



July 13, 2017

The Honorable Thomas E. Price, M.D.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Price:

At our meeting on May 16, we promised to provide you with market-based solutions to the complex challenge of improving quality and reducing prescription drug costs.

The role of pharmacy benefit managers (PBMs) is to help our clients, including the employers, unions, and health insurers who provide prescription drug benefits, to reduce costs and improve health outcomes for consumers. PBMs have a proven track record of delivering high-quality, affordable benefits that address the individual needs of their clients and patients. PBMs administer prescription drug benefits for over 266 million Americans, including enrollees in Part D, where their expertise and the market-based nature of the program have led to affordable premiums, broad choices, and far lower costs to taxpayers than initially anticipated by the Congressional Budget Office. Despite the rise of list prices on certain brand drugs, PBMs have held the rise of overall drug costs to low single-digit increases over the past few years.

It is important to understand that high drug costs are a direct result of the prices drug manufacturers set. Pricing decisions are made by drugmakers with no input from others in the pharmaceutical supply chain and are unrelated to the rebates and discounts manufacturers negotiate with PBMs.

Given current drug pricing trends, the role of PBMs has become more important than ever. While few plans can afford to offer true "first dollar" prescription drug coverage, all want to offer the most affordable benefits for consumers. That is why thousands of America's largest, most sophisticated health purchasers – Fortune 500 companies, insurers, state employee programs, state Medicaid programs, unions, and of course, Medicare Part D plans – choose to hire PBMs, even though none are required to.

Summary of PCMA Policy Recommendations

Below are PCMA's recommendations to strengthen private sector tools, encourage competition, and in doing so reduce drug costs for patients, employers and taxpayers. These recommendations are discussed in further detail later in this letter.

Speed drugs to market and encourage use of biosimilars

- Eliminate use of Risk Evaluation and Mitigation Strategies (REMS) to delay competition.
- Eliminate "pay-for-delay" agreements that keep generics off the market.

- Allow for FDA accelerated approval of brand drugs that have the potential to create competition.
- Require substitutable biosimilars to bear identical labeling and naming.
- Reduce innovator biologic exclusivity to seven years.

Enhance tools in Medicare Part D, Medicaid, and commercial markets to increase competition and affordability

- Create a safe harbor for value-based drug price negotiations from Medicaid Best Price.
- Expand drug coverage options for health savings account (HSA) eligible high deductible health plans (HDHPs).
- Remove Part D's competition-hindering protected classes.
- Make biosimilars subject to the 50% Part D coverage gap discount.
- Encourage greater use of generics for Medicare Part D low income subsidy (LIS) enrollees.

How PBMs Help Clients Reduce Drug Costs for Payers and Cost-Sharing for Patients

PBMs typically reduce costs by 30 percent by, among other things, using their substantial scale and expertise to negotiate aggressive rebates, discounts, and other price concessions on prescription drugs. As a result of these negotiations, PBMs can recommend benefit designs that stretch payers' finite dollars and reduce premiums and cost-sharing. These designs include cost-sharing incentives for patients to use the most affordable drugs, which often are generics. The highest cost-sharing is typically reserved for drugs with the least competitive discounts, or in the case of many high-priced, single-source drugs (e.g., cancer therapies), no discount at all. PBMs also support benefit designs that ensure patients do not pay more in cost-sharing than the cost of an actual drug and innovations like electronic prior authorization that reduce physicians' administrative burden.

How Rebates Lower Costs for Payers and Patients. PBMs' Commitment to Transparency with Clients

Manufacturers have chosen to negotiate discounts on drug prices with PBMs using rebates, which are calculated and paid months after a drug has been dispensed. These rebates are used by payers to reduce premiums and out-of-pocket costs for patients. Each payer determines what percentage of rebates are passed through to it, and how much (if any) it wants the PBM to retain as payment for services. While on average payers elect to receive 90 percent of rebates negotiated by PBMs, an increasing number require PBMs to pass through all of them. About 29 percent of commercial PBM contracts are negotiated with full pass-through of rebates to payers, and 100 percent of rebates in the Medicare Part D program are required to be reported to CMS. PBMs are committed to providing rebate transparency and audit rights to their clients.

There is No Connection Between the Prices Drugmakers Set and the Rebates They Negotiate with PBMs

Long before PBMs became a force in the marketplace, the rebate system was created by manufacturers (and in the case of programs like Medicaid and 340B, public policymakers) to



reduce the net costs of brand drugs. Most rebates reported by manufacturers are actually paid pursuant to these government discount programs, not to plans administered by PBMs.

A recent study of the top 200 self-administered, patent-protected, brand-name drugs shows no correlation between the prices manufacturers set and the rebates they pay to PBMs. There are many cases of high-priced drugs that carry low rebates and low-priced drugs that carry high rebates. Some high-priced drugs have no rebate at all. Like manufacturers in other industries, drugmakers set prices according to supply, demand, and the level of competitive options available.

Considering the confusion surrounding rebates, PBMs encourage manufacturers to offer payers alternative ways to reduce net costs.

How PBMs Help Commercial Clients Explore Trade Offs to Point-of-Sale (POS) Rebates

In the commercial market, PBMs already help payers implement POS rebates. Since POS rebates do not reduce overall costs but redistribute them among different enrollees, payers ask themselves the following questions before choosing this approach:

- Should rebate savings be used to reduce premiums for all enrollees or out-of-pocket costs for certain ones who take certain drugs?
- Do plans have the administrative and financial capacity to reduce costs at POS even though manufacturers do not pay rebates until months after a drug has been dispensed?
- Do plans understand the limitations of POS rebates? Some high-priced drugs carry no rebates at all and others are so expensive that rebates alone will not guarantee access. A \$1,500 drug with a 30% rebate would still cost patients in the deductible \$1,050.
- If plans are willing to exchange higher premiums for lower cost-sharing, would it be simpler to just reduce deductibles or co-pays on certain drugs?

Why POS Rebates Do Not Work in Medicare Part D

While plans with POS rebates can be implemented in the commercial market, they are unworkable in Medicare Part D and pose risks that could destabilize the program. In fact, they are already allowed in Part D and have been tried unsuccessfully in the past. They lead to significant adverse selection and expose plans to other risks, such as being accused of False Claims Acts violations if they incorrectly estimate the size of rebates.

Requiring POS rebates in Part D would dramatically increase costs to the program and taxpayers. According to modeling by the actuarial firm, Milliman, this would result in widespread premium increases and cost taxpayers an additional \$20 billion over the next decade.

Policy Recommendations to Improve Competition and Reduce Costs

Below are details of PCMA's recommendations (outlined earlier in this letter) to improve marketplace competition and strengthen private sector tools to encourage competition and reduce costs for taxpayers and beneficiaries in Medicare Part D.

Speed drugs to market and encourage use of biosimilars

FDA Commissioner Scott Gottlieb is already attacking the generic backlog at FDA, and we commend his efforts to prioritize applications for drugs with fewer than two competitors. We recommend a number of additional strategies to increase competition:

- *Eliminate use of Risk Evaluation and Mitigation Strategies (REMS) to delay competition.* Some manufacturers have used REMS to prevent generic or biosimilar developers from getting sufficient quantities of a drug or biologic to develop a competitor to the innovator product. REMS were never intended for this purpose; this practice should be prohibited.
- *Eliminate “pay-for-delay” agreements.* Patent settlements, or “pay-for delay” agreements that allow drug patent holders to pay off potential competitors who would otherwise produce a competing generic drug, should be prohibited.
- *Allow for FDA accelerated approval of brand drugs based on increasing competition.* Accelerated review is granted to new drug applications that address “unmet need.” The economic need for competition to lower prices should be a criterion of unmet need.
- *Revisit and improve biosimilar labeling and naming.* Substitutable biosimilars should bear identical names and labels to their innovator analogs. Use of different names will confuse patients and providers and inhibit prescribing of biosimilars.
- *Reduce innovator biologic exclusivity to seven years.* Seven years of data exclusivity would still provide a sufficient return to manufacturers, while also speeding more affordable biosimilars to market.

Enhance tools in Medicare Part D, Medicaid, and commercial markets to increase competition and affordability

PBMs and health plans can best drive competition among drug manufacturers when they can give plan enrollees a strong incentive to use a competing, higher-value drug. This reduces costs and helps improve adherence among patients.

In addition, as value-based contracting expands, PBMs support the use of frameworks, such as the Institute for Clinical and Economic Review’s (ICER), to help assess appropriate pricing and value of new and existing therapies. Additional tools are needed to foster creative arrangements that allow payers to compensate manufacturers appropriately when drugs work best.

Below are some strategies to strengthen these efforts.

- *Create a safe harbor for value-based drug price negotiations from Medicaid Best Price.* Today any drug manufacturer must offer state Medicaid programs the lowest price it offers any other payer. This provision is seen as a price floor and is inhibiting creative value-based pricing arrangements.
- *Expand drug coverage options for HSA-eligible HDHPs.* HDHPs associated with HSAs should have the option of covering prescription drugs with low or no cost-sharing prior to reaching the deductible, especially drugs that qualify for a preventive drug list. This policy can be achieved by expanding the current preventive drug list used by HDHPs.
- *Remove Part D’s protected classes.* Designating “classes of clinical concern” where all or substantially all drugs in a class must be covered allows drug manufacturers to name



their price. CMS already applies careful plan formulary coverage checks to assure proper coverage.

- *Make biosimilars subject to the 50% Part D coverage gap discount.* The ACA did not apply to biosimilars the 50% Part D coverage gap discount. This could have the unintended consequence of encouraging prescribing of more expensive innovator biologics when lower cost biosimilars are available.
- *Encourage greater use of generics for Medicare Part D LIS enrollees.* MedPAC recommended allowing the Secretary of HHS to lower cost-sharing on generics and raise it for brands that have generic competition. Increasing the differential between brands and generics and allowing plans to lower generic cost-sharing would save money for enrollees and Medicare.

These are all common sense ideas that would improve affordability for payers, taxpayers, and consumers, and increase competition.

In addition, we recommend addressing the demand side for drugs by eliminating the tax deduction for direct-to-consumer (DTC) drug ads that mention a specific product. While DTC drug ads may encourage some people to see a doctor, they drive up unnecessary utilization and the cost of health care.

With all of this in mind, we look forward to working with you and the Administration as it considers new ways to reduce prescription drug costs.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Merritt". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Mark Merritt
President and CEO

cc: Mr. Mick Mulvaney, Director, Office of Management and Budget
Ms. Seema Verma, Administrator, Centers for Medicare and Medicaid Services