APhA
American Pharmacists Association

October 13, 2023

[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: Proposed Consolidated Rulemaking for the Third Amendment to Insurance Regulation 219 (11 NYCRR Part 450), First Amendment to Insurance Regulation 224 (11 NYCRR 454), Insurance Regulation 226 (11 NYCRR Part 456 New), Insurance Regulation 227 (11 NYCRR Part 457 New), Insurance Regulation 228 (11 NYCRR Part 458 New), and Insurance Regulation 229 (11 NYCRR 459 New)

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 last 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 proposed consolidated rulemaking[1] to make certain the implementation aligns with the full intent of the law and the department's consideration of our previous responses to requests for information.[2,3,4]

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. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-

[1] https://www.dfs.ny.gov/system/files/documents/2023/08/rp_ins_a3reg219_a1reg224_226_227_228_229_text.pdf
[2] https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=-O0p8PxL8KU%3d
[3] https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=JBZN6jhr_48%3d
[4] https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=Lgoh8NkwQIM%3d

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based, patient-centered care. APhA inspires, innovates, and creates opportunities for members and pharmacists worldwide to optimize medication use and health for all.

As a result of the predatory practices of PBMs, patients' access to medications from their local pharmacist across the country has declined[5], taxpayer dollars have been funneled into corporate profits[6], and generationally owned pharmacies have been driven out of business.[7] In a February 2023 national survey conducted by APhA, 91.5% of respondents reported that current PBM practices negatively impact their practice and ability to provide patient care.[8] Appropriate government intervention is necessary to address the misaligned incentives in the PBM industry that prioritize profits over patients. Overall, we are supportive of the proposed consolidated rules and would like to highlight our key support and recommendations within the following areas:

Section 456.1 Applicability

APhA supports the broad definition of a PBM included in *Section 456.1 Applicability* and recommends the inclusion of Group Purchasing Organizations (GPOs) in the definition. In recent years, the largest PBMs in the country have contracted with GPOs. It is possible that with a narrow definition of PBM not encompassing all entities contracting with a PBM, such as these GPOs, a PBM could firewall itself from sharing information with the department.

Section 456.2 Pharmacy contract standards for pharmacy benefit managers.

APhA supports the pharmacy contract standards included in the proposed rules, including banning gag clauses being placed on pharmacists, and prohibiting claw backs. Additionally, we are supportive of the department's efforts to prohibit preferential reimbursement to associated pharmacies, as this has been a documented issue in other states[9] and is one of the focuses of an investigation by the Federal Trade Commission.[10] As an example of this practice, reports have shown that a PBM set the price of the same drug, strength, and quantity at over $3,800 at a PBM-owned pharmacy but on average less than $200 at a non-PBM owned pharmacy.[11]

Section 456.5 Contracts with parties related to pharmacy benefit management services.

As described above, there is concern that PBMs could create barriers to the department receiving transparent information about the terms of contracts. We are supportive of language included in the proposed rules that grant the authority to the department to request terms of contracts at the superintendent's discretion.

Section 456.7. Pricing models

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[5] 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

[6] 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

[7] 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

[8] Survey of Pharmacists: Quantifying the impact of PBM practices. *American Pharmacists Association*. February 2023. https://pharmacist.com/APhA-Press-Releases/apha-releases-survey-results-quantifying-the-impact-of-pbms

[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7251257/

[10] https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry

[11] Pharmacy Benefit Management. Purchaser Business Group on Health. November 30, 2021.

Overall, APhA supports the pricing model included in the consolidated proposed rule.

Other states[12] have taken many different approaches to ensuring reimbursement rates within state Medicaid fee-for-service and managed care programs are adequate. These approaches include using national benchmarks for ingredient costs, such as the National Average Drug Acquisition Cost (NADAC). Other states[13] have developed their own version of a NADAC survey to provide a state-specific metric for ingredient costs. States have begun using regularly recurring cost-of-dispensing surveys conducted by organizations independent of PBMs to determine adequate dispensing fees. Others have taken additional approaches beyond the cost of a dispensing survey to ensure appropriate reimbursement. For example, Ohio implemented a regularly recurring cost of dispensing survey and a tiered structure based on total pharmacy script volume.[14] This allows for fair and equitable reimbursement for independent, regional, and chain pharmacies.

Through the New York proposed pricing model, pharmacies will be able to operate in a more sustainable practice to ensure patients continue to have access to their medications and the services provided by their pharmacists. Similar to other states, we additionally encourage the department to identify a regular process for updating the professional dispensing fee through regularly recurring cost of dispensing surveys. Through this practice, the professional dispensing fee can be adjusted to appropriately cover an increase in the cost of dispensing.

Section 458.2 Prohibited market conduct practices.
We are supportive of rules ensuring patients have the autonomy to choose where to receive their health care and that prohibit patients from being forced or coerced into receiving care at a specific location by a PBM through differences in quantity limits, days' supply limits, or cost-sharing for the patient (copay or coinsurance) between different pharmacies.

Section 458.4: Network adequacy.
The Pharmacy Benefit Bureau should oversee the process for "any willing pharmacy," to join a PBM/plan network, to discourage incentives to restrict pharmacies in the network to those vertically integrated with the PBM.

If there are restrictions on patient access to certain pharmacies, the patient and pharmacy must have a simple process to join the network to ensure that patients can maintain access to their medications and their long-standing relationships with their local community pharmacists. Additionally, we are supportive of language in the proposed rule that prohibits the use of pharmacies that only provide mail-order services to patients as this could result in medication access issues for patients.

Requirements for Audits and Investigations of Pharmacies
PBMs should not be incentivized to receive administrative fees for the completion of activities that they

[12] Arkansas, Delaware, Georgia, Kentucky, West Virginia
[13] Ohio
[14] SPBM and PPAC Frequently Asked Questions (FAQs). Ohio Department of Medicaid. Available at https://managedcare.medicaid.ohio.gov/wps/wcm/connect/gov/de1fcc01-2e43-4085-a676-0ec62b3d21f3/SPBM+Provider+FAQ_September+2022.pdf?MOD=AJPERES&CVID=oe0eQNA

can overuse. For example, reports[15] 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 whether legitimate infractions or clerical errors are suspected. We encourage the department to clearly prohibit retaliatory audits through their proposed rulemaking.

Recommendation to enforce and hold PBMs accountable

While we are overall supportive of the consolidated proposed rules, we are concerned that without appropriate consequences to disincentivize infractions that PBMs will not adhere to the rules. Appropriate consequences to disincentivize infractions may be completed through monetary fines and/or the termination of licensure of a PBM in the state. We recommend that the department include explicit consequences in rules to ensure that PBMs are disincentivized from choosing to disregard the rules.

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,

Michael Baxter

Michael Baxter
Vice President, Federal Government Affairs
American Pharmacists Association

cc: The Honorable Governor Kathy Hochul

[15] 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.