



California Public Employees' Retirement System

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Aaron Zajic
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-P, Room 5527, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

April 4, 2019

Subject: OIG-0936-P – Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Mr. Zajic,

On behalf of the California Public Employees' Retirement System (CalPERS), thank you for the opportunity to comment on the proposal to amend the safe harbor regulation concerning discounts as they relate to prescription drug manufacturer rebates (Proposed Rule).

CalPERS is the largest public employer health benefits purchaser in California and the second largest employer purchaser in the nation after the federal government. We purchase health benefits for approximately 1.5 million active and retired state, local government and school employees and their family members. Our health plan offerings include health maintenance, preferred provider, and exclusive provider organization (HMO, PPO, and EPO) plans. Within these plan offerings are plans specifically for those eligible for Medicare. In 2019, CalPERS expects to spend more than \$9 billion to provide health benefits to our members. Of this expected \$9 billion spend, \$2 billion will be for outpatient prescription drugs alone.

As drafted, the Proposed Rule would revise the discount safe harbor regulation to explicitly exclude prescription drug manufacturer rebates paid to Medicare Part D plan sponsors, Medicaid managed care organizations (MCOs), or pharmacy benefit managers (PBMs) from safe harbor protection. It would also create new safe harbors for certain point-of-sale (POS) price reductions on prescription drugs and for certain PBM service fees paid by manufacturers.

It is our understanding that the Department of Health and Human Services (HHS) has several goals it would like to achieve with this proposal. These include:

- improving alignment of incentives among all parties that may curb list price increases,
- reducing financial burdens on beneficiaries,
- lowering Federal expenditures,
- improving transparency, and
- reducing the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid MCOs.

CalPERS certainly shares these goals. We question, however, whether the Proposed Rule could prompt prescription drug manufacturers to lower their list prices or slow their price increases. To have a direct impact, we would like to have seen a proposed rule that expressly and directly addresses list prices and how fast they can be increased. Without addressing drug list prices directly, we do not think this Proposed Rule will advance HHS' articulated goals.

This Proposed Rule will impact CalPERS Medicare plans and will likely have an indirect impact on the commercial or basic plans we offer, especially if prescription drug manufacturers lessen or eliminate rebates for this line of business should the Proposed Rule be adopted. Currently, we contract with OptumRx (Optum), a PBM and Medicare Part D Plan Sponsor, to administer the outpatient prescription drug benefit provided under CalPERS Medicare PPO health plans and the Anthem Blue Cross of California (Anthem) Medicare Advantage (MA) health plan CalPERS offers. As part of our agreement with Optum, Optum is contractually obligated to give all the prescription drug rebates it receives attributable to CalPERS to CalPERS. We account for these rebates when we establish the annual premiums for the above-mentioned plans. As such, all CalPERS members enrolled in these plans benefit by having lower premiums.

We note that HHS cites actuarial analyses suggesting that the Proposed Rule could increase premiums for prescription drug coverage, and therefore federal expenditures, by \$25-\$50 billion. Under the Proposed Rule, Optum could no longer pass on prescription drug rebates to CalPERS. Accordingly, CalPERS Medicare plan premiums will likely increase due to the loss of these rebates. In fact, CalPERS' analysis indicates a likely average of eighteen to twenty-two percent (18–22%) increase.

We also currently contract with Kaiser Permanente (Kaiser) and UnitedHealthcare (UHC) to provide MA plans. Kaiser and UHC administer the prescription drug benefit provided by their MA plans. They, too, will likely increase the premiums they charge CalPERS to the extent they use rebates to offset the costs of providing prescription drug coverage under these plans.

Under CalPERS Health Benefits Program, premium payment is a shared responsibility between employers, the State of California and the local agencies and schools that contract with CalPERS to provide health benefits, and their employees and retirees (CalPERS members). Consequently, if premiums increase, as predicted under this Proposed Rule, both employers and CalPERS members will face additional costs. While some CalPERS members may benefit by receiving POS reductions when they fill prescriptions, employers, including the State of California, will not receive any benefit from this proposal. This Proposed Rule will penalize these employers by making them pay more for providing prescription drug coverage, as they lose the current benefit associated with these rebates. This is particularly unfair for public employers, such as

state governments, that rely upon taxpayers to help fund public employee and retiree health benefit coverage. Accordingly, we request HHS to provide an exception or exemption from this Proposed Rule for governmental employee benefit plans, which are not subject to the Employee Retirement Income Security Act's (ERISA) provisions (non-ERISA plans).

If an exemption is not granted, then we respectfully request a delay for the Proposed Rule's effective date of January 1, 2020, specifically for non-ERISA plans. The date provided in the Proposed Rule does not provide a sufficient transition period to restructure our current Medicare plan drug rebate arrangements. Moreover, CalPERS adopts health plan premiums for the following year in June of the preceding year. We are currently well into the process of determining health plan premiums for 2020 and will conclude this process in mid-June 2019. To ensure CalPERS compliance with the changes being proposed, at a minimum, we would request that HHS finalize the rule prior to March 31, 2020 with a January 1, 2021 effective date.

If this Proposed Rule is adopted with a January 1, 2021 effective date, CalPERS is strongly concerned it will have adopted Medicare health plan premiums accounting for prescription drug manufacturer rebates, which will be prohibited beginning in 2020. Once these premiums are adopted, they cannot be easily modified due to State Budget and operational considerations. If the January 1, 2020 effective date cannot be delayed, then we respectfully request that any prescription drug manufacturer rebates contained in CalPERS 2020 Medicare plan premiums be considered within the safe harbor regulation and not subject to Anti-Kickback Statute enforcement action.

We also understand that HHS is specifically soliciting comments on whether declining to protect rebates to Medicare Part D plan sponsors, under a safe harbor, might have an impact on beneficiary access to prescription pharmaceutical products due to either an impact on cost or formulary placement. CalPERS believes it will impact access because the Proposed Rule, if adopted in its current form, will cause CalPERS to seriously consider measures to maintain Medicare plan premium affordability. Such actions may include limiting the prescription drug choices, particularly to brand-name drugs, for CalPERS members enrolled in its Medicare plans.

We also note that, while there has been much public discussion on the impact the Proposed Rule could have on costs, there has been little discussion on the impact it would have on fraud and abuse, patient utilization of medication, and provider prescribing behavior. For example, under CalPERS' current Medicare outpatient prescription drug benefit, members have a yearly maximum out-of-pocket obligation. Once a member reaches this level, they enter the "Catastrophic Coverage Stage," where members either pay the lower of a specified coinsurance percentage or a copayment. At this stage, there could be very significant rebates, particularly for specialty drugs. Accordingly, members could literally be receiving an amount exceeding their cost-sharing obligations if they, instead of CalPERS, receive the value of the rebates through a discount at the POS.

The Proposed Rule could result in patients and providers having an incentive to use more expensive drugs, as beneficiaries could receive a discount at the POS that is more than their copay. Such a scenario would likely implicate existing federal law prohibiting fraud, waste and abuse, and lead to higher drug costs. Therefore, we would encourage HHS to clarify that any discounts at the POS cannot exceed a beneficiary's cost-sharing obligations and that any excess

discount should be passed back to the plan to lower premiums for all beneficiaries, particularly for non-ERISA plans. We would also encourage HHS to consider how to mitigate this type of utilization in the final rule.

CalPERS does not support the Proposed Rule as currently drafted, but we stand by as a resource to work with you and your colleagues at HHS to address the concerns we have outlined in this letter. Please contact Danny Brown, Chief of our Legislative Affairs Division, at (916) 795-2565, if you have any questions or wish to discuss these issues further.

Sincerely,

Marcie Frost
Chief Executive Officer

cc: Danny Brown