June 28, 2017

The Honorable Mick Mulvaney
Director
U.S. Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Mulvaney:

As you lead efforts of the Trump Administration to gather ideas from cabinet officials and agencies on prescription drug affordability and availability, the National Community Pharmacists Association (NCPA) is a resource with expertise and solutions to share.

NCPA represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an $81.5 billion health care marketplace and employ more than 250,000 individuals on a full or part-time basis. Our members serve on the front lines of the health care system and help their patients lead happier and healthier lives. Independent pharmacists are among the most accessible health care providers and offer face-to-face counseling and other services such as medication synchronization which helps boost patient adherence to medications which in turn helps reduce overall health care costs. This accessibility also provides our members with first-hand experience on the challenges of ensuring access to prescription drugs and insights on how to reduce prices for both patients and payers alike.

Drug manufacturers ultimately establish list prices and are obviously a factor in this debate. At the same time, another major player, pharmacy benefit managers (PBMs), often fly under the radar while prices continue to escalate.

PBMs Contribute to Higher Drug Costs

There are several PBM practices that contribute to higher costs, which we believe the administration should address as it looks for ways to lower the costs of prescription medications.

First, the use of retroactive direct and indirect remuneration (DIR) fees charged to pharmacies. These are most prevalent in Medicare Part D and can inflate costs for patients and the Medicare program alike. DIR fees are assessed weeks or months after a claim has been processed and adjudicated and result in recoupments by PBMs from pharmacies. However, since these fees are not reflected at point of sale, a report by the Centers for Medicare and Medicaid Services (CMS) found this can push beneficiaries into the coverage gap prematurely, where patients and Medicare pay a bulk of the costs. Moreover, the report indicates that as use of DIR increases, so do the costs to Medicare- while plan liability decreases. [1] This also has a negative impact on small business pharmacies by making it difficult to predict their annual operating revenue. Thus, finalizing pending CMS guidance that would require Part D plans to account for DIR fees at point of sale can potentially reduce costs for taxpayers and beneficiaries, while providing clarity and predictability to pharmacies as to their reimbursements for dispensing. Alternately, guidance prohibiting retroactive reductions in payment to pharmacies, similar to legislative language pending in both houses of Congress (S. 413/H.R. 1038), would address problems associated with

[1] CMS, "Medicare Part D – Direct and Indirect Remuneration," https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

DIR for the Medicare program, beneficiaries and pharmacies without interfering with the ability of plans to offer performance incentives.

PBMs are also the subject of several lawsuits[2] alleging that they increased beneficiary costs in the commercial space through a process known as clawbacks. This is where a patient could have saved money by purchasing the medication off of their insurance because their insurance copay was higher than the cost of the medication. In this scenario, the PBM instructs the pharmacy to collect the full copay then later instructs the pharmacy to remit the difference back to the PBM. This is kept by the PBM, not sent back to the patient. Unfortunately, some PBM contracts inhibit pharmacists from volunteering the information to the patient that they could have saved on out-of-pocket costs. The patient has to specifically ask. Prohibiting these implicit gag clauses altogether would provide greater transparency and could help patients save on their medications.

The administration should also be concerned with potential PBM conflicts of interest. PBMs contract with pharmacies while also owning their own mail order and/or specialty pharmacies. PBMs often design plans that require patients to use the PBM-owned pharmacy option or that of a preferred retail pharmacy. However, this is not necessarily the most cost effective option. A 2013 study by Norman V. Carroll, Ph.D., a Professor at Virginia Commonwealth University, found that the total cost for 90-day prescriptions filled at retail pharmacies were lower than those filled by mail order pharmacies.[3] CMS has also raised concerns over limited networks, stating that pharmacy competition is the best way to reduce costs in the Medicare program. As such, the administration should pursue policies that promote pharmacy competition and patient pharmacy choice.

Furthermore, the administration should examine rebate relationships between PBMs and manufacturers. Manufacturers often offer steep discounts to the PBMs for preferential placement on formularies, or a prescription drug plan's list of covered medications. While in theory this should bring prices down, the savings aren't necessarily passed along to patients and plan sponsors. IMS data demonstrates that the list price of medications is growing at a far faster rate than the net price, which has led some to conclude that most of the increase in drug spending has been from rebates pocketed by PBMs and insurers.[4] Moreover, the country's largest health insurer, Anthem, is suing Express Scripts (ESI), the largest PBM for $15 billion in rebates Anthem says were not passed on by ESI[5]. The state of New York filed a similar lawsuit claiming that ESI failed to pass through $1.5 billion in rebates to the state. These lawsuits suggest that a significant portion of these rebates are retained by the PBM instead of shared with insurers or other plan sponsors.

Additionally, a recent article noted that PBMs prefer the non-transparent nature of higher list prices and higher rebates that provide little insight to the plan sponsor as to what is being passed on and what is kept by the PBM. Citing one pharmaceutical representative from Gilead, "if it (Gilead) slashed Sovaldi's list price by tens of thousands of dollars, the middlemen would 'rip up our contract' and refuse to include the drug in its formulary."[6] This indicates PBMs have an incentive to favor drugs on its formulary that have the highest rebates and not necessarily the lowest net cost.

This masking of rebates from manufacturers also seems to be corroborated by a lawsuit filed by ESI against the drug manufacturer Kaleo. In its legal complaint, ESI indicates that they billed Kaleo thirteen times more in administrative fees

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[2] Brian New. "Pharmacists Point Finger At 'Middlemen' For Soaring Drug Costs." CBS DFW. June 19, 2017 http://dfw.cbslocal.com/2017/06/19/pharmacists-point-finger-at-middlemen-for-soaring-drug-costs/

[3] Norman V. Carroll, Ph.D., "A Comparison of the Costs of Dispensing Prescriptions throughRetail and Mail Order Pharmacies," February 2013

[4] Robert Goldberg. "Most of the Increase in Drug Spending Pocketed By PBMs and Insurers." Drug Wonks. April 15, 2016. http://drugwonks.com/blog/most-of-the-increase-in-drug-spending-pocketed-by-pbms-and-insurers

[5] Alison Kodjak "Anthem Sues Express Scripts For A Bigger Slice Of Drug Savings." *NPR.* March 21, 2016 *http://www.npr.org/sections/health-shots/2016/03/21/471301872/anthem-sues-express-scripts-for-a-bigger-slice-of-drug-savings*

[6] Sandip Shah. "Middlemen not passing on all drug discounts intended for patients." Sonoran News. June 20, 2017. http://sonorannews.com/2017/06/20/middlemen-not-passing-drug-discounts-intended-patients/

than in formulary rebates that would be passed on to plan sponsors[7]. If the administrative fees are included in the percentage of price concessions PBMs tout they obtain from manufacturers, shouldn't these too be passed on to the patients and plan sponsors?

Conclusion

We all agree on the need to ensure prescription drug access and affordability. However, this issue cannot be solved without addressing the role of PBMs in increasing costs. As the PBM role has expanded to include negotiating with manufacturers, contracting with and paying pharmacies, and administering plans and billing plan sponsors, they have grown into oversized players, and that position requires enhanced scrutiny.

We would appreciate the opportunity to meet with you and discuss these issues and some solutions that we believe can help reduce costs. Greater transparency in PBM practices would be a good place to start. It may also be time to think about alternate payment models that utilize advances in technology and empower patients to get the most value from their dollars by promoting free-market principles while returning PBMs to their original mission of adjudicating claims for plans sponsors.

Thank you for your consideration of our views. Please contact me at Doug.Hoey@ncpanet.org or (703) 683-8200 with any questions or to schedule a meeting to discuss these issues.

Sincerely,

B. Douglas Hoey, RPh, MBA

CEO, National Community Pharmacists Association

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[7] Linda Cahn. "Express Scripts Lawsuit Should Raise Everyone's Eyebrows." http://nationalprescriptioncoveragecoalition.com/author/linda/