ATAP
ALLIANCE *for* TRANSPARENT & AFFORDABLE PRESCRIPTIONS

June 26, 2018

Department of Health and Human Services
Office of the Secretary
200 Independence Avenue, SW
Room 600E
Washington, D.C. 20201

RE: Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs; RIN: 0991-ZA49

Submitted electronically via www.regulations.gov

To Whom It May Concern:

The Alliance for Transparent and Affordable Prescriptions (ATAP) consists of nineteen patient and provider groups who are concerned about the role pharmacy benefit managers (PBMs) play in the rising cost of drugs and reduced patient access. As prescribers and patients, we know firsthand how increasing out-of-pocket costs are putting needed treatments out of reach for many Americans, so ATAP appreciates the Administration's efforts to reduce the cost of drugs. Our comments on "American Patients First" pertain to the items that directly or indirectly relate to PBMs, as that is the focus of our coalition. We hope you will find our perspectives helpful as you work towards our shared goal of helping patients access safe, affordable medications that are priced in a rational, transparent manner.

Part B Competitive Acquisition Program

The Department of Health and Human Services (HHS) has previously attempted to implement a Competitive Acquisition Program (CAP) for Part B drugs, but suspended that effort at the end of 2008. The following year, the Centers for Medicare and Medicaid Services (CMS) issued a report evaluating the program, which highlighted the implementation challenges.[1] One of these

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.

challenges was the lack of vendors: only one entity became an approved CAP vendor. This raised a number of concerns, in particular with the lack of recourse in the event that the vendor performed poorly. CMS noted in its 2009 report that physicians would be stuck with the vendor even if they were dissatisfied.[2] This is concerning to prescribers and patients.

Assuming that a sufficient number of vendors participate and the CAP is successfully implemented this time around, ATAP is concerned that third party entities administering the program could begin to conduct medical reviews. Indeed, in its 2009 report, CMS stated that a specialized Medicare carrier would process vendor claims and that such a carrier would have, among other duties, the responsibility to conduct medical reviews.[3] We would be extremely concerned that establishing medical review procedures by a middleman in Part B would lead us to the aggressive utilization management beneficiaries and providers currently experience in Part D. This utilization management has led to documented access issues in Part D that do not exist in Part B, due to the latter's open formulary structure. As early as 2008, just two years after implementation of Part D, access issues were noted "as a direct result of Part D formularies that are created with cursory regard to medical concerns and are subject to minimal outside review either before or after implementation."[4] We do not wish to extend this approach to Part B drugs in any way, and we are concerned that providing third party entities with medical review authority would be the first step down that road.

If CMS reestablishes a CAP program for Part B drugs, ***ATAP urges the agency to ensure that an adequate number of vendors participate so that beneficiaries and prescribers have options for recourse. Additionally, we strongly object to any third party entity in Part B conducting medical reviews or instituting any utilization management.***

Moving drugs from Part B to Part D

Elsewhere, the Blueprint and RFI ask several sets of questions related to policy proposals that seek to bring accountability and transparency to PBMs. That is why the concept of bringing more products within the purview of these entities is counterintuitive. For the reasons explained below, unless the practices of middlemen in Part D can be controlled, moving additional drugs into Part D will shift more costs onto beneficiaries and create more access issues for patients.

Given the perverse incentives in Part D's current structure, we would be extremely concerned about the concept of moving drugs from B into D. First, Part D has done little to control list prices. By contrast, prices in Part B have been better controlled. CMS' Drug Spending Dashboard highlights this:

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.
[3] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2730081/.

Figure 1: High Annual Increases in Spending, Medicare Part B

Medicare Part B					
	Brand Name	**Generic Name**	**Annual Growth Rate (2012-2016)**	**Average Monthly Spending Per Beneficiary in 2016**	**Manufacturers**
1	Orencia*	Abatacept*	17.2% ($22 to $41)	$2,136	BMS Primarycare
2	Neulasta	Pegfilgrastim	8.5% ($2,788 to $3,869)	$1,195	Amgen
3	Xolair	Omalizumab	8.0% ($22 to $30)	$1,821	Genentech, Inc.
4	Vaccine Influenza Injection Muscle (Fluzone High-Dose)**		6.9% ($30 to $39)	N/A	
5	Sandostatin Lar*	Octreotide Acetate, mi-Spheres*	6.8% ($123 to $160)	$3,202	Novartis

Figure 2: High Annual Increases in Spending, Medicare Part D

Medicare Part D					
	Brand Name	**Generic Name**	**Annual Growth Rate (2012-2016)**	**Average Monthly Spending Per Beneficiary in 2016**	**Manufacturers**
1	Renvela	Sevelamer Carbonate	21.6% ($3 to $6)	$630	Genzyme
2	Lantus	Insulin Glargine, Hum.Rec.Anlog	18.6% ($13 to $25)	$209	Sanofi-Aventis
3	Zetia	Ezetimibe	18.3% ($5 to $9)	$181	Merck Sharp & D
4	Enbrel	Etanercept	18.2% ($498 to $972)	$2,741	Amgen
5	Humira Pen	Adalimumab	18.0% ($1,019 to $1,976)	$2,835	Abbvie US LLC

Of the 15 drugs with the highest total spending in Medicare Part B, only a single drug had an annual spending growth rate in excess of 10 percent and only the top three products saw growth rates over eight percent. By contrast, during the same period, of the 15 drugs with the highest total spending in Medicare Part D, 11 had annual spending growth rates in excess of 10 percent and one had an annual spending growth rate in excess of 20 percent.

These data suggest that the current Part D system accelerates spending growth rates, which negatively impacts the Medicare program and its beneficiaries. These data also suggest that the average sales price methodology used to set payments for Medicare Part B drugs may actually be better at constraining spending.

Second, moving medicines from Part B to Part D would result in out-of-pocket costs increasing for beneficiaries. In 2011, Acumen modeled a move from Part B to Part D for six categories of products and found that the increase in beneficiary out-of-pocket costs "is an important concern in examining the effects of the proposed consolidation, as it could impede beneficiary access to needed medication."[5] Across all six modeled categories, "decreases of approximately $230 for Medicare and $100 for Medicaid are partially offset by an increase of $200 for beneficiaries." In other words: the savings for Medicare almost "wash out" with the increase in cost for beneficiaries. This illustrates the fact that moving drugs from B to D is nothing more than a shift of cost responsibility from the program to beneficiaries.

Given that most beneficiaries in traditional Medicare have some type of wraparound coverage in the form of Medicaid, employer-provided coverage, or Medigap, the impact of cost-sharing is mitigated.[6] By contrast, in Medicare Part D, there is no wraparound coverage, rendering the beneficiary fully responsible for any cost-sharing requirements. Since there is evidence that beneficiaries are paying their coinsurances based on list prices as opposed to negotiated prices, this can make products unaffordable for many beneficiaries. ***Prior to moving any additional products into Part D, we must accomplish meaningful reform to reduce list prices and/or mandate a pass-through of price concessions.*** Unless that is accomplished, program "savings" would come from a simple cost shift to beneficiaries in the form of higher cost-sharing based on higher list prices. Additionally, as the blueprint notes, 27% of beneficiaries do not have Medicare prescription drug coverage. Prior to moving any products into Part D, the Administration must ensure these beneficiaries will not experience a disruption in treatment.

Reducing the impact of manufacturer rebates to Pharmacy Benefit Managers

PBMs receive a variety of fees, rebates, and other price concessions from manufacturers and pharmacies. In Medicare Part D, additional compensation after the point-of-sale is called direct and indirect remuneration (DIR) and is factored into CMS' calculation of final Medicare payments to Part D plans.

When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries do not see any reduction in their cost-sharing obligations as a result of PBM negotiations. Additionally, the lack of pass-through of price concessions increases costs for the Medicare program itself, because the calculation of when beneficiaries move through the four phases of the benefit is based on the negotiated prices reported at the

[5] Estimating the Effects of Consolidating Drugs under Part D or Part B," Acumen LLC (September 2011), available: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf.

[6] https://www.kff.org/report-section/a-primer-on-medicare-what-types-of-supplemental-insurance-do-beneficiaries-have/.

point of sale. Beneficiaries move through the benefit into catastrophic coverage more quickly when price concessions are not passed on to them.

Price concessions not included in the negotiated price at the point of sale put downward pressure on plan premiums to the extent that plan bids reflect accurate DIR estimates. However, if a plan receives DIR above the projected amount factored into its bid, that DIR contributes primarily to plan profits, not lower premiums. CMS analysis indicates that in recent years, the DIR amounts that Part D sponsors and their PBMs actually received have consistently exceeded projected amounts. Moreover, sponsors sometimes opt for higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative. This is a twofold blow to patients: first they are pushed to a higher cost drug and then they receive no cost-sharing reduction from the very price concession structure that led the plan to prefer the higher cost drug in the first place.

Additionally, the current leeway given to PBMs on how to classify price concessions negatively affects the competitive balance in Part D. Some sponsors include price concessions in negotiated prices while others include them in DIR. When negotiated prices do not have a consistent meaning across the Part D program, beneficiaries cannot make educated choices when selecting a plan. The decision of how to treat price concessions may also provide a competitive advantage based on no substantive benefit to beneficiaries. For example, if Plan A applies price concessions as DIR at the end of the coverage year rather than using them to reduce drug prices at the point of sale, Plan A may be able to provide a lower premium than Plan B, which does apply price concessions at the point of sale. This could allow Plan A to capture additional market share by making its plan look more attractive to beneficiaries. However, that competitive advantage in the form of lower premiums results only from the technical, definitional difference in how Plan A treats its price concessions compared to Plan B. In other words, allowing PBMs the choice of how to treat their price concessions results in bids that are not actually comparable. And, while the beneficiary may be attracted by the lower premium cost in his or her plan selection, he or she may ultimately be worse off financially, due to higher out-of-pocket costs for prescription drugs.

The RFI asks whether HHS should ban the use of rebates in federal programs. We have argued in the past that, ***first, there must be common definitional terms, since what qualifies as a "rebate" may vary from contract to contract. Once we have agreed upon nomenclature, we can explore policy options such as mandatory pass-throughs or banning the use of rebates altogether.*** If we ban rebates without a common definition of what a rebate is, all we will accomplish is a redefining of money streams by PBMs to minimize "rebates."

Copay discount cards

The RFI asks whether there would be "circumstances under which allowing beneficiaries of federal healthcare programs to utilize copay discount cards would advance public health benefits such as medication adherence, and outweigh the effects on list price and concerns about program integrity[.]" Copay discount cards help patients access medicines that they otherwise might not be able to afford, but there is data indicating that these cards drive

adherence to brand products and prevent generic uptake.[7] Regardless, these cards are only band-aids to fix a symptom of the greater problem: a broken system with an incentive for high list prices. The only way to truly address this problem is to reform the current system where manufacturers set ever-higher list prices as they factor in ever-growing price concessions – which are not shared with patients. ***If this Administration succeeds in reforming that system, the discussion of how to control copay cards becomes less pressing. Until then, these cards are a critical tool for many patients and HHS must use caution in further limiting their use.*** These cards are particularly critical in the context of diseases for which there are only branded treatments available, as there are no cheaper alternatives. In such cases, the cards truly may make the difference between the patient accessing treatment, or not. In commercial plans, our members have seen PBMs and payers deny use of copay cards, which renders patients unable to afford their needed medications.

Incentives to lower or not increase list prices

HHS asks whether an appropriate "reward" for a manufacturer that has not raised prices over a certain level during a certain lookback period could be eligibility for the protected classes. Presumably, a product that sees price increases above the threshold would not be eligible for the protected classes. We would be concerned about limiting the protected classes in Part D in this manner because it would potentially punish patients for the actions of manufacturers. Our drug supply chain is rife with these types of misaligned incentives. We urge CMS to hold manufacturers accountable for the actions of manufacturers. ***Instead of leveraging the protected classes to control prices, CMS should reform or eliminate the rebate system***, as discussed above.

Fiduciary duty for Pharmacy Benefit Managers

The RFI asks whether PBMs should have a fiduciary duty to the entities for which they are managing pharmaceutical benefits. However, comments by Secretary Azar suggest that the Administration is not seeking to impose a fiduciary duty on PBMs; rather, it was meant "directionally."[8] This is contradictory to the RFI and has led to confusion about what the Administration means. Given this contradiction, we request that the Administration provide guidance and clarify what it means by "fiduciary duty." If it is something less than the well-established principles of a fiduciary duty, then the Administration should use different nomenclature to distinguish it. Additionally, the Administration should provide a full definition of this duty.

In regards to imposing specific legal duties, the approach that ATAP has taken thus far could best be summarized as "transparency first." ATAP believes that PBMs should be accountable for their actions, just as physicians have a standard of care that holds them accountable for their actions. Many physicians feel that some of the utilization management tactics have become so heavy-handed that they amount to the practice of medicine. While we support

[7] https://www.hbs.edu/faculty/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf.

[8] https://insidehealthpolicy.com/daily-news/azar-backpedals-trump%E2%80%99s-plan-make-pbms-act-fiduciaries.

creating transparency and accountability for PBMs, we advise a cautious approach to this issue. Before imposing any additional legal duty on any stakeholder in the drug supply chain, the Administration should conduct a financial analysis to determine that it will not have a significantly negative impact on drug prices.

Federal Preemption of Pharmacy Gag Clause Laws

The RFI notes that some contracts between PBMs and pharmacies include so-called "gag clauses" and asks what purposes these clauses serve "other than to require beneficiaries [to] pay higher out-of-pocket costs[.]" To our knowledge, these clauses serve no other purpose and should be banned in federal programs. While legislation has been introduced to accomplish this, ***we urge HHS to use its regulatory authority to ban gag clauses***. A gag clause may also come in the form of a "non-disparagement" clause. If such a clause is included in the contract between the PBM and the pharmacy, it has the same effect as a traditional gag clause. When a pharmacy tells a patient that the medicine would be cheaper without insurance, the PBM may consider this "disparagement" per the contract and penalize the pharmacy, or even omit them from the network. ***We ask that HHS ban these clauses in all of their forms, across all federal health programs.***

Thank you again for your thoughtful questions on topics that directly affect patients and prescribers. We appreciate your consideration of our viewpoints. If you require additional information, please contact Ally Lopshire, ally@wjweiser.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
International Foundation for Autoimmune & Autoinflammatory Arthritis
Kentuckiana Rheumatology Alliance
Lupus and Allied Diseases Association, Inc.
National Organization of Rheumatology Managers
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Rheumatology Alliance of Louisiana
Rheumatology Nurses Society
Tennessee Rheumatology Society
U.S. Pain Foundation