ATAP
ALLIANCE *for* TRANSPARENT & AFFORDABLE PRESCRIPTIONS

House Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

December 13, 2017

Chairman Burgess, Ranking Member Green, and Members of the Subcommittee:

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 Subcommittee for scheduling today's hearing entitled "Examining the Drug Supply Chain." ATAP was formed on a shared concern that PBMs play an increasingly harmful role in our 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 rebates with pharmaceutical manufacturers and manage drug utilization by beneficiaries. Unfortunately, there is very little transparency surrounding PBMs and their role within the delivery system, nor is there any requirement to pass negotiated savings onto patients.

PBMs allege that they are saving costs through negotiating rebates and discounts, but patients have seen little to no benefit from those "savings." As physicians and patients, we have seen firsthand how out-of-pocket costs have risen year after year, even as patients' ability to access the medicines they need is compromised through restrictive formularies, tiering, and other aggressive utilization management techniques. In fact, the current system seems to encourage

manufacturers to increase their list prices—which are just the starting point for negotiations—and yet, patient cost-sharing is often based on those inflated list prices.

We urge you to consider the following policy goals to build a better system:

1. **Increase transparency** in the rebate system through agreed-upon definitions and public disclosure of price concessions.
2. **Reduce patient cost-sharing** obligations via flow-through of price concessions.
3. **Improve access** to treatments through transparent, clinically sound formularies.

Increase Transparency

The current lack of transparency, especially with respect to PBMs, has done little to reduce drug costs. One particularly problematic aspect stems from the reclassification of rebates and discounts received from manufacturers. Since there is currently no industry standard for key terms used in PBM contracts with manufacturers, plan sponsors, and pharmacies, each PBM can define terms on an *ad hoc* basis. Because they are typically only contractually obligated to pass onto plan sponsors a specified portion of manufacturer "rebates," PBMs exploit the non-transparent nature of their contract negotiations with manufacturers to reclassify a portion of the rebates received as "fees" and other designations, allowing them to keep a significant portion of the rebate amount as profit.[1]

Another example revolves around the classification of products as "brands" versus "generics." 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 treating single-source

[1] "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.

generic drugs as brand products when financially beneficial or inflating generic substitution rates for products that were invoiced as brands.[2] 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.

There are other examples of varying treatment of money streams and definitional games and trapdoors. Indeed, in the recent Part D rule[3] released by the Centers for Medicare and Medicaid Services (CMS), the agency notes that variation in the treatment of rebates and price concessions may have a negative effect on the competitive balance under the Part D program. Additionally, the quality of information available to Part D beneficiaries is even less conducive to producing efficient choices when price concessions are treated differently by different Part D sponsors.

Thus, as a first step in improving our current system, Congress must urge the Department of Health and Human Services to establish, with stakeholder input and subject to public comment, agreed upon definitions for terms commonly used in PBM contracts in any prescription drug plan financed by the government. In addition to creating industry standards, this will bring clarity and transparency to the various streams of money flowing to and from PBMs. Once definitional clarity exists, disclosure will be meaningful.

Reduce Cost-Sharing

Reducing patient out-of-pocket exposure may require different approaches depending on the payer. For example, in Medicare Part D, patient out-of-pocket costs could be calculated at the point of sale based on net prices that take into account rebates and other price concessions. In

[2] "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.
[3] "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program."

the Part D rule[4] referenced above, CMS included a Request for Information (RFI), indicating that the agency is considering such a requirement. The agency notes that, in recent years, only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale." CMS adds that "sponsors may have distorted incentives as compared to what we intended in 2005."

As a result, the Part D rule contains an RFI related to requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a Part D drug in the drug's negotiated price at the point of sale. In other words: CMS is considering whether it should require sponsors to share with Medicare beneficiaries at least some portion of the price concessions negotiated by intermediaries. CMS provides ten-year impact estimates of a forced pass-through of 33%, 66%, 90%, and 100% of manufacturer rebates at the point of sale: ***at the lowest point of that range (33%), beneficiaries would save $19.6 billion dollars in their out-of-pocket costs***. While a pass-through policy would increase premiums, that increase is more than offset by the deep reductions in cost-sharing at every level of pass-through. Similarly, the per-member-per-month savings estimates provide by CMS tell us that, **at a 33% pass-through, beneficiaries would save $30.33 per month, while, at a 100% pass-through, beneficiaries would save $88.13 per month**.

Any argument that the policy would increase premiums is disingenuous as it does not factor in the offsetting impact of the large reductions in cost-sharing: the overall savings numbers calculated by CMS are the result of slight increases in premiums that are more than offset by large reductions in cost-sharing. With regard to requiring that all pharmacy price concessions be used to lower the price at the point of sale, CMS notes that such a policy "would affect beneficiary, government, and manufacturer costs largely in the same manner as discussed previously in regards to moving manufacturer rebates to the point of sale."

We strongly support a pass-through policy and will file comments with the agency urging CMS

[4] *Id.*

to proceed with such a proposal. Similar policies must be implemented in all prescription drug plans in which the government is a partner.

Improve Access

We understand that formularies and other utilization management techniques are a necessary part of reducing healthcare spending. However, the current system for developing formularies does not seem to be based on sound scientific evidence or accepted clinical guidelines, but rather on the cost of the product to the PBM. As prescribers and patients, we recognize that the formulary placement of a drug is in large part just the result of annual negotiations between the PBM and the manufacturer, and not the result of the latest science or clinical outcomes.

To improve access to medically necessary prescriptions, any PBM involved in administering a prescription benefit plan related to any federal health program should publish up-to-date, accurate, and complete formulary lists. That would provide patients with information on tiering structures and any cost-sharing requirements for each tier, as well as restrictions on how and when the product can be obtained by the patient (such as dose or quantity limits, prior authorization, etc.). In addition, there should be one, single, transparent formulary used by both the PBM and the plan sponsor on whose behalf the PBM administers the prescription benefit to avoid duplicative or conflicting formularies.

In closing, we also urge Congress to require the Federal Trade Commission to closely examine the PBM industry in its current form, as many of the aforementioned problems may be related to market consolidation. Combined, the two largest PBMs cover more than 170 million lives.[5] That is more than three times the size of the entire Medicare program.[6] Such a consolidated

[5] 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.)
[6] "An Overview of Medicare" by the Kaiser Family Foundation (April 1, 2016), available: http://kff.org/medicare/issue-brief/an-overview-of-medicare/.

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. Any additional consolidation of this industry should be avoided lest we inadvertently make a bad problem worse. To that end, we have urged the Federal Trade Commission to closely scrutinize the recently announced CVS Health acquisition of Aetna.[7] 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 Subcommittee for holding this important hearing and hope to be a partner as you examine pharmaceutical access and pricing. This is a crisis we can no longer ignore. For too long, the health of patients – both physical and financial – has suffered due to a morass of middlemen whose only incentive is to protect the bottom line. The good news is: it is not too late to change those incentives in a manner that prioritizes patients. We hope to work with the Subcommittee to accomplish just that. 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
Coalition of State Rheumatology Organizations
Florida Society of Rheumatology
Global Healthy Living Foundation

[7] 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.

Lupus and Allied Diseases Association, Inc.
National Organization of Rheumatology Managers
New York State Rheumatology Society
North Carolina Rheumatology Association
Rheumatology Alliance of Louisiana
Rheumatology Nurses Society
Tennessee Rheumatology Society
U.S. Pain Foundation