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Federal and State Drug Pricing Regulation: What Laws and Changes Do We Anticipate in the Next 6-12 Months?

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Medicaid Drug Rebate Program 2021

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Agenda

- Key Federal Legislative and Administrative Proposals
  - Drug Pricing Reform Landscape
  - Drug Pricing Proposals in Play
  - Outlook
- State Legislative Trends
- Questions

Key Federal Legislative and Administrative Proposals

Drug Pricing Reform Landscape

- The 2020 election cycle brought unified Democratic control of Congress and the White House, reinvigorating calls for drug pricing reform in the 117th Congress.
- Congress has largely focused on pandemic relief and stimulus measures.
- Drug pricing reform remains a central element of the majority's domestic policy agenda and is now being considered as a major offset for the President's Build Back Better Plan.

Drug Pricing Reform Landscape

- The landscape of the 117th Congress presents significant challenges to moving major reforms
  - 50/50 Senate
  - 3 seat majority in the House
  - Divided Democratic caucus in both chambers
  - Reconciliation
  - 2022 election pressure
  - Crowded congressional calendar

Congressional Action in the 117th: Reconciliation

- Democratic leadership has elected to pursue drug pricing reform through the budget reconciliation process as part of a broader legislative package encompassing the President's Build Back Better Plan.
- Reconciliation enables expedited consideration of certain spending, tax, and debt limit legislation with simple majority in the Senate.
- Reconciliation bills aren't subject to filibuster, but policy provisions are considered extraneous if they don't change spending or revenue levels or if the impact is merely incidental to the non-budgetary aspects of the provision.
- Previous bills moving through reconciliation include the 2017 tax cuts led by the Republican Congress, and the amendments to the Affordable Care Act in 2010.

Reconciliation Pathway

In August, the Senate approved the FY 2022 Budget Resolution, which includes instructions to Senate and House committees to draft legislation with specific spending and savings levels

Last month, House committees released legislative text and held markups to approve their respective bills including policy provisions within their jurisdiction

At the end of September, the respective committee-approved bills were combined and considered at Budget

Next, the combined bill will be considered by the Rules Committee, and ultimately on the House floor

The bill then moves to the Senate for consideration, and potentially back to the House to approve any changes accepted in the Senate

Drug Pricing Proposals in Play

- H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act
- Wyden Drug Pricing Principles
- Prescription Drug Pricing Reduction Act (“Grassley-Wyden”)
- Reduced Costs and Continued Cures Act (“Peters-Schrader”)

Build Back Better Act

Spend

Enhanced education support
Child care support
EV rebates
Clean energy investments
ACA premium support
Medicare dental, hearing, vision
Medicaid expansion
Workforce training
Enhanced paid leave

Offsets

Increased individual and corporate tax rates
Savings generated by drug pricing reform (H.R. 3)
Part D Rebate rule repeal
Refunds for discarded drug

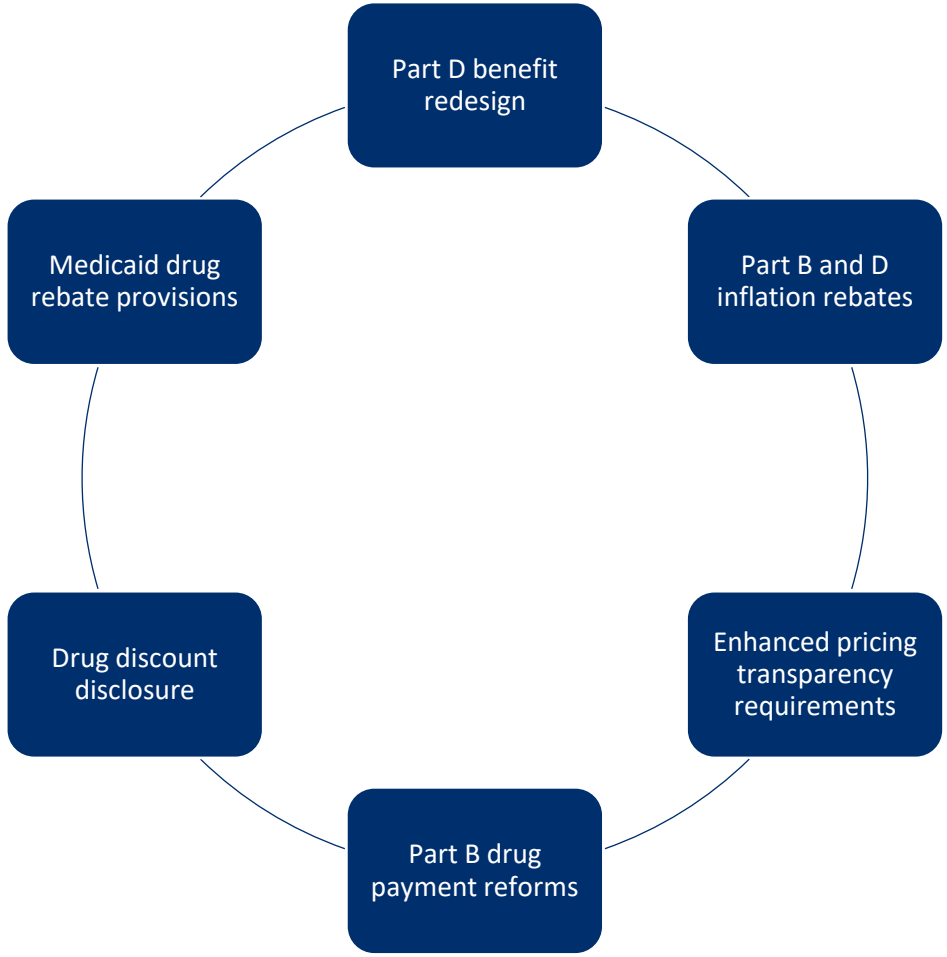
Sen. Wyden's Drug Pricing Principles

- In June, Senate Finance Committee Chair Ron Wyden (D-OR) released his drug pricing principles, which he announced would guide the development of an updated drug pricing reform legislative package.

- Medicare must have the authority to negotiate with pharmaceutical companies, especially when competition and market practices are not keeping prices in check.
- American consumers must pay less at the pharmacy counter.
- Prices of drugs that increase faster than inflation will not be subsidized by patients and taxpayers.
- Drug pricing reforms that keep prices and patient costs in check should extend beyond Medicare to all Americans, including those covered by employer and commercial health plans.
- Drug pricing reforms should reward scientific innovation, not patent games.

Prescription Drug Pricing Reduction Act (PDPRA) (S. 2543)

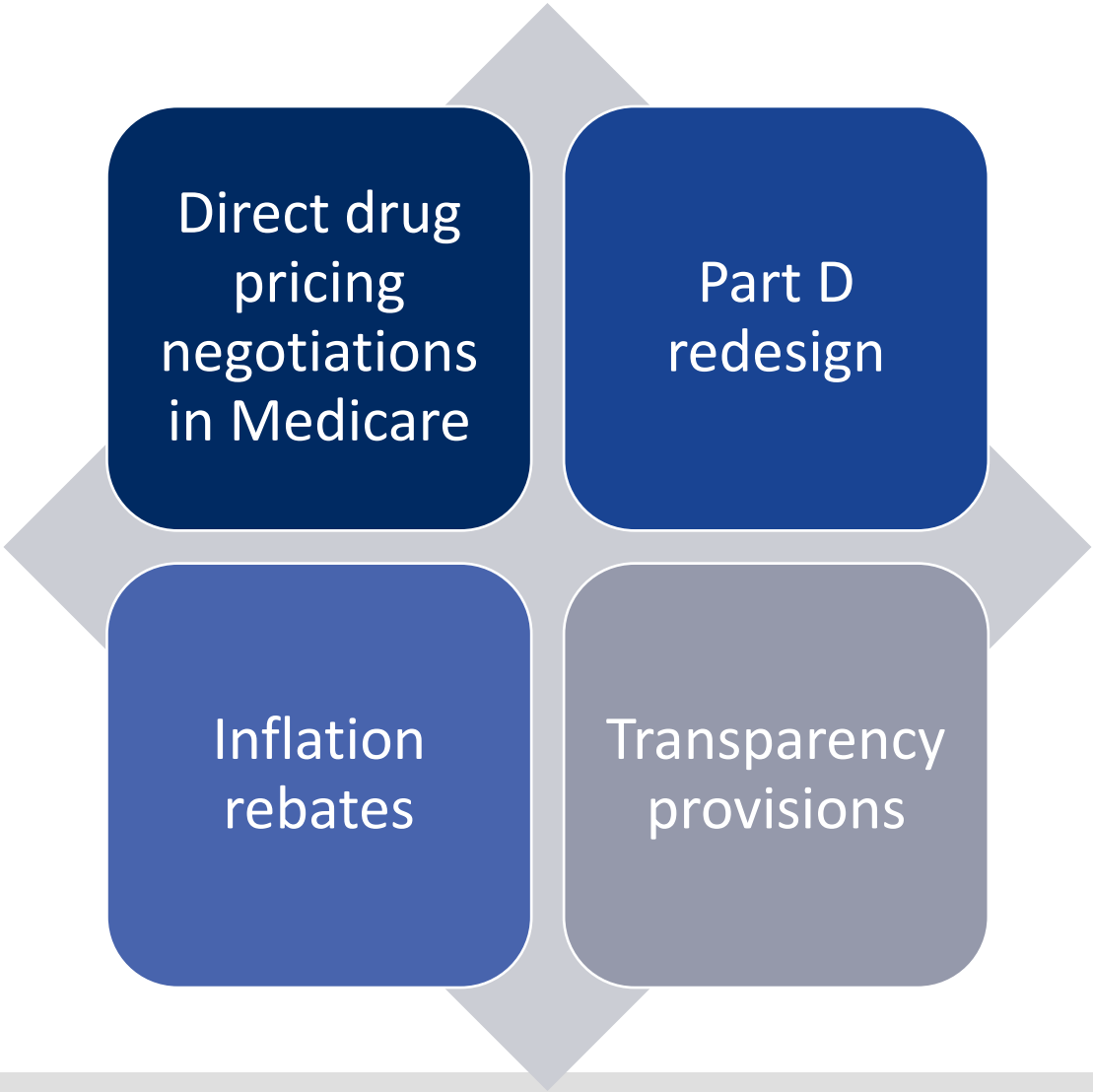
- Introduced in the 116th Congress and reflected a bipartisan deal between then Senate Finance Chair Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR).
- Senate counterpart to H.R. 3.
- The bill was favorably reported out of the Finance Committee despite strong objections among Republican members to inflation rebates, with the understanding the bill would be refined before floor consideration. However, the bill never received floor consideration.



Reduced Costs and Continued Cures Act (H.R. 5237)

- Introduced by Reps. Scott Peters (D-CA) and Kurt Schrader (D-OR) with three additional sponsors.
- The bill, among other provisions, would:
  - Allow for government negotiation of prices for certain Medicare Part B drugs, but would not allow for government negotiation of Part D drug prices
  - Part D redesign to establish an out-of-pocket cap scaled to income levels and provide for patient smoothing
  - Establish out of pocket cap for insulin
  - Base beneficiary cost-sharing at the pharmacy on the net (post-rebate) price
  - Increase PBM reporting requirements
  - Require manus to justify “significant” price increases
  - Ban pay for delay

Key Policy Proposals in Top Bills in Play



Policy Proposal: Medicare Negotiation

Build Back Better Act

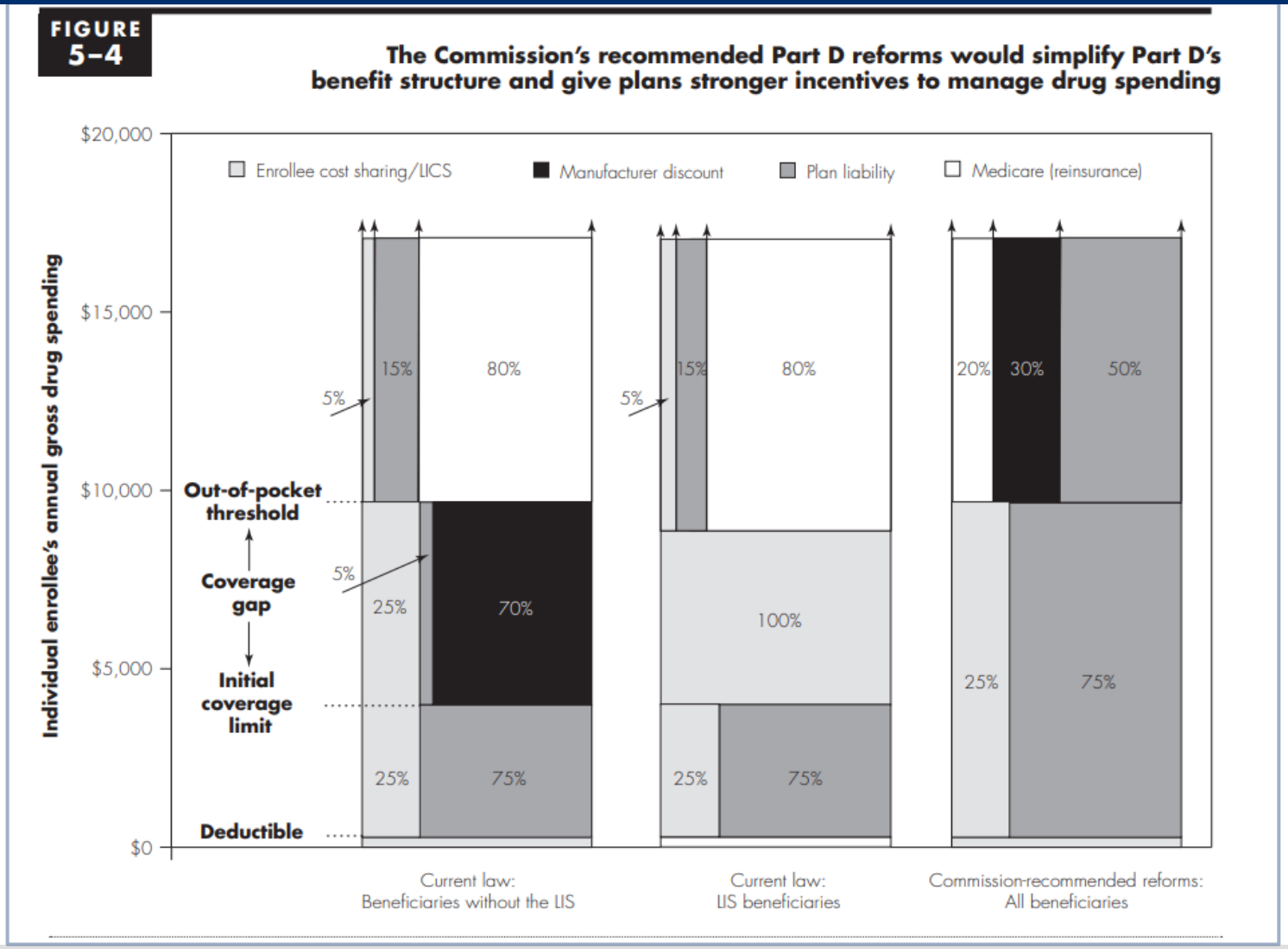
- Establishes a Fair Price Negotiation Program for qualifying single-source drugs.
- Requires the Secretary to annually publish a list of “selected drugs” that are projected to result in the greatest savings to the federal government or a fair price-eligible individual.
  - List must include at least 25 drugs in 2025 and at least 50 drugs in 2026 and subsequent years.
- Secretary must enter into an agreement to negotiate the maximum fair price of the selected drugs with the applicable manufacturer.
  - Maximum fair price may not exceed 120% of the Average International Market (AIM) price, which is the net average price of the drug in Australia, Canada, France, Germany, Japan, and the UK.
- Manufacturers that refuse to enter negotiations or leave negotiations early are subject to an escalating excise tax.
  - Starts at 65% of gross sales, increasing to a maximum of 95%.

Policy Proposal: Medicare Negotiation

Reduced Costs and Continued Cures Act

- Allows the Secretary to negotiate prices in Part B for certain single-source drugs and biologicals.
  - Regulatory data protections, exclusivity, and patents must have expired.
  - No approved generic or biosimilar alternative.
- If the Secretary and the manufacturer cannot agree on a “maximum allowable cost,” the Secretary may set the cost at an amount that is between 65-75% of the average sales price during the preceding one year.

Policy Proposal: Part D Redesign



Source: MedPAC , *Report to the Congress: Medicare and the Health Care Delivery System* (June 2020)

Policy Proposal: Part D Redesign

	Build Back Better Act	Grassley-Wyden (116th)	Cassidy-Menendez	Peters-Schrader
OOP Cap	$2,000	$3,100	$3,100	Sliding Scale based on income ($1,200 to $3,100)
Initial Phase	25% coinsurance 10% manufacturer discount 65% plan	20% coinsurance 7% manufacturer discount 73% plan	20% coinsurance 10% manufacturer discount 70% plan	25% coinsurance 10% manufacturer discount 65% plan
Coverage Gap	Eliminate	Eliminate	Eliminate	Eliminate
Catastrophic Phase	20% Medicare 30% manufacturer discount 50% plan	20% Medicare 14% manufacturer discount 66% plan	20% Medicare 10% manufacturer discount (ramp up for “specified manufacturers”) 70% plan	20% Medicare 10% manufacturer discount (ramp up for “specified manufacturers”) 70% plan
Patient Smoothing	Yes	Yes	Yes	Yes

Policy Proposal: Inflation Rebates

Build Back Better Act

Part B Inflation Rebate

- Applies to single-source drugs or biologicals (including biosimilars), but excluding vaccines.
- Manufacturers would be required to pay a rebate on any amount that the ASP exceeds the inflation-adjusted payment amount for the drug since the benchmark quarter (Q1 2016).

Part D Inflation Rebate

- Applies to covered Part D drugs and biologicals.
- Manufacturers would be required to pay a rebate on any amount that the AMP exceeds the inflation-adjusted payment amount for the drug since the benchmark year (2016).

Policy Proposal: Refunds for Discarded Drug

Infrastructure Investment and Jobs Act

- Would require a manufacturer of a "refundable single-dose container or single-use package drug" to pay a refund on the discarded amount of such drug.
  - Applies to a "single source drug or biological" or "biosimilar biological product" for which payment is made under Part B and that is furnished from a single-dose container or single-use package, with certain exceptions.
- For quarters on or after January 1, 2023, manufacturer would be required to pay a rebate to Medicare if the product of the units of discarded drug and the Part B payment amount for such drug exceeds the "applicable percentage" of the estimated total allowed charges for such drug under Part B during the quarter.
  - Applicable percentage generally = 10%, but the Secretary can increase the percentage for drugs with "unique circumstances" through notice and comment rulemaking.
  - Units of discarded drug = the total number of units discarded during the quarter, as determined by the JW modifier (or any successor deemed appropriate by the Secretary). Would not include any units that are packaged into the payment amount for an item or service and that are not separately payable.

Policy Proposal: Drug Price Transparency

H.R. 3 (not included in Build Back Better Act)

- Requires manufacturers of a qualifying drug to submit a report to the Secretary if:
  - There is an increase in WAC of 10% or more within 12 months or 25% or more within 36 months, beginning on or after January 1, 2021;
  - The estimated price or spending per individual for the applicable year is at least $26,000; or
  - There is an increase in WAC that is 10% or more within 12 months or 25% or more within 36 months that begins and ends during the five-year period preceding January 1, 2023.
- This report must be submitted to the Secretary 30 days prior to the effective date of the price increase.
- The Secretary shall make these reports available on a public website.

Outlook: Challenges

- House leadership is trying to advance legislation by the end of this month, but this is an ambitious timeline.

House	Senate
• Moderates object to the topline spending number, as well as key policies like drug price negotiations. • Outcome of infrastructure vote could undermine support of even a smaller reconciliation bill. • Progressives want a bigger package. • House members may ultimately be forced to take a tough vote on a bill that might not pass the Senate.	• Sen. Joe Manchin (D-WV) wants a smaller package. • Sen. Kyrsten Sinema (D-AZ) wants a smaller package and opposes major policy provisions like drug price negotiations. • Sen. Bob Menendez (D-NJ) opposes drug price negotiations.

- Decisions on government funding legislation will impact reconciliation negotiations.
- The 2022 election cycle has already begun.

Administration Proposal: Part D Rebate Rule

- The Part D Rebate Rule would:
  - Create new safe harbors to the Anti-Kickback Statute (AKS) protecting
    - Pharmacy point-of-sale discounts in Part D and Medicaid managed care
    - Flat, fixed service fees paid by manufacturers to PBMs
  - Eliminate existing discount safe harbor protection for rebates paid to Part D plans and their PBMs (unless rebates are required by law)

Administration Proposal: Part D Rebate Rule

Proposed Rule
(February 6, 2019)

OMB Announces Withdrawal
(July 10, 2019)

Final Rule
(November 20, 2020)

Original Effective Date for Most Provisions
(January 29, 2021)

Original Effective Date for Discount Safe Harbor Modifications
(January 1, 2022)

Court-Stipulated Effective Date
(January 1, 2023)

Effective Date under IIJA (if passed)
(January 1, 2026)

Build Back Better Act would repeal the Rebate Rule

Administration Proposal: Most-Favored Nation (MFN)

- On November 27, 2020, CMS released the MFN interim final rule:
  - Mandatory CMMI model in all States and US territories for seven performance years.
  - Applies to top 50 separately payable, single-source Medicare Part B drugs with the highest aggregate Part B total allowed charges.
  - Payment amount based on the price of each drug in OECD member countries with a GDP per capita of at least 60% of the U.S.'s, with a fixed add-on payment per dose.
  - Scheduled to take effect on January 1, 2021.

- Status:
  - On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction.
  - On August 10, 2021, CMS issued a proposed rule to rescind the MFN Model.

Administration Proposal: Comprehensive Plan for Addressing High Drug Prices

- Mandated by the Executive Order on Promoting Competition in the American Economy
- Supports several Congressional efforts, including drug price negotiation, Part D reform, and inflationary rebates.
- Proposes administrative actions, including:
  - CMMI models to test:
    - Part B: value-based payments, shared savings, bundled payments for treatment episodes.
    - Part D: additional cost-sharing support to LIS beneficiaries using biosimilars or generics.
    - Total cost of care within Part B and Part D, including incentives for high-value therapies, biosimilars, and generics.
  - Improved data collection from insurers and PBMs about prices, rebates, and OOP spending.

I think we need to see what happens in Congress.

Center for Medicare and Medicaid Innovation Director Elizabeth Fowler, *Inside Health Policy*

State Legislative Trends

State Transparency Initiatives

Reporting triggered by price increases, based on WAC

- Threshold ranges from 10-50% depending on state
- "Lookback": may be based on a prior calendar year(s), or immediately preceding 12+ months
- Typically based on "cumulative" increase across lookback that exceeds threshold
- Current states: CA, ME, ND (implementation pending), OR, TX, UT (2022 implementation)
- Effective in 2022: MN, VA

Reporting triggered by WAC at commercial introduction

- Threshold is Medicare Part D Specialty Tier Threshold in most states
- Currently $670 (may change)
- Current states: CA, ME, ND, NH, OR, VT, WA
- Effective in 2022: MN

Reporting triggered by new drug approvals

- Not contingent on WAC
- Report due to WA after receiving "PDUFA date"
- Report due to CT after receiving approval
- Form due in TX for new drugs in Medicaid / state drug assistance programs

State Transparency Initiatives (cont'd)

Reporting Requirement When Identified by the State Based on Cost		
Connecticut	**Nevada**	**Vermont**

• Reporting triggered if included in:
  • OHS annual study of pipeline drugs, due to cost to state;
  • OHS list of not more than ten outpatient drugs which OHS determined are provided at substantial cost to the state or are critical to public health and meet specified WAC increase thresholds.
	• Reporting triggered by DHHS list of:
	  • (A) drugs deemed "essential" for treating diabetes in NV;
	  • (B) drugs included in (A) that meet specified WAC increase thresholds;
	  • (C) drugs with a WAC exceeding $40 for a "course of therapy" and that meet specified WAC increase thresholds.
		• Reporting triggered if identified by AG as 1 of up to 15 drugs, based on:
		  • Reports from DVHA of prescription drugs on which DVHA spends significant amounts and which meet certain WAC or net cost increase thresholds; and
		  • List from private payors of up to 10 drugs where net cost increased over specified threshold.

Councils/Boards that Cap and Negotiate Pricing

- Several states have established boards to examine or cap prices:

Colorado S.B. 21-175 (2021)	Maine L.D. 1499 (2019)	Maryland H.B. 768 (2019)	Massachusetts H.4000 (2019)
New Hampshire H.B. 1280 (2020)	New York Pub. Health Law § 280 (2017) Social Services Law § 367-a(7)(e) (2020)	Ohio H.B. 166 (2019)	Oregon S.B. 844 (2021)

- Such boards often:
  - Focus on net cost to state purchasers or state drug coverage (e.g., Medicaid, state employee benefits)
  - Identify drugs contributing to or exceeding cost cap
  - Conduct an affordability review
  - Negotiate supplemental rebates or threaten other coverage/purchasing consequences

Questions?

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