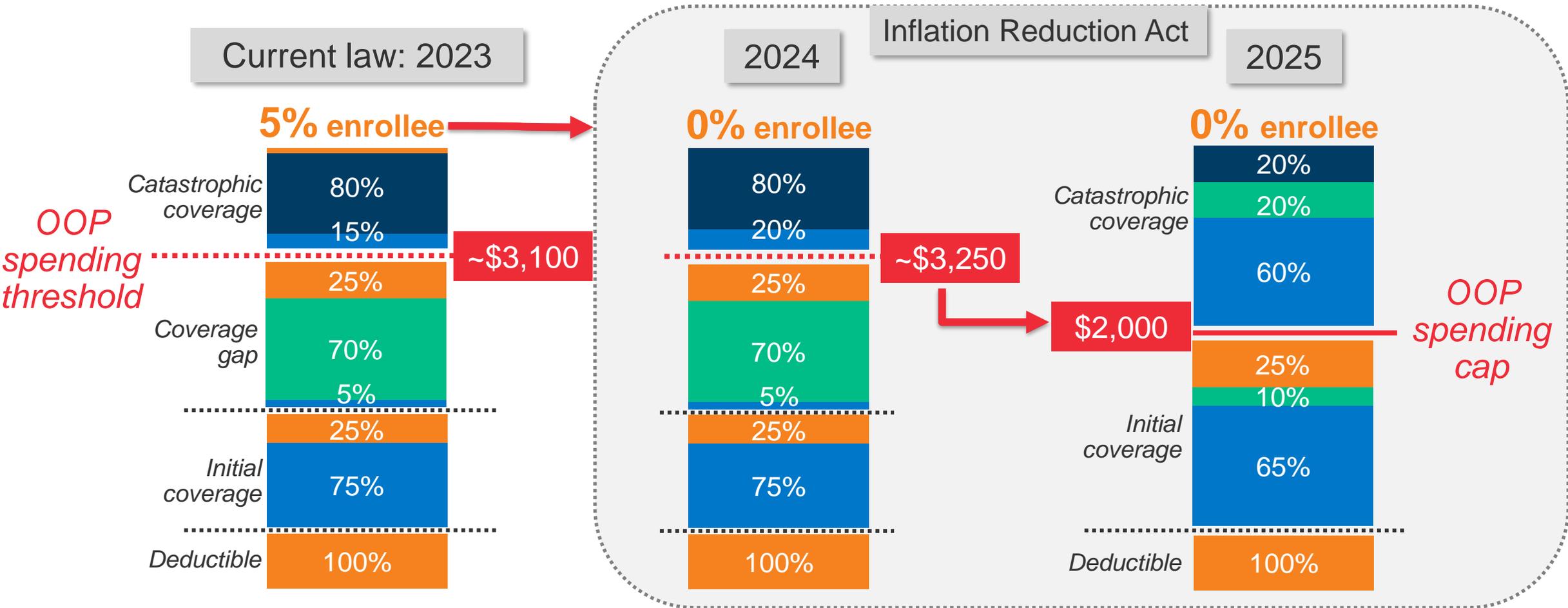
Capping Medicare Part D Out-of-Pocket Spending and Other Part D Benefit Changes

Changes would lower beneficiary spending, reduce Medicare's liability for high drug costs, and increase Part D plan and manufacturer liability for high drug costs

Beneficiaries	Medicare	Part D Plans	Drug Companies
<ul style="list-style-type: none">• Eliminates 5% coinsurance for catastrophic coverage in 2024• Caps out-of-pocket drug spending at \$2,000 beginning in 2025• Allows spreading out of out-of-pocket costs over the year• Limits premium growth to no more than 6% per year for 2024-2030	<ul style="list-style-type: none">• Lowers share of costs above the out-of-pocket spending cap ("reinsurance")	<ul style="list-style-type: none">• Increases share of costs above the out-of-pocket spending cap• Modifies share of costs below the out-of-pocket spending cap	<ul style="list-style-type: none">• Requires a price discount on brand-name drugs above the out-of-pocket spending cap• Modifies the price discount on brands below the out-of-pocket spending cap

Changes to Medicare Part D for Brand-Name Drug Costs

Share of **brand-name drug** costs paid by: ● Enrollees ● Part D Plans ● Drug manufacturers ● Medicare



NOTE: OOP is out-of-pocket. The out-of-pocket spending threshold will be \$7,400 in 2023 and is projected to be \$7,750 in 2024 and \$8,100 in 2025, including what beneficiaries pay directly out of pocket and the value of the manufacturer discount on brand-name drugs in the coverage gap phase. These amounts translate to out-of-pocket spending of approximately \$3,100, \$3,250, and \$3,400 (based on brand-name drug use only).



Limits Monthly Copayments for Insulin in Medicare

- Beginning in 2023, **limits copayments to \$35 per month** per prescription for **covered insulin** products in **Medicare Part D** plans and for insulin furnished through durable medical equipment under **Medicare Part B, with no deductible**
- For 2026 and beyond, limits monthly Part D copayments for insulin to the lesser of:
 - \$35
 - 25% of the maximum fair price (in cases where the insulin product has been selected for negotiation)
 - 25% of the negotiated price in Part D plans

Expands Eligibility for Full Benefits Under the Medicare Part D Low-Income Subsidy Program

The Part D Low-Income Subsidy (LIS) Program helps beneficiaries with their Part D premiums, deductibles, and cost sharing. Beneficiaries qualify for full or partial benefits depending on their income and resources.

■ Current law:

- Beneficiaries qualify for **full LIS benefits** if they have **income up to 135% of poverty and lower resources** (up to \$9,900 individual, \$15,600 couple in 2022*)
- Beneficiaries qualify for **partial LIS benefits** if they have **income between 135-150% of poverty and higher resources** (up to \$15,510 individual, \$30,950 couple in 2022*)

■ Inflation Reduction Act:

- Expands eligibility for full LIS benefits to individuals with **incomes between 135% and 150% of poverty** and **higher resources** (at or below the limits for partial LIS benefits), and eliminates the partial LIS benefit

NOTE: *Includes a \$1,500 per person allowance for funeral/burial expenses.

Eliminates Cost Sharing for Adult Vaccines in Medicare Part D and Improves Access to Adult Vaccines in Medicaid & CHIP

Medicare Part D

- Eliminates cost sharing for adult vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP), such as for shingles

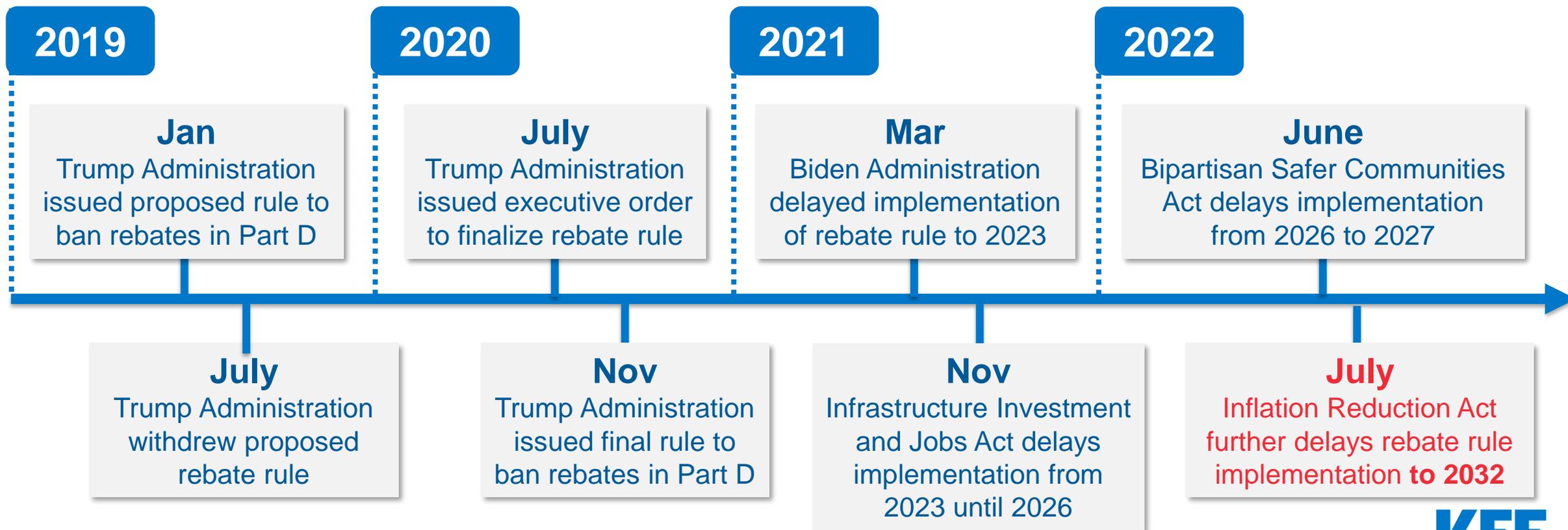
Medicaid and CHIP

- Requires state Medicaid and CHIP programs to cover all approved vaccines recommended by ACIP and vaccine administration, without cost sharing

Delays Implementation of the Trump Administration's Rebate Rule

What is the Rebate Rule?

It would eliminate rebates negotiated between drug manufacturers and pharmacy benefit managers (PBMs) or health plan sponsors in Medicare Part D by removing the safe harbor protection currently extended to these rebate arrangements under the federal anti-kickback statute. The rule was estimated to result in higher Medicare spending and higher Part D premiums.



Number of Medicare Beneficiaries Potentially Affected by Selected Provisions in the Inflation Reduction Act

Eliminating the 5% coinsurance requirement for Medicare Part D catastrophic coverage

1.3 million

Medicare Part D enrollees without low-income subsidies had spending above the catastrophic coverage threshold in 2020

Capping out-of-pocket drug costs in Medicare Part D at \$2,000

1.4 million

Medicare Part D enrollees without low-income subsidies had annual out-of-pocket drug spending of \$2,000 or more in 2020

Eliminating cost sharing for adult vaccines covered under Medicare Part D

4.1 million

Medicare Part D enrollees received a vaccine covered under Part D in 2020

Expanding eligibility for full benefits for Medicare Part D Low-Income Subsidies up to 150% FPL

0.4 million

Medicare Part D enrollees received partial benefits under the Low-Income Subsidy program in 2020

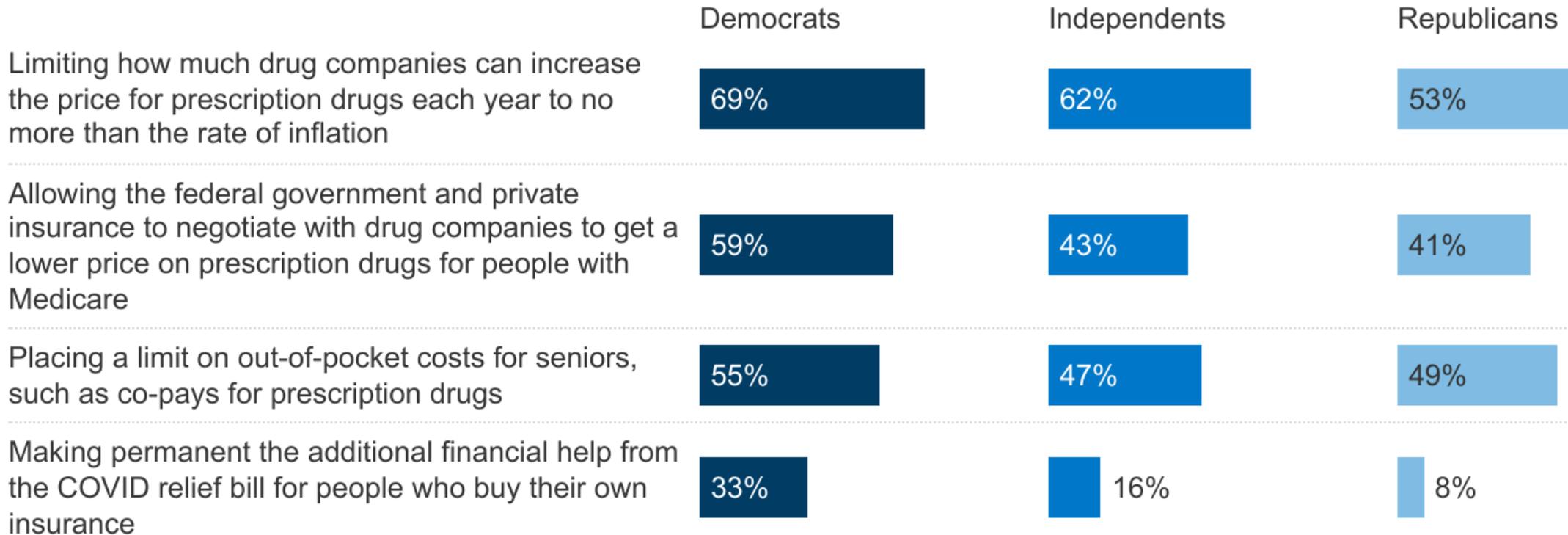
NOTE: Estimates of beneficiaries potentially affected by these provisions are likely to be conservative because they are based on 2020 data and do not reflect increases in drug spending from 2020 to the year of implementation, growth in the population, or any increase in drug use and spending attributable to reduced financial barriers.

SOURCE: KFF, "How Would the Prescription Drug Provisions in the Senate Reconciliation Proposal Affect Medicare Beneficiaries?" July 2022.



Many Democrats, Independents, and Republicans Say Prescription Drug Policies Should Be Top Priorities for Congress

*Percent who say each of the following should be a **top priority** for Congress:*



Overall Favorability Towards Drug Price Negotiation Remains Unchanged After Public Hears Arguments on Both Sides

Do you favor or oppose allowing the federal government to negotiate with drug companies to get a lower price on prescription drugs for people with Medicare and private insurance?

Argument against: This would have the government too involved and will lead to fewer new drugs being available in the future

Argument in favor: This is needed because Americans pay higher prices than people in other countries, many can't afford their prescriptions, and drug company profits are too high

■ Strongly favor
 ■ Somewhat favor
 ■ Somewhat oppose
 ■ Strongly oppose

Total adults



Democrats



Independents



Republicans

