



# Pension and Health Benefits Committee Agenda Item 10

June 14, 2016

**Item Name:** Drug Price Relief Act

**Program:** Health Benefits

**Item Type:** Information

## **Executive Summary**

If approved by voters in November 2016, the California Drug Price Relief Act (Act) would prohibit California state entities from paying more for a prescription drug than the lowest price paid for the same drug by the United States Department of Veterans Affairs (VA).

The proponent's intent to lower drug prices for certain Californians, such as California Public Employees' Retirement System (CalPERS) members, is very attractive and might possibly provide cost savings; however, passage and implementation of the Act would drastically change the current drug purchasing landscape and could result in unintended consequences.

## **Strategic Plan**

This item supports CalPERS 2012-17 Strategic Plan Goal C to engage in state and national policy development to enhance the long-term sustainability and effectiveness of our programs.

## **Background**

United States (U.S.) pharmaceutical prices are among the highest worldwide. Of particular concern are specialty drugs, which are expensive and increasing in use. To help control rising pharmacy expenditures, many states have considered actions such as price transparency requirements, bans on price gouging, and bans on direct-to-consumer advertising.

Many commercial health plan members in the U.S., including CalPERS members, receive their prescription drugs via pharmacy benefit managers (PBMs) and health plan insurance carriers, which negotiate prices, discounts, and rebates with drug manufacturers. Although PBMs and health plans can negotiate reductions from the suggested list price of drugs, they rarely obtain lower net prices than Medicaid because of that program's federally-mandated rebates.<sup>1</sup>

Medicaid always receives the "best price"<sup>2</sup>, or the lowest price paid by any private-sector purchaser for a drug, and manufacturers must provide additional rebates to Medicaid if they offer commercial health plan members a lower price. Only certain federal agencies, such as the VA, are permitted to receive drug prices lower than the Medicaid best price<sup>3</sup>. The VA updates its

<sup>1</sup> U.S. Government Accountability Office. *Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices*. June 2014. <http://www.gao.gov/assets/670/664521.pdf>.

<sup>2</sup> 42 C.F.R. 447.505

<sup>3</sup> 42 U.S.C. 1396r-8(c)(1)(C)

website twice a month with its pharmaceutical pricing data<sup>4</sup>; however, this public data omits “restricted” agency-specific prices and cost reductions via rebates paid to the VA.<sup>5</sup> In general, this lack of complete price transparency occurs because contracts between drug manufacturers and other entities contain provisions that make agreements confidential and proprietary.

To highlight the differences in purchasing power, the VA purchases drugs at prices below the Medicaid best price whereas CalPERS contracts with a PBM and with health plans to administer prescription drug benefits and then re-negotiates with these entities annually to ensure that CalPERS’ drug pricing remains competitive. CalPERS purchases drugs for over 1.4 million active and retired state, local government, and school employees and their family members and, in 2014, total spending for outpatient retail and mail-order prescription drugs for all CalPERS health plans, including Medicare plans, was \$1.8 billion. The VA purchases drugs on behalf of over 5 million military veterans, and approximately 59 million people (including children, low-income adults, pregnant women, disabled individuals, and low-income seniors)<sup>6</sup> have access to drugs under Medicaid.

### Analysis

According to the proponent of the Act, Michael Weinstein, president of the AIDS Healthcare Foundation, the Act’s passage would result in “significant cost savings to California and its taxpayers for prescription drugs.”<sup>7</sup> Advocates of the act estimate the Act could help at least 5 million Californians who receive drugs through state programs<sup>8</sup>.

The Act applies to “the State of California, and each and every state administrative agency or other state entity.” The Act specifically excludes “drugs purchased or procured, or rates developed, pursuant to or under any Medi-Cal managed care program” from its provisions; however, it does not exclude CalPERS managed care plans. As related to CalPERS, then, the Act would:

- Apply the VA price ceiling to programs where the state is the ultimate payer for a drug, which could include CalPERS even if CalPERS does not purchase the drug directly;
- Require responsible state agencies, such as CalPERS, to enter into agreements with drug manufacturers for further price reductions so that the net cost of the drug, as determined by the California Department of Health Care Services (DHCS), is the same or less than the lowest price paid for the same drug by the VA,
- Require CalPERS to implement and comply with the law no later than July 1, 2017, and
- Allow CalPERS to create regulations to implement the Act.

The Legislative Analyst’s Office (LAO), in its May 2016 report to the Joint Hearing of the Senate and Assembly Committees on Health (Attachment 1), indicated that the overall fiscal effect of the Act is “highly uncertain” 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.”

<sup>4</sup> See <http://www.herc.research.va.gov/include/page.asp?id=pharmaceutical-costs> and <http://www.va.gov/oal/business/fss/pharmPrices.asp>.

<sup>5</sup> U.S. Department of Veterans Affairs FAQ, *How does VA determine the cost of drugs submitted for reimbursement?* <http://www.va.gov/cbo/payerinfo/faqpbmtpp.pdf>, dated January 2011.

<sup>6</sup> See <https://www.medicaid.gov/medicaid-chip-program-information/by-population/by-population.html>.

<sup>7</sup> The California Drug Price Relief Act, [https://oag.ca.gov/system/files/initiatives/pdfs/15-0009%20\(Prescription%20Drug%20Costs\).pdf](https://oag.ca.gov/system/files/initiatives/pdfs/15-0009%20(Prescription%20Drug%20Costs).pdf).

<sup>8</sup> Seipel, Tracy. *Measure slashing drug prices may go to California voters next fall*. San Jose Mercury News. November 3, 2015. [http://www.mercurynews.com/health/ci\\_29062082/measure-slashing-drug-prices-may-go-california-voters](http://www.mercurynews.com/health/ci_29062082/measure-slashing-drug-prices-may-go-california-voters).

The Act's intent to lower drug prices for Californians is very attractive; however, if the Act is approved by voters and becomes law, it may cause:

- a. Increased drug prices for the VA, instead of decreased prices for CalPERS and other state entities as intended;
- b. Disruption of CalPERS PBM and health plan contract administration efforts;
- c. Decreased access to certain drugs for CalPERS members; and,
- d. Compliance challenges.

#### Potential Increase in Drug Prices

The Act could cause pharmaceutical manufacturers to increase their VA prices instead of lowering the prices paid by California state purchasers such as Medi-Cal and CalPERS. One example of similar unintended consequences occurred after the passage of the federal Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), which amended sections of the Social Security Act that cover payments for outpatient drugs.

Among other provisions, OBRA 1990 required manufacturers of brand-name drugs to begin giving certain governmental entities the best price for drugs in the U.S. The best price includes rebates and discounts, is "the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States," and, at the time of its passage, governmental entities included Medicaid, the VA, the Department of Defense (DOD), and other federal programs.

Following the passage of OBRA 1990, the U.S Government Accountability Office found in 1991 that both the VA and DOD experienced increases in prescription drug purchase prices.<sup>9</sup> Subsequently, Congress passed the Veterans Health Care Act of 1992,<sup>10</sup> which excluded drug prices obtained by the VA and by selected other entities<sup>11</sup> from the calculation of best prices, leaving Medicaid as the sole recipient of "best price." Years later, the negative effects of OBRA 1990 were still being felt. The Congressional Budget Office found in 1996 that the Medicaid best price provision increased the prices paid by some purchasers in the private sector because "pharmaceutical manufacturers are much less willing to give large private purchasers steep discounts off the wholesale price when they also have to give Medicaid access to the same low price."<sup>12</sup>

#### Potential Effects on CalPERS PBM and Health Plan Contracting

The Act's requirement for state entities to enter into agreements with drug manufacturers for further price reductions less than or equal to what the VA pays would be a significant departure from CalPERS' current reliance on a PBM or health plan to negotiate prices, procure drugs from manufacturers, and deliver them to members.

Contracting separately with drug manufacturers would likely conflict with PBM contract terms. If contracts could not be amended, leaving CalPERS without a tenable PBM arrangement,

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<sup>9</sup> U.S. Government Accountability Office. *Medicaid: Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions*. September 1991. <http://www.gao.gov/products/HRD-91-139>.

<sup>10</sup> See <https://www.congress.gov/bill/102nd-congress/house-bill/5193/text/enr>.

<sup>11</sup> Also excluded were the Indian Health Service, state veterans homes, Department of Defense, Public Health Service, the Federal Supply Schedule of the General Services Administration, and state pharmaceutical assistance programs.

<sup>12</sup> U.S. Congressional Budget Office. *How The Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*. January 1996. At <https://www.cbo.gov/sites/default/files/104th-congress-1995-1996/reports/1996doc20.pdf>.

CalPERS might be forced to collaborate with other state agencies to procure, warehouse, and distribute drugs. This new arrangement would create supply chain hurdles, and it is doubtful such a massive build-out could be accomplished by the Act's compliance date of July 1, 2017.

Finally, there is no current provision in the PBM or health plan contracts that would allow CalPERS to transmit net cost drugs price data to DHCS for comparison with the lowest net price paid by the VA. Because such cost data are considered confidential, the transmission would require contract amendments and an Interagency Agreement with DHCS that includes confidentiality and non-disclosure agreements.

#### Potential Decreased Access to Drugs

As noted by the LAO, affected state entities could modify their formularies in response to the Act. For example, state entities might include only those drugs that the VA does not purchase and drugs that manufacturers will offer at the lowest VA price. The Act could cause difficult formulary choices if a manufacturer does not offer the VA price to the CalPERS PBM or health plans for certain drugs.

#### Potential Compliance Challenges

If CalPERS staff determines that regulations are necessary to comply with Act requirements, there may be insufficient time between November 8, 2016, and July 1, 2017, to complete the California Office of Administrative Law (OAL) regular rulemaking process, which can take up to a full calendar year. An alternative would be to request adoption of emergency regulations, which would involve proving to the OAL that the situation requires immediate action to avoid serious harm to the public peace, health, safety, or general welfare. Lack of such approval could cause CalPERS to be non-compliant with the Act.

Even with regulations, it may be impossible for CalPERS or DHCS to discover the lowest price paid for the same drug by the VA in a way that complies with the Act for the following reasons:

- The Act does not provide a definition of "same drug." It is unclear whether that would require that two drugs have the same National Drug Code<sup>13</sup>, or whether it is sufficient that two drugs have the same active ingredient (e.g., two generic equivalents for the same brand-name drug).
- The definition of "lowest price paid" by the VA is unclear. Because DHCS is to compare this with "net cost of the drug," CalPERS staff believes that the author intended to refer to the "lowest net price paid," in which case there is no public information on rebates and other discounts that are included in the total price paid by the VA for drugs. Although the VA's website shows the price the VA pays to its contracted source manufacturers for a specific drug by dosage, quantity, and packaging, this price is not necessarily the net price paid by the VA.

Ultimately, it is questionable whether the Act and subsequent implementing regulations developed at the state level will be effective. Courts have construed the Supremacy Clause of the United States Constitution (Article VI, Clause 2) to hold that the activities of the federal government are free from regulation by any state. If the VA does not cooperate with California state agencies by disclosing their drug pricing, the state agencies could make Freedom of Information Act (FOIA) requests for information the VA may have. However, the VA may be able to shield the disclosure of information requested based on an exemption recognized by FOIA. In testimony at the May 2016 Joint Hearing of the Senate and Assembly Committees on Health,

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<sup>13</sup> A unique 10-digit number for each drug that includes information about the manufacturer/distributor, strength, dosage form, formulation; and package size/type.

the LAO reported that in response to a FOIA request, the VA offered only information that was already publicly available.

### **Budget and Fiscal Impacts**

Consistent with the LAO finding, CalPERS staff has been unable to quantify potential savings or costs to the Health Care Fund.

CalPERS staff agrees with the LAO finding that the Act "would introduce new state operations costs." For CalPERS, these costs would include collaborating with DHCS to verify that CalPERS net 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 CalPERS purchases prescription drugs.

### **Benefits and Risks**

#### 1. Benefits

According to proponents, the Act may:

- Reduce drug prices for millions of Californians.
- Result in savings to state taxpayers.

#### 2. Risks

If the Act becomes law, it may cause:

- Increased drug prices for the VA, instead of decreased prices for CalPERS and other California state entities as intended;
- Disruption of CalPERS PBM and health plan contract administration efforts;
- Decreased access to certain drugs for CalPERS members;
- Potential challenges for CalPERS to comply with the law's requirements in a complete and timely manner; and,
- Increased administrative costs.

### **Attachments**

Attachment 1 – Legislative Analyst's Office Handout

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