



June 17, 2022

[Submitted electronically via: PBM@dfs.ny.gov]

Adrienne A. Harris
Superintendent
New York State Department of Financial Services
1 State Street
New York, NY 10004-1511

Re: PBM2022-01 - Request for Public Comments on the Duty, Accountability and Transparency of Pharmacy Benefit Managers to Health Plans under Public Health Law Section 280-a(2)

Dear Superintendent Harris:

The American Pharmacists Association (APhA) would like to express our sincere gratitude on behalf of our pharmacist members and their patients for the leadership of Governor Hochul in signing into law comprehensive legislation earlier this year to increase transparency and regulation of the pharmacy benefit manager (PBM) industry. APhA recognizes that appropriate implementation of this legislation is vital to ensure patients continue to have access to services provided by their pharmacist and to lifesaving medications at their local community pharmacy. APhA appreciates the opportunity to provide feedback on the department's request for comment to make certain the implementation aligns with the full intent of the law.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health. In New York, APhA represents pharmacists and students that practice in numerous settings and provide care to many of your constituents. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-based, patient-centered care. APhA inspires, innovates, and creates opportunities for members and pharmacists worldwide to optimize medication use and health for all.

We also support the submitted comments from the Pharmacists Society of the State of New York (PSSNY).

As a result of the predatory practices of pharmacy benefit managers (PBMs), patients' access to medications from their local pharmacist across the country has declined¹, taxpayer dollars have been funneled into corporate profits², and generationally owned mom and pop pharmacies have been driven out of business.³ Appropriate government intervention is necessary to address the misaligned incentives in the PBM industry that prioritize profits over patients. We would encourage your department to consider the following comments related to the Pharmacy Benefit Bureau's rulemaking process:

Rules concerning the funds received by the PBM in relation to providing pharmacy benefit management services, which shall be received by the PBM in trust and shall be used or distributed only pursuant to the pharmacy benefit manager's contract with the health plan or applicable law; including how the use of spread pricing should impact the application of these rules.

Robust transparency, independent oversight, and appropriate consequences to disincentivize infractions are vital themes that must be included in the promulgation of rules by the Department. Transparency is needed to ensure PBM business practices that prioritize profits over patients are minimized. More robust oversight and transparency of spread pricing is also needed. For example, scrutiny of spread pricing must also account for effective rate clawbacks that deploy advanced drug pricing mechanics as a means to harvest spread outside the scope of traditional spread audits.^{4,5} Independent oversight of the PBMs is necessary to regularly monitor activities and complete audits as frequently as needed to ensure compliance with state laws and regulations. Authority for this oversight may be granted to either or both an independent organization with no financial ties to the PBM and the department. Appropriate consequences to disincentivize infractions may be completed through monetary fines and/or the termination of licensure of a PBM in the state.

Rules concerning PBM administrative fees, including limitations on their form and use.

Administrative fees should be limited, transparent, proactive, equitable, and should not be dependent on activities that PBMs would be incentivized to overuse. Pharmacists and pharmacies should not be subject to oblique and retroactive fees that minimize their ability to plan for the financial implications for their business. Along with "clawbacks," these fees have contributed to the unsustainability of the community pharmacy business model, which has resulted in the closure of pharmacies across the state, limiting patients' access to pharmacists as needed health care professionals.

¹ Rose J, Krishnamoorth R. Why your neighborhood community pharmacy may close. *The Hill*. Available at <https://thehill.com/blogs/congress-blog/healthcare/530477-why-your-neighborhood-community-pharmacy-may-close>

² 3 Axis Advisors. Analysis of PBM Spread Pricing in New York Medicaid Managed Care. Available at <http://www.ncpa.co/pdf/state-advoc/new-york-report.pdf>

³ Callahan C. Mom-and-pop pharmacies struggle to hang on. *Times Union*. Available at <https://www.timesunion.com/hudsonvalley/news/article/Mom-and-pop-pharmacies-struggle-to-hang-on-16187714.php>

⁴ Rowland D. Ohio launches probe of PBM practice that critics say gouges patients and taxpayers. *The Columbus Dispatch*. Available at <https://www.dispatch.com/story/news/2021/12/29/health-care-drug-prices-pharmacy-benefit-manager-pbm-money-maneuver-under-investigation-ohio/9037045002/>.

⁵ Tepper N. PBM clawbacks sidestep state bans on spread pricing. *Modern Healthcare*. Available at <https://www.modernhealthcare.com/payment/pbm-clawbacks-sidestep-state-bans-spread-pricing>.

Additionally, PBMs should not be incentivized to receive administrative fees by the completion of activities that they can overuse. For example, reports⁶ have described that when PBMs conduct audits of pharmacies they can keep a percentage when infractions or clerical errors are identified. This can only incentivize PBMs to abuse the audit system as a way to increase their revenue, regardless of if legitimate infractions or clerical errors are suspected.

Rules concerning the PBM’s accounting to the health plan for any of the following: pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other benefits received by the pharmacy benefit manager.

Due to the evidenced history of the PBM industry concealing information from health plans and pharmacies in an effort to take advantage of the supply chain, it is vital that consistent transparency, reports, and audits of PBM practices be the norm moving forward in New York. We would encourage the use of an independent organization to monitor pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other benefits received by the PBM. This independent organization should have no financial, governance, or leadership ties to the PBM and should have complete transparency to monitor benefits received by the PBM. Regular reports should be submitted to the Department of Financial Services, and the Superintendent should have the authority to conduct an audit of the PBM at any time. If the audit identifies infractions, the Superintendent should have the authority to fine the PBM and/or terminate their licensure to serve as a PBM in the state.

This model ensures transparency and oversight with appropriate consequences to disincentivize PBM business practices to inflate benefits they may receive.

Rules concerning the health plan’s access to all financial and utilization information of the PBM in relation to pharmacy benefit management services provided to the health plan.

Rules concerning the PBM’s disclosure to the health plan of the terms and conditions of any contract or arrangement between the PBM and any party relating to pharmacy benefit management services provided to the health plan including but not limited to, dispensing fees paid to the pharmacies.

Rules concerning the PBM’s disclosure to the health plan of any activity, policy, practice, contract, or arrangement of the PBM that directly or indirectly presents any conflict of interest with the pharmacy benefit manager’s relationship with or obligation to the health plan.

Transparent and regulated financial utilization information, disclosure of contract or agreement terms and conditions, and disclosure of any activity, policy, practice, contract, or arrangement of the PBM that directly or indirectly presents any conflict of interest are vital to ensure PBM compliance with New York law and regulations. These three issues are addressed jointly below.

Robust transparency of all aspects of the PBM, including financial utilization information, disclosure of contract or agreement terms and conditions, and disclosure of any activity, policy, practice, contract, or

⁶ Mann HJ, Rutherford G, Murphy EM, et al. Current issues and recommendations to manage prescription drug benefits for public health programs. *Res Social Adm Pharm.* 2022 Jan 24;S1551-7411(22)00028-6.

arrangement of the PBM that directly or indirectly presents any conflict of interest is needed. These terms need to be transparently available to the department, health plans, and any independent organizations overseeing the activities of the PBMs.

To ensure enforceability, APhA encourages that the definition of a PBM in rules be broad to encompass all entities that a PBM may be passing contracts through or acting on behalf of a PBM. In recent years, the largest PBMs in the country have contracted with Group Purchasing Organizations (GPOs). It is possible that with a narrow definition of PBM not encompassing all entities contracting with a PBM, such as these GPOs, that a PBM could firewall itself from sharing information with the department.

As well as comprehensive definitions, it is vital the department incentivize compliance through appropriate consequences and fines if infractions are identified.

Thank you again to Governor Hochul, your department, the Pharmacy Benefit Bureau, and your work to prioritize patients' access to health care services and medications over corporate profits. We are confident that with the appropriate implementation of this law, New York will be seen as a leader of transparency in the drug supply chain. If you have any questions or require additional information, please don't hesitate to contact E. Michael Murphy, PharmD, MBA, APhA Advisor for State Government Affairs by email at mmurphy@aphanet.org.

Sincerely,

A handwritten signature in black ink, reading "E. M. Murphy". The signature is fluid and cursive, with a horizontal line underneath the name.

E. Michael Murphy, PharmD, MBA
Advisor for State Government Affairs
American Pharmacists Association

cc: The Honorable Governor Kathy Hochul