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L E G I S L A T I V E A N A L Y S T ' S O F F I C E

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State Prescription Drug Purchases. Pricing Standards. Initiative Statute.

Presented to:
Assembly Health Committee
Hon. Jim Wood, Chair
and
Senate Health Committee
Hon. Ed Hernandez, Chair





Summary

- ☑ This measure prohibits state entities from paying more for any prescription drug than the lowest price paid by the United States Department of Veterans Affairs (VA) for the same drug. The measure applies both to direct purchases by the state and where the state is the ultimate payer of the drug. The fiscal impact of this initiative is unknown due to:
 - A lack of transparency around what prices the VA pays.
 - Uncertainty around how manufacturers might alter prescription drug prices as a market response to this initiative.



Background



The State Is a Purchaser or Payer of Prescription Drugs.

The state purchases or pays for prescription drugs in a number of programs, for example by providing comprehensive health care coverage to the state’s low-income residents through the Medi-Cal program and by providing health care, including prescription drug therapies, to the state’s inmate population. The state also pays for prescription drugs by providing health coverage to state workers and retirees.



Annual State Drug Expenditures Totaled More Than \$4 Billion in 2014-15.

As shown in the figure below, the state spent more than \$4 billion on prescription drugs in 2014-15. This estimate excludes prescription drug expenditures on the managed care side of the Medi-Cal program.

Annual State Drug Expenditures—Selected Agencies/Programs		
<i>2014-15, All Funds</i>		
Entity/Program	Recipients Served	Drug Expenditures (In Millions)
Medi-Cal	Medi-Cal recipients	\$1,809 ^a
Public Employees’ Retirement System	Public employees, dependents, and retirees	1,730
University of California	Students, clinics, and hospital patients	334
Corrections	Inmates	211
Public Health	AIDS Drug Assistance Program recipients	57
State Hospitals	State hospital patients	35
Developmental Services	Developmental center residents	8
California State University	Students	4
Juvenile Justice	Juvenile wards	0.4
Total		\$4,189

^a Net of rebates. Amount does not include Medi-Cal managed care drug expenditures.

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- ☑ ***State Entities May Purchase Drugs Directly From Drug Manufacturers.*** State entities sometimes purchase prescription drugs directly from manufacturers. For example, the Department of General Services (DGS) enters into contracts with drug manufacturers that set prices for the prescription drugs purchased directly by multiple state departments and programs, including the California Department of Corrections and Rehabilitation and the Department of State Hospitals.

 - ☑ ***State Entities May Be Ultimate Payers of Drugs.*** In cases where the state does not purchase drugs directly from the manufacturer, the state can still act as the ultimate payer of prescription drugs. For example, similar to the way it contracts with manufacturers, DGS establishes pricing agreements with drug *wholesalers* on behalf of departments that purchase drugs directly from wholesalers. In other cases, state agencies are the ultimate payer of prescription drugs even though they do not purchase the drugs directly. For example, in the Medi-Cal fee-for-service (FFS) outpatient drug program, the state reimburses retail pharmacies for the costs of the drugs the pharmacies purchase and then dispense to program beneficiaries.

 - ☑ ***Drug Purchasers Often Pay Different Prices for the Same Drugs.*** The price charged by a drug manufacturer is often unique to each individual purchaser.

 - ☑ ***Prices Paid for Prescription Drugs Are Often Subject to Confidentiality Agreements.*** Prescription drug purchase agreements often contain confidentiality clauses that bar public disclosure of the negotiated prices. As a result, the prescription drug prices paid by a particular purchaser may be unavailable to the public. However, where a state or federal governmental purchaser is involved, the California Public Records Act or the federal Freedom of Information Act (FOIA) must be considered to see whether public disclosure is required or whether an exemption applies.



State Strategies to Reduce Prescription Drug Spending.

California state entities pursue a variety of cost containment strategies to reduce prescription drug spending. For example:

- ***Department of Health Care Services' (DHCS) Medi-Cal Program Negotiates Supplemental Rebates.*** On top of certain federally mandated rebates that all state Medicaid programs receive, DHCS negotiates contractual agreements directly with drug manufacturers for supplemental rebates in exchange for removing prior authorization requirements for the rebated drugs. (Retail pharmacies that dispense the drugs and are reimbursed by DHCS for the drugs' costs are not a party to these agreements.)
- ***DGS Negotiates on Behalf of Several State Entities.*** DGS negotiates prescription drug pricing agreements on behalf of five participating state departments that purchase drugs. By negotiating as a single, larger body, the participating state departments are able to obtain lower prices.
- ***California Public Employees' Retirement System (CalPERS) Employs a Pharmacy Benefits Manager.*** CalPERS, for a subset of its health plans, employs a pharmacy benefits manager that purchases prescription drugs on behalf of members of multiple, competing health plans.



Programs to Reduce Federal Prescription Drug Expenditures.

The federal government has established discount programs that place upper limits on the prices paid for prescription drugs by selected federal payers, often resulting in lower prices than those available to private purchasers.



The VA Obtains Additional Discounts From Drug Manufacturers. On top of the mandatory federal discount programs described above, the VA regularly negotiates additional discounts from drug manufacturers that lower its prices below what other federal departments pay. Manufacturers provide these discounts in return for placement on the VA's formulary—the list of drugs that VA doctors may prescribe. The VA's formulary is relatively narrow, giving manufacturers an incentive to grant price concessions in exchange for their drugs being made available to VA health care consumers.

Proposal

- Measure Establishes a Price Ceiling on Prescription Drug Prices Paid for by the State Equal to the VA's Lowest Price Paid.*** This measure would prohibit state entities from paying more for a prescription drug than the lowest price paid by the VA for the same drug (if the VA has paid for that drug) after all rebates and other discounts are factored in for both California state entities and the VA. The measure extends the price ceiling to both direct purchases by the state and where the state serves as the ultimate payer of the drugs.
- Medi-Cal Managed Care Exemption From Price Ceiling.*** DHCS administers two distinct Medi-Cal service delivery systems. Under the FFS system, a health care provider receives a payment from DHCS for each individual medical service obtained by a Medi-Cal beneficiary. In contrast, under managed care, DHCS pays a health plan a preset, monthly, per-person amount in exchange for the health plan providing comprehensive health care to the beneficiary. The measure exempts Medi-Cal's managed care program from its price ceiling requirements.
- DHCS Verifies That State Drug Prices Do Not Exceed the VA's.*** The measure requires the DHCS to determine whether state entities are paying the same or less than the lowest price paid by the VA on a drug-by-drug basis.
- Certain State Entities Required to Enter Into Rebate Programs With Drug Manufacturers.*** In cases where the state does not purchase drugs directly from manufacturers, the measure would require that the state, when necessary, establish additional rebate-like programs whereby drug manufacturers make payments to the state until the cost of each drug equals the lowest price paid by the VA for that same drug.



Overall Fiscal Effects

- Overall Fiscal Effect of Measure Highly Uncertain.*** Estimating this measure's effect on state prescription drug spending is challenging due to uncertainty around (1) whether the lowest prices the VA pays for prescriptions drugs are publicly available and (2) how drug manufacturers would respond in the market if this measure were enacted provided that the lowest effective VA prices can be identified. Both areas of uncertainty lead to difficulty assessing the measure's impact on state drug spending under a range of plausible scenarios, discussed further below.

- Measure Would Introduce New State Operations Costs.*** The measure requires new state activities, including verifying that state drug prices are less than or equal to VA drug prices, establishing the operational capacity to collect rebates from drug manufacturers, and making other front-end operational changes to the way state programs pay for or purchase prescription drugs. These new state operations costs are uncertain, but likely to be minor.



Fiscal Effects— If Lowest VA Drug Prices Cannot Be Identified

- Uncertain Whether Lowest VA Prescription Drug Prices Are Publicly Available.*** The measure prohibits the state from paying more for prescription drugs than the lowest VA price. While the VA publishes prices of the prescription drugs it purchases, it is unknown to what extent these listed prices are the lowest prices the VA pays. The VA has not confirmed whether the published drug prices accurately identify the lowest prices the VA pays. It is also uncertain whether public disclosure of the lowest prices paid would be required or exempt under FOIA.

- Confidentiality of VA Drug Prices Compromises the State's Ability to Implement This Measure.*** If the VA declines to disclose the lowest prices it pays for prescription drugs, DHCS would be unable to assess whether the state is paying less than or equal to the lowest price paid by the VA. This could impair the state's ability to implement the measure and achieve full potential savings related to prescription drug spending. This is because it is uncertain what discretion would be afforded the state to implement the measure based on its best estimate of the lowest VA price.



Fiscal Effects— If Lowest VA Drug Prices Can Be Identified

- Fiscal Effect Remains Indeterminate Even if Lowest VA Drug Prices Can Be Identified.*** Drug manufacturers may respond to the measure in a variety of ways, and how they do so would have a significant effect on the fiscal impact of the measure. Below, we outline three plausible of many possible manufacturer responses, none of which is mutually exclusive and each of which could be pursued to varying degrees in the circumstance where the lowest VA prices can be identified or estimated.
- Scenario #1: Drug Manufacturers Offer Lowest VA Prices to the State.*** If manufacturers choose to offer the lowest VA prescription drug prices to the state, this measure may achieve state savings to the extent that the lowest price paid by the VA is lower than that paid by state entities. However, these savings could be at least partially offset if manufacturers respond by raising the prices of other drugs paid for by the state but not purchased by the VA.
- Scenario #2: Drug Manufacturers Decline to Offer Lowest VA Prices to the State.*** The measure places no obligations on drug manufacturers to offer prescription drugs to the state at the lowest VA price. Therefore, drug manufacturers may decline to offer the state some or all of the drugs purchased by the VA at the lowest price paid by the VA. This manufacturer response could result in various state responses, each of which generates further uncertainty around the fiscal effects of the measure. These state responses could include:

 - ***State Programs Could Modify Formularies.*** Most state departments and programs have discretion over which drugs they make available to their beneficiaries. Should manufacturers decline to extend VA pricing on some or all drugs to these state entities, the entities may change which drugs they make available, offering only (1) those drugs that the VA does not purchase and (2) drugs that manufacturers will offer at the lowest VA price.



Fiscal Effects— If Lowest VA Drug Prices Can Be Identified (Continued)

- ***DHCS May Have to Disregard Measure's Price Ceiling.*** DHCS, as administrator of California's Medi-Cal program, is required by federal Medicaid law to offer most Food and Drug Administration (FDA)-approved prescription drugs to beneficiaries. Failing to offer an FDA-approved drug would likely result in the loss of federal financial participation in the pharmacy portion of the Medi-Cal program. Should manufacturers decline to extend VA pricing to Medi-Cal, DHCS may have to disregard the measure and pay higher prices than the measure allows in order to comply with federal Medicaid law. Furthermore, the measure could endanger the supplemental rebates that DHCS collects from drug manufacturers because these rebates derive from voluntary state agreements with manufacturers that, were the negotiated prices higher than the VA's, could contravene the measure's provisions about allowable agreements. In such circumstances, the measure could raise DHCS spending on prescription drugs.



Scenario #3: Drug Manufacturers Raise VA Drug Prices Given Their New Pricing Benchmark Role. To continue to be able to offer prescription drugs to state entities and minimize reductions in their revenues, drug manufacturers may elect to raise VA drug prices. The fiscal effect of the measure would vary under this scenario depending on the extent to which manufacturers raise VA prices and tie state prices to the higher VA prices. When VA drug prices were previously extended to Medicaid nationally, drug manufacturers responded by raising VA drug prices before the U.S. Congress subsequently removed the linkage between VA and Medicaid pricing.