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Re: Oregon PDAB policy proposal brief

PDAB Policy Recommendation: Adopt National Academy for State Health Policy (NASHP) model legislation to reduce prescription drug expenditures by setting reference prices for state-regulated commercial markets using Medicare Drug Price Negotiation Program Maximum Fair Price (MFP)

Background: The 2022 Inflation Reduction Act (IRA) includes several of the most significant changes to the Medicare Part D prescription drug program since its 2006 implementation.[1,2] Most notably, the IRA removed statutory restrictions prohibiting the program from directly negotiating prices ("non-interference" clause) for drugs managed by Part D (outpatient pharmacy benefit). The drug price negotiation provisions are intended to reduce spending on drugs that impose a substantial cost on the program. To give manufacturers time to recoup research investments and be rewarded for innovation, negotiation is limited to drugs that have been on the market, free of generic or biosimilar competition, for a prolonged period. Specific criteria for drugs identified for negotiation are summarized in the box.

Criteria for drugs selected for Medicare Drug Price Negotiation Program

- >$200 million in annual spending
- Single source branded small molecule or biologic products without therapeutically equivalent generics or biosimilars that are approved, licensed, and marketed.
  - Small molecule drugs must be at least 7 years post approval
  - Biologics must be at least 11 years post approval

•Not drugs exclusively indicated for orphan designated conditions. (exclusions broadened through HR.1[2025])
•Not a plasma-derived product or from a smaller biotech firm

For each drug identified, CMS has developed a negotiation process for establishing a Maximum Fair Price (MFP) for the program.[3,4] Negotiations for MFP start with a statutorily defined ceiling price based on the lower of net prices Medicare already pays for drugs (both Part D and Part B) or a percentage of the non-federal Average Manufacturer Price (a benchmark price used by the Department of Veterans Affairs). This ceiling price is the starting point during the negotiation process with manufacturers to ultimately establish MFP. The Medicare program has negotiated prices for ten drugs in 2024, going into effect in 2026. A second cycle of 15 drugs was negotiated in 2025, and will go into effect in 2027. Negotiations for the third cycle of 15 drugs are ongoing with MFP unveiled later in 2026 for implementation in 2028, bringing the total number of drugs with MFP to 40.

While the Medicare Drug Price Negotiation Program applies only to the federal Part D and Part B program, several states have explored adoption of Medicare negotiated MFP as benchmark reference prices for drugs purchased in their state. Both Maryland's (Jardiance, Ozempic) and Colorado's (Enbrel) PDABs have identified drugs that are affordability challenges in their state and have benchmarked payment limits to Medicare's MFP. Although Colorado's 2027 UPL implementation was paused due to a preliminary injunction, the state will appeal this decision.

The National Academy for State Health Policy (NASHP) has advanced model legislation that enables states to adopt Medicare MFP as a reference price for state markets.[5] NASHP's model legislation (see model language below) includes a process by which states can evaluate the potential savings for adoption of drug-specific MFP. Oregon's PDAB is ideally positioned to validate and estimate savings accrued for adoption of drug-specific payment limits statewide. Additionally, Oregon's PDAB can capture feedback from stakeholders (e.g. patients, plans, manufacturers) about the potential impact of proposed payment limits. In some cases, adoption of Medicare MFP as a statewide reference price may not be financially advantageous (e.g. proliferation of generic or biosimilar products). Model legislation stipulates that plan savings from implementation of the payment limits must be used to lower health care costs for members, and that plans must report how those savings were passed on to members. Although NASHP cites several analyses which suggest savings accrued through selected implementation may be significant, a comprehensive study in Oregon has not been conducted. Adoption of NASHP model legislation would necessitate a detailed analysis describing drug and payer-specific impact of payment limits across Oregon commercial markets. The model legislation excludes Medicaid because of the added complexity of the state/federal match and the significant discounts (e.g. best price, inflationary rebates) already experienced in this program. To partially estimate the financial impact of such a proposal, the analysis below projects potential savings for adopting Medicare MFP-based payment limits for commercial plans in Oregon for selected drugs reviewed by Oregon's PDAB.

Among the 25 drugs reviewed in the first two years of the Medicare Drug Price Negotiation program, seven were also reviewed by Oregon's PDAB. Of these seven, three would likely not generate significant savings because substitutable generics have come to market (Entresto, Jardiance, Xarelto). Commercial spending, existing rebates, and projected savings through MFP-based payment limits are summarized in Table 1 below. Based on data reported in Oregon PDAB's affordability reports, these four drugs (Eliquis, Trelegy Ellipta, Vraylar, Ozempic) account for over $86 million in annual *net* spending for commercial plans. MFP-based discounts from list price were 23% to 34% greater than rebates reported in Oregon PDAB affordability reports. Based on historic APAC utilization and MFP-based reference prices for these four drugs, total net spending avoided was estimated to be $36,392,445, with drug-specific estimates

ranging from $1.7 (Trelegy Ellipta) to $25.2 million (Ozempic). Costs avoided per enrollee ranged from $781 (Eliquis) to $2,464 (Vraylar) per enrollee.

Table 1: MFP-based reference price commercial spending projections for drugs reviewed by Oregon PDAB

Drug	Eliquis	Trelegy Ellipta	Vraylar	Ozempic
30-day list price (2023)[1]	$521	$654	$1,376	$959
MFP 30-day[1]	$231	$175	$770	$274
MFP discount off list[1]	55.7%	73.2%	44.0%	71.4%
APAC year[2]	2023	2023	2023	2024
APAC gross spend[2]	$30,683,588	$7,157,460	$5,653,379	$108,507,109
APAC Rx count[2]	46,684	11,859	4,549	109,488
APAC gross spend per rx[2]	$657	$604	$1,243	$991
Oregon PDAB carrier rebate[3]	31.1%	48.8%	10.4%	48.2%
APAC net spend per rx (calculated)[4]	$453	$309	$1,114	$513
APAC net spend (calculated)[5]	$21,140,992	$3,664,620	$5,065,428	$56,206,682
APAC MFP-based net spend per rx (calculated)[6]	$291	$161	$695	$283
APAC MFP-based net spend (calculated)[7]	$13,604,432	$1,915,222	$3,163,591	$31,002,031
MFP-based spend avoided, total (calculated)[8]	**($7,536,561)**	**($1,749,397)**	**($1,901,836)**	**($25,204,651)**
MFP-based spend avoided, per enrollee (calculated)[9]	($781)	($893)	($2,464)	($1,470)

1: CMS Fact Sheet, Negotiated Prices IPAY 2026; CMS Fact Sheet, Negotiated Prices IPAY 2027;
2: Oregon PDAB Affordability reviews 2025 – APAC commercial utilization; Oregon PDAB Affordability reviews 2026 – APAC commercial utilization;
3: Oregon PDAB Affordability reviews 2025, 2026 – Insurance carrier submitted data on discounts
*4: APAC net spend per rx = gross spend per rx * (1 - Oregon PDAB carrier rebate)*
*5: APAC net spend = APAC net spend per rx * APAC Rx count*
*6: APAC MFP-based net spend per rx = APAC gross spend per rx * (1 - MFP discount off list)*
*7: APAC MFP-based net spend = APAC MFP-based net spend per rx * APAC Rx count*
8: MFP-based spend avoided, total = APAC MFP-based net spend - APAC net spend
9: MFP-based spend avoided, per enrollee = MFP-based spend avoided, total / APAC patients (not reported above, see data in 2)

Costs avoided in context: In 2024, commercial plans reported $2.5 billion in gross pharmacy spending across 1,178,384 enrollees (Oregon PDAB state reference report 2026). Assuming 20% discount factor on aggregate gross spending[6], net pharmacy spending is estimated to be approximately $2 billion in 2024. Thus, MFP-based reference price purchasing limits for these four drugs have the potential to save commercial plans in the state 1.8% of their net pharmacy spending.

Assumptions and Limitations

- Estimates are based on historical reports of utilization, gross spending, and carrier reported discounts. Changes in market dynamics (e.g. successful patent challenges), reimbursement frameworks (e.g. rebate changes), and utilization (e.g. shifts in use) would affect these figures.
- Estimates reflect universal adoption of MFP-based reference price by the plans that report data to the Oregon APAC. NASHP model legislation allows for opt-out for ERISA plans or other state-specific language.

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This model bill updates a previous model released by NASHP in November 2022 directing a state to use the Medicare maximum fair prices as upper payment limits. This update includes a process for validating savings and for public comment.

An Act to Reduce Prescription Drug Costs Using Reference-Based Pricing

Section 1. Statement of Legislative Intent

[Notes and Drafting Considerations: In some states these types of statements of intent are considered helpful, but in some states the rules of legislative drafting discourage them. They can help future users of the bill, including implementers, legislators, and even judicial authorities to interpret language and purpose in case there is any dispute about legislative intent. States that use this type of statement of purpose may want to modify it to include any available state-specific information regarding the impact of high drug costs.]

The purpose of this chapter is to protect the safety, health, and economic well-being of **[State]** people by safeguarding them from the negative and harmful impact of the high cost of prescription drugs. In enacting this Act, the legislature finds that

1) Access to prescription drugs is necessary for **[State]** people to maintain or achieve good health;

2) High drug costs negatively impact the ability of **[State]** people to obtain prescription drugs and rising costs that exceed reasonable levels thereby endanger the health and safety of **[State]** people to maintain or achieve good health;

3) High costs for prescription drugs threaten the economic well-being of **[State]** people and endanger their ability to pay for other necessary and essential goods and services, including housing, food, utilities, and other health care;
4) High costs for prescription drugs contribute significantly to a dramatic and unsustainable rise in overall health care costs and the cost of commercial health insurance that threaten the overall ability of **[State]** people to obtain health coverage and maintain or achieve good health;
5) High costs for prescription drugs contribute significantly to rising state costs for health care provided and paid for through health insurance programs for public employees, including employees of the state, municipalities and counties, school districts, institutions of higher education, and retirees whose health care costs are funded by public programs, thereby threatening the ability of the state to fund those programs adequately and further threatening the ability of the state to fund other programs necessary for the public good and safety, such as public education and public safety;
6) The federal government, as required by law, has entered into agreements with certain drug manufacturers resulting in a determination of a maximum fair price for certain high-cost prescription drugs covered by the Medicare program. The adoption of those maximum fair prices to drug reimbursements in **[State]** would result in health care savings to the benefit of the people of **[State];**
7) Based on findings (1) through (6), the legislature finds that high costs for prescription drugs threaten the safety and well-being of **[State]** people and find it is necessary to act to protect [State] people from the negative impact of high costs.

Section 2. Definitions

(a) "State Entity" means any agency of state government that purchases prescription drugs on behalf of the state for a person whose health care is paid for by the state, including any agent, vendor, fiscal agent, contractor, or other party acting on behalf of the state. State Entity does not include the medical assistance program established under 42 U.S.C. §1396 et seq.
(b) "Health Plan" means **[State's definition of health plan as defined in insurance statute]**.
(c) "ERISA Plan" means a plan qualified under the Employee Retirement Income Security Act of 1974.
(d) "Participating ERISA Plan" means an ERISA plan that has elected to participate in the requirements and restrictions of this subchapter as described in Section 6 below.
(e) "Maximum Fair Price" or "MFP" means the maximum rate for a drug published by the Secretary of the United States Department of Health and Human Services pursuant to Section 1195 of P.L. 117-169 (2022), including any adjustments to an initial determination of Medicare Fair Price based upon annual inflationary adjustments or renegotiations.
(f) "Price Applicability Period" means the period of time defined in Section 1191 of P.L. 117-169 (2022).
(g) "MFP Drug" means a drug subject to a Maximum Fair Price.

(h) **"[Implementing Authority]" means XXXXXXX**

(i) "Upper Payment Limit" means the maximum amount that a state entity, health plan, or participating ERISA plan may reimburse for an MFP Drug.

[Notes and Drafting Considerations: This definition is a placeholder for the state actor that will have the primary authority to implement and oversee the actions described in this model bill. For example, some states may decide that the superintendent of insurance is the appropriate authority to oversee this. States that have entities specifically looking at health care costs might determine that those entities are more appropriate as an implementing body, especially if those entities have subject matter expertise related to prescription drug pricing and distribution. States that have resources within their health care agency or Medicaid program or related to the administration of their state employee health plan may want resources within those agencies to take a leading role.

Section 3. Determination of MFP Drugs Subject to State Review

(a) The **[Implementing Authority]** shall annually review the list of MFP Drugs for which CMS has negotiated a price with manufacturers.

Section 4. Validation of Drug Selection and Cost Savings

[Notes and Drafting Considerations: This section maps out the process that a state will follow to determine whether referencing to the MFP will provide meaningful savings. There are several reasons why a state would decide to conduct its own savings analysis rather than simply setting a reference price based on the federal determination. By conducting its own analysis a state ensures it is not imposing an upper payment limit in situations where the data suggest there would be minimal savings or no savings. A state may also find value in performing its own due diligence versus relying solely on work performed by the federal government.

The ability of a state to conduct a complete and accurate assessment of potential savings will heavily depend on the availability of data and resources. States that have existing assets such as a well-developed All Payer Claims Database or drug price transparency program that requires supply chain entities to submit data on a regular basis may already have access to some key data. States that do not have those resources will need to determine whether mandating the reporting of information by pharmacy benefit managers (PBMs) and payers is a necessary step in conducting the analysis needed to estimate savings.

Because evaluating net price requires data that most states do not readily have (because data are treated as proprietary by PBMs and payers), states may need to purchase publicly available information necessary to estimate net price. For this reason, the model suggests that the implementing agency be given the authority to purchase external data sources and analytical capacity from third parties. The model also empowers the state to request net price information and other data from payers, participating ERISA plans,

and PBMs. States should consider how they will respond to requests to keep this information confidential and the extent to which a process to protect some information from public disclosure could be accounted for in statute or in regulation. Data from the state employee health plan or other state purchasers could be an accurate source of information and a good proxy for costs incurred by commercial plans.]

(a) For each MFFP Drug the **[Implementing Authority]** shall estimate the total cost savings to the health care system in the state if the state were to implement the MFP as an upper payment limit for the MFP Drug.

1. In making its determination of significant cost savings the **[Implementing Authority]**:

A. May consult as necessary with the Medicaid pharmacy director and the administrator of the State Employee Health Plan;

B. Shall have the authority to contract with third party entities for the purpose of analyzing potential savings;

C. Shall have the authority to procure third party data sources necessary for estimating savings;

2. Upon request from the **[Implementing Authority]**, any payers, participating ERISA Plans, and pharmacy benefit managers shall submit to the **[Implementing Authority]** 1) its current net price for the MFP drugs and 2) its annual spending on a per unit, per prescription, and aggregate basis.

3. No later than **XXXXXXX** of each year each health plan and participating ERISA plan shall provide to the **[Implementing Authority]** the estimated savings that it would expect to achieve with respect to each MFP drug if the MFP were implemented as an upper payment limit.

(b) No later than **XXXXXX** of each year the **[Implementing Authority]** shall publish the estimated aggregate annual savings with respect to each of the drugs described in Section 4(a) above and the estimated overall savings. The information published by the **[Implementing Authority]** shall describe how the **[Implementing Authority]** calculated the savings and in addition will also include:

1. An estimate of the number of people in the state who use the MFP drug annually

2. The total amount spent on each of the MFP drugs in the state

(c) After publishing the estimated annual savings, the **[Implementing Authority]** shall invite and receive public comment. The **[Implementing Authority]** shall specifically notify each of the manufacturers of MFP drugs for which the commissioner has made a determination of significant savings as described in Section 4 above of the opportunity to submit public comment. The **[Implementing Authority]** shall specifically invite public comments on whether the state should use the MFP as a basis for an upper payment limit.

Section 5. Setting of MFP as an Upper Payment Limit

(a) If, after the public hearing described in Section 4(c), the **[Implementing Authority]** determines that there are significant savings with respect to any of the MFP drugs, the **[Implementing Authority]** shall establish an upper payment limit for the MFP drug. An upper payment limit shall not be less than the MFP. If the **[Implementing Authority]** establishes an upper payment limit that is above the MFP the **[Implementing Authority]** shall explain its reasoning.

(b) The upper payment limit is the maximum payment for an MFP drug and applies to all purchases of the MFP drug and reimbursements for a claim for the MFP drug during the price applicability period when the MFP drug is dispensed, delivered, or administered to an individual in the state in person, by mail, or by other means. The upper payment limit does not include a dispensing fee paid to a pharmacy for dispensing an MFP drug, and nothing in this chapter shall be interpreted to prevent a retail pharmacy from receiving a dispensing fee in addition to the MFP.

(c) Only the establishment of an upper payment limit shall constitute final action for the purpose of this title and any person or entity alleging to be aggrieved by the decision of the **[Implementing Authority]** to establish an upper payment limit may request judicial review within 30 days of the Board's decision.

Section 6. ERISA Plan Opt-In

An ERISA plan may elect to participate in the provisions of this chapter. Any ERISA plan that desires its purchase of MFP drugs to be subject to the upper payment limit described in Section 5 shall notify the **[Implementing Authority]** in writing.

Section 7. Rulemaking Authority

[Notes and Drafting Considerations: Constitutional and statutory considerations around rulemaking will vary significantly from state to state. Some states may decide to use rulemaking to provide additional detail and guidance to implementers with respect to many of the items above, including the drug selections process, the calculation of savings, the determination of which level of savings are "significant," and the setting of any upper payment limit. States may want to use rulemaking to specify timeframes for the tasks described in this model bill. A state may want to add processes for monitoring for drug shortages for drugs impacted by an upper payment limit.]

The **[Implementing Authority]** shall have the authority to implement regulations under **[Cite state's Administrative Procedures Act]** to fully implement the requirements of this chapter.

Section 8. Registered Agent and Office within the State

Any entity that sells, distributes, delivers, or offers for sale any drug in the state is required to maintain a registered agent and office within the state.

Section 9. Use of Savings

(a) Any savings generated as a result of the requirements in this Act must be used to reduce health care costs. Any state entity, health plan or participating ERISA plan must calculate such savings and use such savings directly to reduce costs for its members.

(b) No later than April 1 of each calendar year, each state entity, health plan and participating ERISA plan subject to this chapter shall submit to the **[Implementing Authority]** a report describing the savings achieved for the previous calendar year and how those savings were used to achieve the requirements of subsection (a) above.
(c) The **[Implementing Authority]** shall implement rules setting forth the method for calculating savings and the format and submission requirements for the report described in this section.

Section 10. Enforcement

Each violation of this chapter shall be subject to a fine of $10,000. Every individual transaction in violation of this Act is determined to be a separate violation. The attorney general is authorized to enforce the provisions of this statute. The attorney general is authorized to recover all costs and attorneys fees from any person or entity determined to be in violation of this statute.

Section 11. Prohibition on Withdrawal of MFP Drugs for Sale

(a) It shall be a violation of this chapter for any manufacturer or distributor of a referenced drug to withdraw that drug from sale or distribution within this state for the purpose of avoiding the impact of the rate limitations set forth in this Act
(b) Any manufacturer that intends to withdraw an MFP drug from sale or distribution from within the state shall provide a notice of withdrawal in writing to the **[Implementing Authority]** and to the attorney general 180 days prior to such withdrawal.
(c) The **[Implementing Authority]** shall assess a penalty on any manufacturer or distributor that it determines has withdrawn an MFP drug from distribution or sale in the state in violation of subsection (a) or (b) of this section. With respect to each MFP drug for which the **[Implementing Authority]** has determined the manufacturer or distributor has withdrawn from the market, the penalty shall be equal to $500,000.

Section 12. Severability Clause

If any provision of this chapter or the application thereof is determined to be invalid, the invalidity does not affect other provisions or applications of this subchapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.