Prescription Drug Affordability

October 18, 2023
Commission Meeting

Purpose of the briefing

- SB 1338 (Edwards) was referred to JCHC for study
  - Proposed extending Virginia's PBM requirements to PBMs servicing ERISA plans
- Members requested information on two topics:
  - Impact of federal changes in the Inflation Reduction Act on prescription drug affordability in Virginia
  - Implications of federal court rulings on state regulation of ERISA plans

PBM = Pharmacy Benefit Manager; ERISA = Employee Retirement Income Security Act

Agenda

Prescription drug spending trends

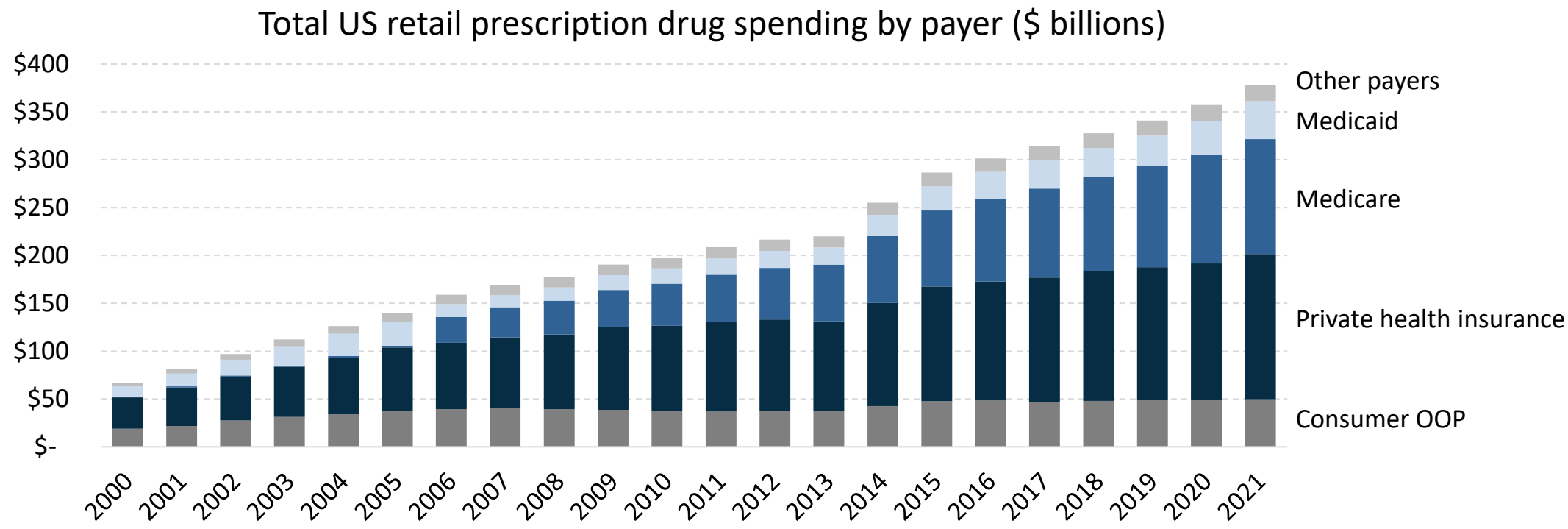
Potential impact of IRA provisions on spending

State-level approaches to prescription drug affordability

Impact of federal court rulings on state policy levers

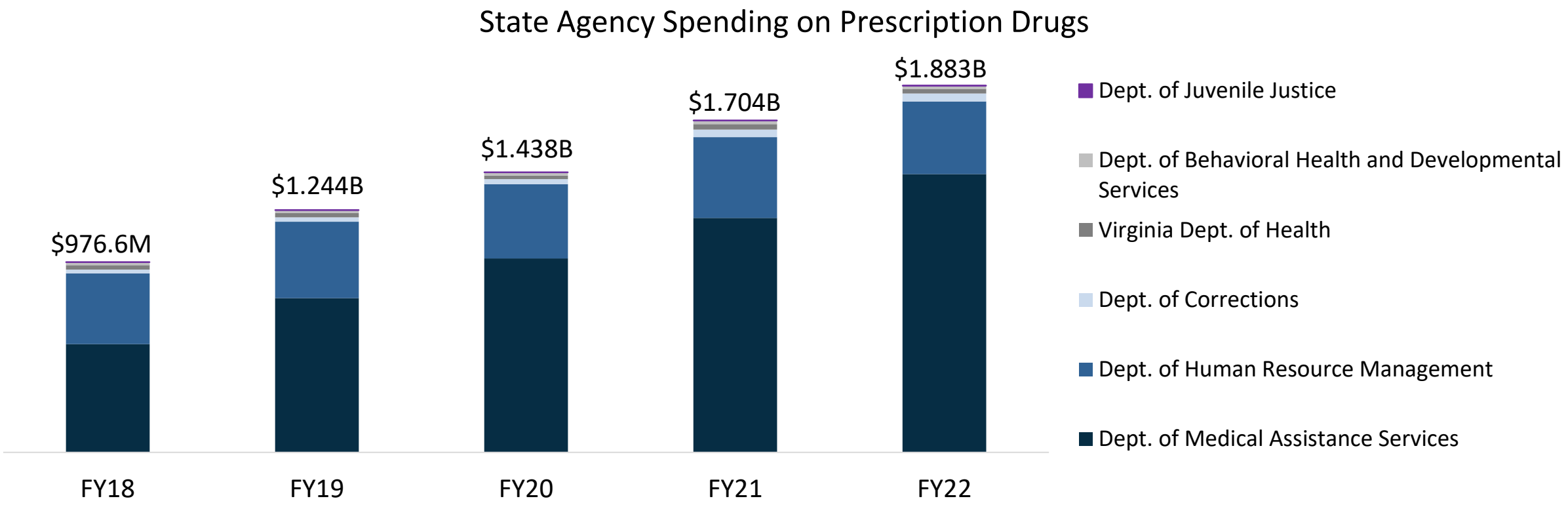
IRA = Inflation Reduction Act

Retail prescription drug spending increases an average of 7.3% annually



SOURCE: JCHC analysis of National Health Expenditure Data. NHE data is deflated to represent uninflated dollars.
NOTE: Examples of other payers are Children's Health Insurance Program (CHIP), Department of Veterans Affairs, and workers compensation programs.
OOP = out-of-pocket

State spending on prescription drugs was near $1.9 billion in FY22



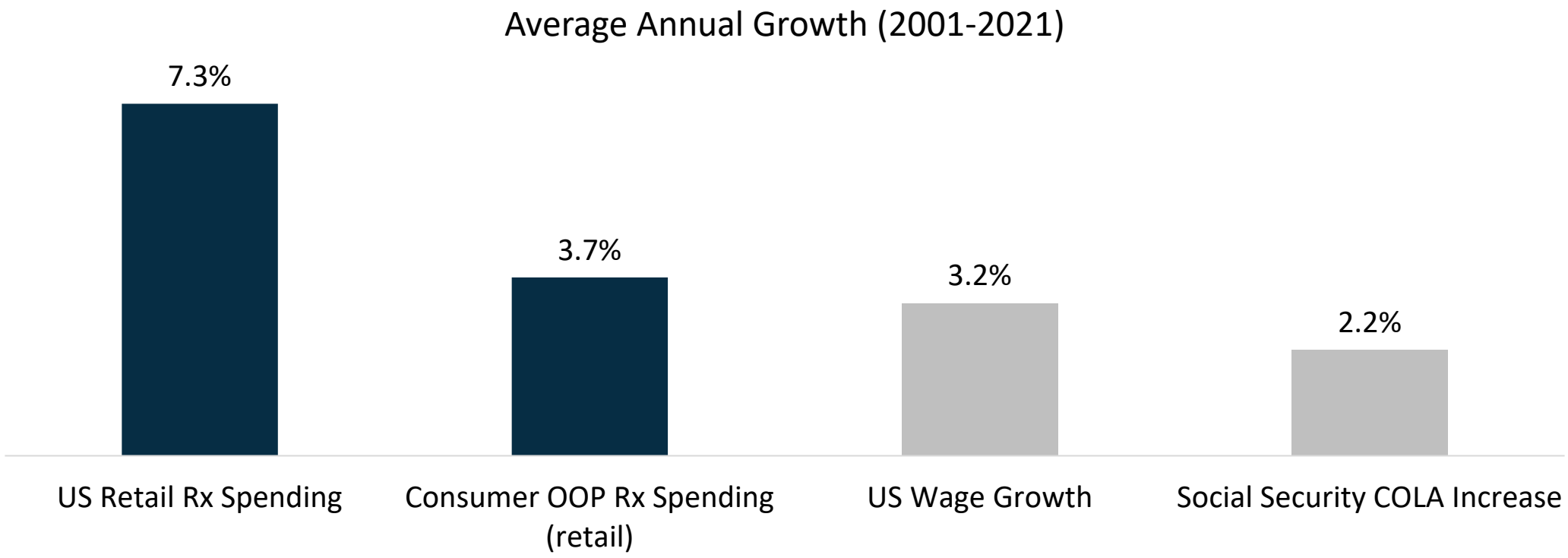
SOURCE: JCHC analysis of data provided by state agencies.

Specialty drugs and other expensive classes are driving spending growth

- Launch prices for new drugs are growing significantly, led by specialty and oncology drugs
  - Specialty drugs account for most new drugs in the last decade
  - Specialty drugs are used by 3% of patients but account for 51% of total spending
  - Median annual cost of new drugs range from about $25,000 to $260,000 (oncology)

NOTE: Specialty drugs are defined as those treating chronic, complex, or rare diseases and requiring additional distribution, care delivery, or cost characteristics.

Prescription and OOP spending have outpaced income growth



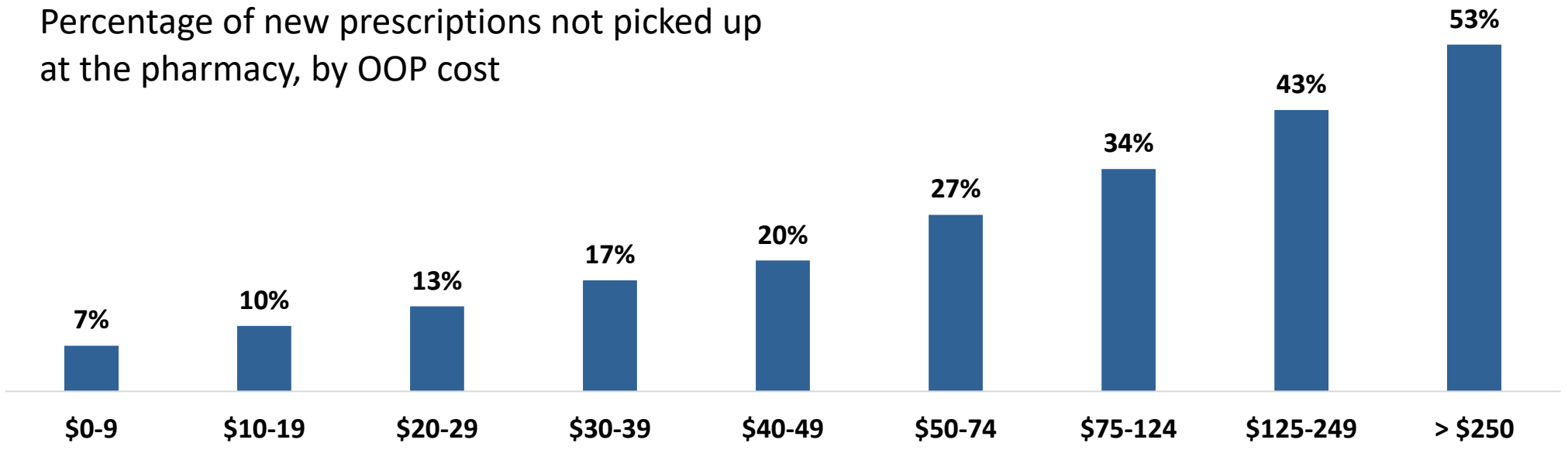
SOURCE: JCHC staff analysis of National Health Expenditure data, Bureau of Labor Statistics Data, and Social Security Administration data; all data are non-inflation adjusted.
OOP = out-of-pocket; COLA = cost of living adjustment.

Prescription OOP costs are high for a small percentage of consumers

- A minority of consumers face financial burdens paying for medications
  - 7% paid more than $500 OOP annually for prescription drugs (all payers)
  - 16% of Medicare enrollees paid more than $500 OOP annually for prescription drugs
- Majority of consumers experience limited OOP costs for prescription drugs
  - More than 70% paid $100 or less annually
  - 28% paid zero dollars OOP in 2022

OOP = out-of-pocket

High OOP costs lead to consumers forgoing prescriptions



SOURCE: IQVIA National Prescription Audit, New to Brand. From IQVIA "Use of Medicines, 2023" report.
OOP = out-of-pocket

Key Findings – Spending Trends

Total prescription drug spending continues to grow faster than income and inflation.

Increased spending impacts OOP costs for consumers.

OOP spending has been flat for most consumers, but a minority of consumers face significant financial challenges affording necessary medications.

OOP = out-of-pocket

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Inflation rebate periods for drugs paid for by Medicare started in 2022

- Requires manufacturers that raise their drug prices faster than the rate of inflation to pay Medicare a rebate
- CMS calculates a reference price for each drug by indexing a historical average price to inflation
- If the sale price is higher than the reference price in a given year, the manufacturer pays a rebate on Medicare covered drugs

CMS = Centers for Medicare and Medicaid Services

Impact of rebates depends on manufacturer decisions

- Manufacturers with significant portion of sales through Medicare may constrain price increases to avoid rebates
- Manufacturers with more sales outside of Medicare may pay the rebate to maintain higher prices for other payers
- CBO expects manufacturers to constrain price increases on existing drugs; new drugs may have higher launch prices

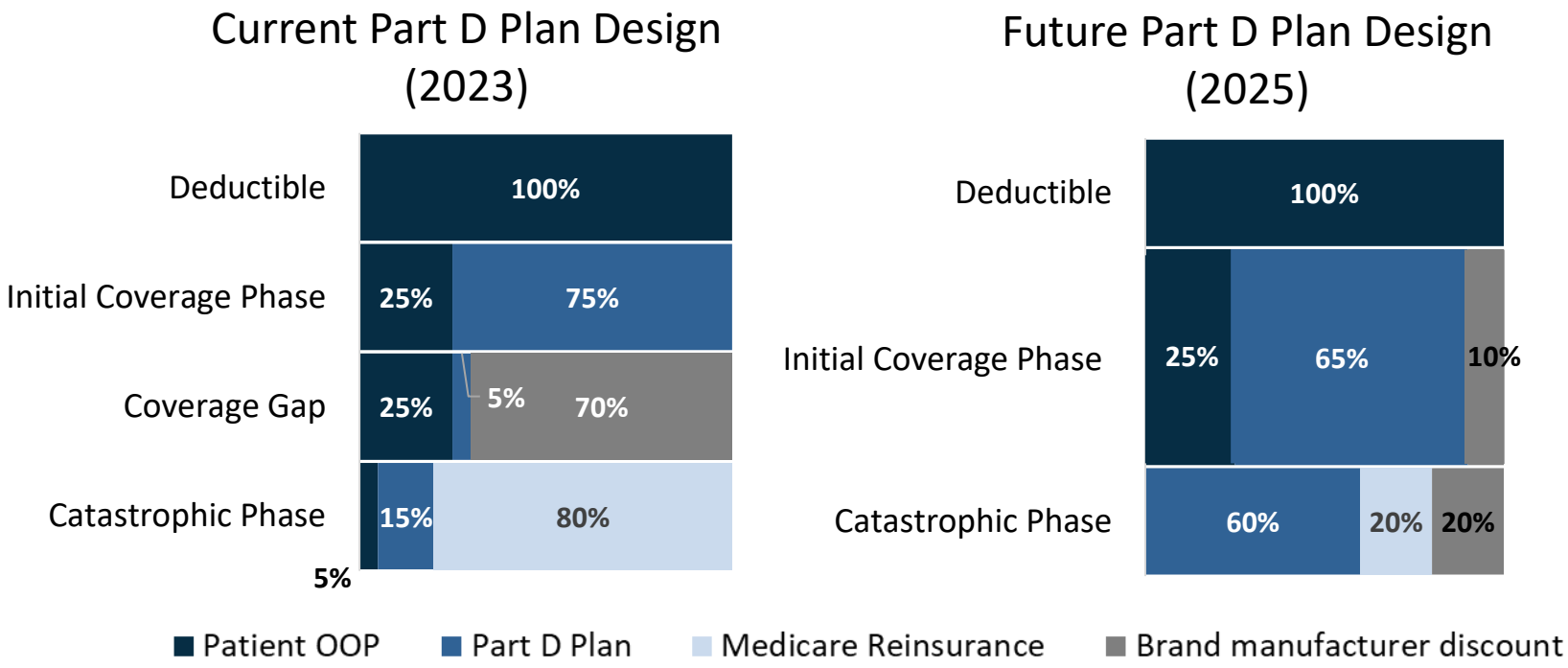
CBO = Congressional Budget Office

Reductions in prices will also reduce Medicaid rebates

- There are existing statutory drug rebates in Medicaid which are based on average manufacturer prices
- As Medicare inflation rebates constrain growth in the price of drugs, Medicaid rebates will also decrease
- CBO estimates that net prices for drugs covered by Medicaid will increase because of smaller rebates and higher prices for newly launched drugs

CBO = Congressional Budget Office

Medicare Part D benefit will be significantly different in 2025



OOP = out-of-pocket

Benefit redesign most helpful to those with high prescription drug costs

Hypothetical Medicare enrollee: $250,000 oncology medication	Current (2023)		Future (2025)	
	Total Prescription Costs	Patient OOP	Total Prescription Costs	Patient OOP
Deductible	$505	$505	$505	$505
Initial Coverage Phase	$4,155	$1,039	$5,980	$1,495
Coverage Gap	$6,164	$1,541	N/A	N/A
Catastrophic Phase	$239,176	$11,959	$243,515	$0
Total Cumulative Costs	$250,000	$15,044	$250,000	$2,000

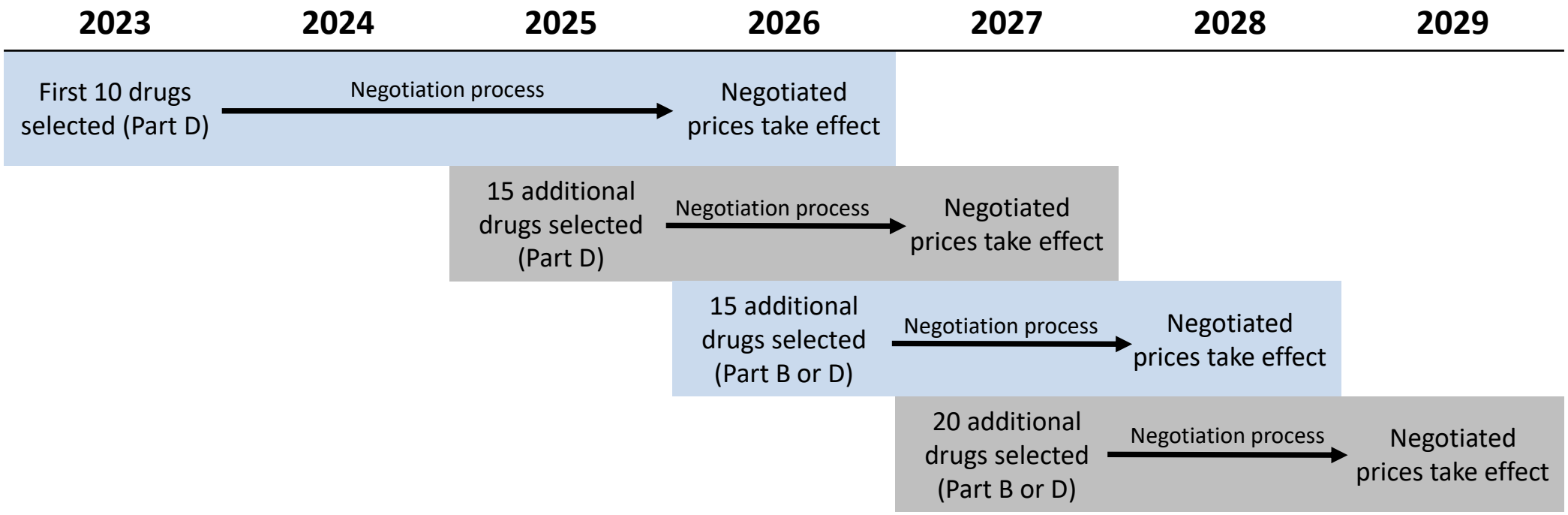
NOTE: Current Medicare benefit design includes a 'coverage gap', where patients pay 25% of the cost of drugs. New benefit design does not include this phase.
OOP = out-of-pocket

Redesign will reduce OOP spending for a small number of beneficiaries

- Less than 4% of Medicare beneficiaries will see lower OOP spending, but savings will be significant
  - CBO estimates $13 billion reduction in OOP costs in 2031
  - Estimated $281 million in OOP savings for Virginia Medicare enrollees

OOP = out-of-pocket; CBO = Congressional Budget Office

First negotiated prices will go into effect in 2026



SOURCE: Congressional Budget Office analysis of Inflation Reduction Act provisions.
NOTE: Negotiation is only for Part D drugs.

Only certain drugs are eligible to be selected for negotiation

- Negotiations will target drugs still under patent protection but after some price exclusivity has occurred
  - Must be on the market for 7 years for small molecule drugs; 11 years for biologics
  - Drugs may not be selected if they have competition from an approved generic equivalent or biosimilar
- Drugs must be among the top 50 largest expenditures in either Part B or Part D

Negotiations will only directly impact Medicare drug prices

- CBO estimates that prices for selected drugs will decrease by 50% on average based on negotiations
- CBO estimates that by 2031 negotiated drugs will account for less than 20% of total Medicare drug spending

CBO = Congressional Budget Office

Key findings – IRA Provisions

Most significant impact on consumer OOP spending will come from the Part D benefit redesign.

Medicare inflation rebates may slow price increases for some drugs for all payers, but full impact is still unclear.

Federal negotiating authority is likely to reduce the Medicare price of some of the highest cost medications.

OOP = out-of-pocket

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Prescription drug affordability has been a very active area of state health policy

- In 2023, the most recently completed legislative year:
  - 46 states introduced 311 bills addressing affordability
  - 29 states passed 47 laws addressing affordability

State policies focus on different aspects of drug pricing

Type of policy	Number of states	Number of laws	Virginia law?
PBM regulation and oversight	50	157	Yes
Consumer OOP costs	28	48	Yes
Price transparency	20	31	Yes
Affordability review boards	9	12	No
Generic substitution	7	7	Yes
Drug importation	6	11	No
Volume purchasing arrangements	3	3	No

SOURCE: National Association for State Health Policy (NASHP) prescription drug affordability legislative tracker.
NOTE: Table includes laws passed since 2017
PBM = Pharmacy Benefit Manager; OOP = out-of-pocket.

PBMs operate in the middle of the distribution chain for prescription drugs

Employer/ Insurer	Drug Manufacturer	Pharmacy
• PBM manages prescription drug benefits of health plans	• PBM negotiates discounts and rebates	• PBM contracts with pharmacy to reimburse for drugs dispensed

PBM = Pharmacy Benefit Manger

Regulation of PBMs has been the biggest focus for states

- States have increasingly regulated PBMs in recent years
  - Licensing and reporting requirements
  - Auditing standards between PBMs and pharmacies
  - Contract provisions such as gag clauses and spread pricing
- This has led to challenges of state laws by the PBM industry, particularly laws that seek to regulate PBMs working with or owned by ERISA plans

NOTE: Employer sponsored, self-insured plans are regulated by the federal ERISA (Employee Retirement Income Security Act) statute. More than one third of Virginians are covered by an ERISA-regulated plan.
PBM = Pharmacy Benefit Manager

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Impact of federal court rulings on state prescription benefit manager policy

Erin Fuse Brown, JD, MPH

Applicability of ERISA preemption

- All non-governmental employer sponsored group health plans are regulated by the federal ERISA statute
- While states *may* apply their insurance laws to fully insured plans, ERISA preempts all state laws as applied to self-funded employer plans
- More than one third of Virginians are covered by a self-funded ERISA plan

ERISA = Employee Retirement Income Security Act

ERISA has a broad preemption clause that limits state regulation

- Any state law or regulation that "relates to" an ERISA plan is preempted (not allowed)
- State laws "relate to" an ERISA plan if they bear a connection with or refer to ERISA plans
  - Connection with is interpreted as a law governing a central matter of plan administration
  - Refer to is interpreted as a law that "acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation."

ERISA = Employee Retirement Income Security Act

“Connection with” an ERISA plan

- Does the state law govern a central matter of plan administration or interfere with nationally uniform plan administration?
- Three examples of preempted state laws:
  - Laws that require plans to **structure benefits** in a particular way
  - Laws that bind plan administrators to **specific rules for determining beneficiary status**
  - Laws that create **acute, indirect economic effects that force the plan to adopt a certain scheme of substantive coverage**.

ERISA = Employee Retirement Income Security Act

Rutledge upheld state cost or rate regulation between PBMs and pharmacies

- The Arkansas law being challenged required PBMs to reimburse pharmacies at least the amount it cost the pharmacy to purchase the drug. *Held: not preempted by ERISA*
- Law impacts PBMs servicing any plan type, not just ERISA
- Supreme Court held, "ERISA does not preempt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage."

Rutledge v. Pharmaceutical Care Management Assn., (U.S. Supreme Court, 2020).
PBM = Pharmacy Benefit Manager; ERISA = Employee Retirement Income Security Act

PCMA v. Mulready: 10th Cir. strikes down Oklahoma's PBM pharmacy network laws

- Oklahoma passed a law in 2019 applying its full PBM regulation to ERISA and Medicare Part D plans
- U.S. Court of Appeals held four provisions of Oklahoma law to be preempted by ERISA and one to be preempted by Medicare Part D because they "govern a central matter of plan administration – benefit design."
- Law includes four provisions regulating PBM's pharmacy networks
  - Access: Retail pharmacy network adequacy standards, only counting retail pharmacies for network access (no mail order)
  - Discount: no cost-sharing discounts for individuals to receive drugs from their choice of in-network pharmacy
  - Any-willing-pharmacy: PBM must accept all pharmacies willing to accept the terms to be a preferred provider.
  - Probation: prohibiting PBMs from terminating a provider's contract because an employee is on probation but still actively licensed by Board of Pharmacy

Precedent on PBM preemption of state laws

Type of State PBM law	Not Preempted (*Rutledge* – Supreme Court)	Preempted (*Mulready* – 10th Circuit)	Unclear
Cost regulation: e.g., minimum reimbursement rates, spread pricing	✓		
Pharmacy network requirements: e.g., AWP, network adequacy		✗	
Other PBM oversight: licensing, transparency, audits, reporting			?

PBM = Pharmacy Benefit Manager

SB 1338 would extend Virginia's current PBM statute to ERISA plans

- Virginia's current PBM statute applies to state-regulated health plans (passed in 2019; amended in 2022)
- Virginia PBM statutes includes several major provisions, including:
  - Requires PBMs to be licensed by State Corporation Commission
  - Prohibits spread pricing
  - Requires regular reporting on payments and rebates
  - Sets standards for PBM audits of pharmacies
  - Sets several network and contracting requirements related to 340B covered entities, affiliated pharmacies, and mail order pharmacies

PBM = Pharmacy Benefit Manager; ERISA = Employee Retirement Income Security Act

Some regulatory mechanisms are unclear based on AR and OK rulings

- **Permitted:** cost or rate regulations, minimum reimbursement provisions, spread pricing prohibitions, price transparency, rebate pass-through, etc.
- **Preempted:** mandating benefits, coverage of certain groups of people, or in 10th Cir., directing benefit design, including network restrictions
- Preemption unclear:
  - Audit requirements, PBM licensing, or oversight
  - Nondiscrimination against 340B participating pharmacies
  - Data reporting requirements may be preempted based on precedent, *Gobeille v. Liberty Mutual (2016)*

PBM = Pharmacy Benefit Manager

Key takeaways

- The Supreme Court unanimously held in *Rutledge v. PCMA* that PBM cost-regulations, even if they increase costs or change incentives for plans, are not preempted.
- *Mulready v. PCMA* suggests that (at least in 10th Cir.) pharmacy network restrictions are preempted as a form of interference with benefit design.
- State laws should apply to PBMs generally, not to the ERISA plans.
- Any novel attempt at state regulation of ERISA plans or their contracted intermediaries is likely to face a legal challenge. . . But whether the state law will survive the challenge is a separate question.

PBM = Pharmacy Benefit Manager; ERISA = Employee Retirement Income Security Act