

June 1, 2023

The Honorable TK Keen
Chair
Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001

Re: AMA comments on draft Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation

Dear Chair Keen:

On behalf of the physician and student members of the American Medical Association (AMA), thank you for the opportunity to submit comments on the National Association of Insurance Commissioners' (NAIC) Pharmacy Benefit Management Regulatory Issues Subgroup's (the Subgroup) draft Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation (draft paper).

The AMA considers the draft paper to be very well done and believes the final paper could serve as an important tool for stakeholders who seek to address the role of Pharmacy Benefit Managers (PBMs) as "middlemen" among payers, pharmaceutical manufacturers, pharmacies, and patients. The AMA urges two additions to the draft paper's recommendations as outlined below.

First, the AMA asks that the Subgroup include a recommendation that: **the NAIC examine the impact of PBMs' utilization management requirements on patients, physicians, and the health care system, as well as how these requirements may exacerbate health disparities.** As noted in the draft paper, the role of PBMs now goes beyond the negotiation of drug prices on behalf of their clients. The ability of patients and physicians to have the information they need to make key decisions regarding medication, including specialty drugs, and of policymakers to craft viable solutions to escalating pharmaceutical costs, has been hampered by these arrangements that are driving higher prices without a clear and justifiable reason. Patients today are facing insurmountable costs and administrative barriers to obtaining prescription drugs from a pharmacy, PBM, or through physician-administered treatments. The burden is not solely caused by the escalating cost of pharmaceuticals, but also the increase in utilization management policies.

The opaque nature of PBM negotiations and operations makes it difficult for physicians to determine what treatments are preferred by a particular payer at the point-of-care, what level of cost-sharing their patients will face, and whether medications are subject to prior authorization, step therapy, or other utilization management requirements. Utilization management requirements put in place by PBMs often have disastrous effects on patient outcomes and result in wasted health care resources. For example, [AMA survey data](#) show that 94 percent of physicians report care delays due to prior authorization and 33 percent report that such requirements have led to a serious adverse event for a patient including hospitalization, permanent impairment, or death. The same data show that 64 percent of physicians report that prior authorization has led to ineffective treatments, 62 percent report that prior authorization

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has led to additional office visits, and 46 percent report that prior authorization has led to immediate care or emergency room visits. Moreover, in a health care delivery system in which racial and ethnic health care disparities are known to exist, market-driven barriers to care only perpetuate these disparities.

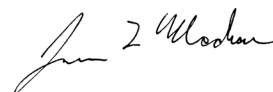
In addition to examining PBMs utilization management practices, the AMA also urges the Subgroup to include in the final paper a recommendation that: **NAIC further study and address horizontal and vertical integration in PBM markets and particularly its impact on patients' costs and access to care.** In October 2022, the AMA released the findings from a new analysis that suggests widespread low levels of competition in local PBM markets across the United States where PBMs provide services to commercial health insurers.¹ This analysis sheds light on variations in market shares and competition among PBMs and on the extent of vertical integration between health insurers and PBMs at the state and MSA-levels.

According to the analysis, commercial insurers largely use an external PBM for three services: rebate negotiation; retail network management; and claims adjudication (rather than conducting them in-house). The analysis assessed market competition for those three PBM services and concluded that, at the national level, a handful of PBMs have a large collective market share. The 10 largest PBMs had a collective share of 97 percent; and just as concerning, the four largest PBMs had a collective share of roughly 66 percent.

At both the state and MSA-levels, the analysis found a high degree of market concentration for each of the three PBM services assessed by the study. Specifically, more than three of four (about 78 percent) states had highly concentrated PBM markets; and more than four of five (85 percent) of MSAs had highly concentrated PBM markets.

In terms of the extent of vertical integration between health insurers and PBMs, the study found that 69 percent of drug lives at the national level are covered by an insurer that is vertically integrated with a PBM. On average, 63 percent of state-level drug lives and 65 percent of MSA-level lives are vertically integrated. Moreover, six of the 10 largest PBMs are used exclusively by one insurer or a set of Blue Cross Blue Shield insurers. Vertically integrated insurers may not allow non-vertically integrated insurer competitors to access their PBMs, or they could raise the cost of those PBM services. This could adversely affect nonvertically integrated insurers and ultimately patients through higher premiums.

In conclusion, we thank the Subgroup and NAIC staff for the significant amount of work that went into writing this draft paper. We look forward to the final paper and working with the NAIC on the recommendations included in the document. Please contact Emily Carroll, Senior Attorney, AMA Advocacy Resource Center, at emily.carroll@ama-assn.org with any questions.



James L. Madara, MD

¹ José R. Guardado, Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs, AMA Policy Research Perspectives (2022), <https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf>.