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ALLIANCE *for* TRANSPARENT &
AFFORDABLE PRESCRIPTIONS

December 7, 2017

To Whom It May Concern:

The Alliance for Transparent and Affordable Prescriptions (ATAP) consists of seventeen patient and provider groups who are concerned about the role of pharmacy benefit managers (PBMs) in the rising cost of drugs. ATAP is funded entirely by membership dues and does not take funding from outside sources.

We thank the Federal Trade Commission (FTC) for hosting its November 8 workshop entitled “Understanding Competition in U.S. Prescription Drug Markets: Entry and Supply Chain Dynamics.” The FTC seeks comment on five specific questions, two of which are directly related to intermediaries and will be the focus of our comments:

- *What role do intermediaries, such as pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) play in prescription drug pricing, consumer access, and quality? What are the benefits and costs of intermediaries in the pharmaceutical supply chain? Has consolidation affected price, access, or quality?*
- *How do companies assess the benefits, costs, and risks of contracting with intermediaries? How well do consumers understand intermediaries’ roles? Is more information necessary?*

ATAP was formed on a shared concern that PBMs play an increasingly anti-competitive and harmful role in the pharmaceutical supply chain. PBMs are third-party entities that manage and administer prescription drug plans for payers, including Medicare Parts C and D plans, TRICARE, the Federal Employees Health Benefits Program, employers, and health insurers. Among other functions, PBMs negotiate retroactive discounts off drug prices with pharmaceutical manufacturers in the form of rebates and manage drug utilization by beneficiaries.

Unfortunately, there is very little transparency surrounding PBMs and their role within the delivery system, nor are there any requirements to pass negotiated savings onto payers or patients. Additionally, the PBM industry has become overly consolidated. Combined, the two



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largest PBMs cover more than 170 million lives.¹ By contrast, the entire Medicare program covers about 55 million people.² Such a consolidated market, combined with a lack of transparency, means that PBM contracts with pharmaceutical manufacturers and pharmacies are one-sided and may amount to a “take it or leave it” demand for rebates and fees by the PBMs—with poor results for patients and drug spending in our federal health programs. As the National Community Pharmacists Association pointed out, “since 1987, when Advance PCS/Caremark (now CVSHealth) became the last of the original ‘big 3’ PBMs to incorporate, the others being Medco and Express Scripts which merged in 2012, total prescription drug expenditures have skyrocketed 1010% and per capita expenditures have increased 756%.”³

Even so, PBMs allege that they are saving costs. But the question is: for whom? As patient and physician organizations, we have seen firsthand out-of-pocket costs for patients rise year after year, even as their ability to access the medicines they need has become increasingly compromised through restrictive formularies, tiering, and other aggressive utilization management techniques. PBMs negotiate rebates and discounts, but patients have seen little to no benefit from those “savings.” In fact, the current system seems to encourage manufacturers to increase their list prices—which are just the starting point for negotiations and do not reflect the actual cost of the drug—and yet, patient cost-sharing is often based on those inflated list prices.

Most consumers have never heard of PBMs. The average person does not realize that their prescription medicine must travel through several intermediaries before they can pick it up at the pharmacy or receive it at the doctor’s office. The average patient also does not understand that PBMs control formularies and that formulary placement is often based on the size of the rebate received from the manufacturer, rather than clinical data.

Although the current supply chain seems overwhelmingly complex, there are simple, common sense solutions that could be very effective in remedying some of the concerns outlined above.

¹ Express Scripts covers 83 million. (Express Scripts Corporate Overview, downloadable at <http://lab.express-scripts.com/about>.) CVS Caremark covers approximately 90 million. (CVS Health At A Glance, <https://www.cvshealth.com/about/facts-and-company-information>.)

² “An Overview of Medicare” Kaiser Family Foundation (April 1, 2016), available: <http://kff.org/medicare/issue-brief/an-overview-of-medicare/>.

³ National Community Pharmacists Association, <http://www.ncpanet.org/advocacy/pbm-resources>.



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One such solution revolves around definitions. There are currently no industry standards for key terms used in PBM contracts with manufacturers, plan sponsors, and pharmacies, allowing each PBM to advantageously define those terms on an ad hoc basis. For example, PBMs are not required to follow Food and Drug Administration (FDA) definitions for what is and is not a “generic” drug. This allows the PBM to define as “generics” products that were not approved pursuant to Abbreviated New Drug Applications (ANDAs) by FDA, which is the generally understood definition of the term “generic.” Conversely, it allows the PBM to define as “brands” products that *were* approved pursuant to ANDAs when that is financially beneficial. This lack of definitional agreement enables sleights of hands such as the PBM treating single-source generic drugs as brand products when financially beneficial or inflating generic substitution rates for products that were invoiced as brands.⁴ For this particular example, the solution is to require PBMs to classify a product as a generic or a brand according to how the product was approved by the FDA, consistently across the product life.

While this may sound like a micro-solution, definitional agreement and consistency are the foundation to most other policy solutions. For example, any requirement for PBMs to pass through to plans and patients a portion of rebates and other price concessions depends on a common definition of “rebate,” “discount,” “fee,” and any other term the PBM may use. Without such clarity, PBMs would be able to circumvent a rebate pass-through requirement by reclassifying a portion of the rebates and discounts received from manufacturers as fees or other designations. In fact, PBMs already use such reclassifications to avoid pass-through obligations under their contracts with plan sponsors.⁵

We urge the FTC to work with the Department of Health and Human Services to establish, with stakeholder input and subject to public comment, agreed upon definitions of terms commonly used in PBM contracts by any PBM that contracts with: (1) a prescription drug plan under Medicare or Medicare Advantage, (2) a qualified health benefits plan offered through an exchange established under the Patient Protection and Affordable Care Act, (3) a TRICARE plan, or (4) a Federal Employee Health Benefits Plan. This would bring much needed clarity and

⁴ “When is a brand a generic? In a contract with a PBM.” Linda Cahn, *Managed Care* (Sept. 2010), available: <https://www.managedcaremag.com/archives/2010/9/when-brand-generic-contract-pbm>.

⁵ “Comparing Pharmacy Benefit Managers: Moving Well Beyond the Simple Spreadsheet Analysis” by David Calabrese, RPh, MHP, *Am. Health Drug Benefits*, 2008 Jun; 1(5): 9-19.



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transparency to the various streams of money flowing to and from PBMs. Once definitional clarity exists, other policy solutions such as mandated disclosures or pass-through of savings can advance in a meaningful way.

In closing, we also urge FTC to closely examine any future PBM mergers, as many of the current problems are related to market consolidation. Any further consolidation of this industry should be avoided lest we inadvertently make a bad problem worse. To that end, we urge the FTC to closely scrutinize the recently announced CVS Health acquisition of Aetna.⁶ It is highly likely that this level of consolidation in an already consolidated, opaque market will cause far more harm than good for patients.

We thank the FTC for holding this important workshop and hope to be a partner as the Commission examines pharmaceutical access and pricing. For more information, please visit: <https://atapadvocates.com>.

Sincerely,

American Association of Clinical Urologists
American Bone Health
American College of Rheumatology
Association of Women in Rheumatology
California Rheumatology Alliance
Coalition of State Rheumatology Organizations
Florida Society of Rheumatology
Global Healthy Living Foundation
Lupus and Allied Diseases Association, Inc.
National Organization of Rheumatology Managers
New York State Rheumatology Society

⁶ https://www.washingtonpost.com/business/economy/what-the-cvs-aetna-deal-means-for-the-future-of-health-care/2017/12/05/e14a8d18-d907-11e7-a841-2066faf731ef_story.html?utm_term=.dcc383e8c5c8.



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North Carolina Rheumatology Association

Rheumatology Alliance of Louisiana

Rheumatology Nurses Society

Tennessee Rheumatology Society

U.S. Pain Foundation