October 16, 2023

Pharmacy Benefits Bureau
New York State Department of Financial Services
Via email: Kristina.Magne@dfs.ny.gov

RE: Third Amendment to 11 NYCRR 450 (Insurance Regulation 219)
First Amendment to 11 NYCRR 454 (Insurance Regulation 224)
New 11 NYCRR 456 (Insurance Regulation 226)
New 11 NYCRR 457 (Insurance Regulation 227)
New 11 NYCRR 458 (Insurance Regulation 228)
New 11 NYCRR 459 (Insurance Regulation 229)

Dear Pharmacy Benefits Bureau:

The National Community Pharmacists Association (NCPA) is pleased to comment in support of the Department of Financial Services' (DFS) proposed amendments to Insurance Regulations 219, 224, and new Insurance Regulations 226-229, a series of wisely crafted policies to regulate Pharmacy Benefit Management companies (PBMs). Although we offer a few recommendations to further assist DFS reach its policy objectives, NCPA applauds the proposal for its thoughtfulness and scope.

NCPA represents the interest of America's community pharmacists, including the owners of more than 19,400 independent community pharmacies across the United States and more than 2,500 independent community pharmacies in New York State. These pharmacies employed nearly 32,000 individuals and they filled approximately 163 million prescriptions in 2021, generating more than $10.3 billion in total sales.

To help DFS achieve optimal impact for its proposed rules, NPCA strongly recommends revisiting and clarifying the definition of "a substantial number of beneficiaries who work or reside in this state" found in Section 450.1 of Insurance Regulation 219. To define the substantial number of beneficiaries as 50 percent or more is to invite unintended consequences, with PBMs likely to manipulate plans and markets to avoid being subject to the policies and oversight of these proposed rules. We recommend striking this definition and instead clarifying that the proposed rules apply to all PBM's who are licensed in New York.

We recommend two additional definitions in Insurance Regulation 219 be further clarified. We suggest additional clarification in Section 450.1(k), the definition of pharmacy services

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administration organization, so as to not inadvertently include entities such as group purchasing organizations or clinically integrated pharmacy provider networks. Similarly, we suggest additional clarification for defining switch companies in Section 450.1(M), so as not to inadvertently include pharmacy software system companies.

We also recommend clarification in Section 450.7 to ensure the diligent work of DFS is realized to its fullest extent. PBMs that perform pharmacy benefits management for plans that are subject to the Employee Retirement Income Security Act of 1974 (ERISA) should be subject to all provisions of the rule that are not expressly exempted by state law. Without this clarification, the DFS proposal could potentially apply to only a modest portion of New York State's covered lives. We suggest the following:

Section 450.7 Applicability.

(a) Applicability. The following provisions of this Chapter shall not apply to a pharmacy benefit manager's provision of pharmacy benefit management services to a Medicare prescription drug plan offered pursuant to the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003," codified at 42 U.S.C. section 1395w-101 et. seq., as amended: section 456.2(a)(2) to (4), section 456.2(a)(7)(i) to (7)(iv), section 456.6, section 458.2(d), section 458.4, and Part 459 of this Title. To the extent a pharmacy benefit manager is providing services for other health plans in addition to Medicare prescription drug plans, the provisions of this Chapter shall continue to apply to the pharmacy benefit manager in its performance of pharmacy benefit management services to those other health plans. The following provisions of this Chapter shall apply to all other plans, including those subject to the Employee Retirement Income Security Act of 1974 (ERISA), unless expressly exempted by state law.

We strongly support the proposed language in Section 456.6 pertaining to maximum allowable cost lists and appeals and urge DFS to include the entirety of this proposed language in the final rule. We applaud the proposed policy for when appeals are upheld. If an appeal is upheld, we agree the maximum allowable cost should be adjusted for all pharmacies in the network of the health plan for which the appeal is upheld and all pharmacies that are in networks of other health plans for which the PBM provides pharmacy benefits management services. We urge DFS to include this critical language in the final rule.

NCPA strongly supports using a transparent reimbursement pricing model using cost-based reimbursement methodology as proposed in Section 456.7. This is not a novel approach as both

the states of West Virginia[1] and Tennessee[2] have enacted similar provisions. This transparent reimbursement approach will ensure that both the insured and plan sponsor know how their money will be spent. We support the proposal's use of transparent benchmarks such as the national drug acquisition cost (NADAC), which is updated on a weekly basis. We similarly support use of a regularly updated dispensing fee based on pharmacies' cost to dispense, such as was intended with the proposed $10.18. That said, the $10.18 figure reflects pharmacies' average cost to dispense at one point in time. We recommend this rulemaking contemplate future costs to dispense by basing the dispensing fee on the Centers for Medicare and Medicaid Services (CMS)-approved professional dispensing fee per the Covered Outpatient Drugs Rule, which can be periodically updated.

We also recommend the rule language specify net reimbursement amounts to ensure DFS achieves its objective of transparent reimbursement. We are concerned that, without proper oversight, PBMs will increase the number and amount of permissible fees. Approximately half of states have legislated prohibitions against adjudication fees and/or retroactive claims adjustments, but these safeguards are not provided in New York State law. We urge DFS to prevent such fees and to ensure transparent reimbursement with the following:

> Section 456.7. Pricing models. (a) Pharmacy reimbursements. A pharmacy benefit manager may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in ~~an~~ a net amount less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed, plus a professional dispensing fee ~~of $10.18~~ based on the CMS-approved professional dispensing fee found in the New York Medicaid State Plan. The net amount is inclusive of all transaction fees, adjudication fees, price concessions, and all other revenue passing from the pharmacy to the PBM. If the national average drug acquisition cost is not available at the time a drug is administered or dispensed, a pharmacy benefit manager shall not reimburse in ~~an~~ a net amount that is less than the wholesale acquisition cost of the drug plus a professional dispensing fee ~~of $10.18~~ based on the CMS-approved professional dispensing found in the New York Medicaid State Plan.

NCPA further recommends adding broad enforcement authority to the Office of the Superintendent of DFS to ensure compliance with Section 456.7 and all other provisions of these rules. We ask that you create an enforcement scheme that includes fines that are increasing for repeat violations and with no ceiling limit; authority to perform audits of PBMs; and an administrative action process that includes options to bar offending PBMs from doing business in

[1] West Virginia Code 33-51-9 (e)
[2] Tennessee Code 56-7-3206 (c)(1) and (f)

the state. We offer West Virginia as an example for such an enforcement scheme, noting how the Insurance Commissioner has fined PBMs for under-reimbursement in a similar model as proposed here.[3] We also urge DFS to create an online PBM-specific complaint form for capturing pharmacy and patient complaints in a format that can be aggregated and analyzed.

We appreciate the proposed language of Section 456.8 and offer a recommendation to help DFS meet its policy objective more efficiently. For a PBM's application documentation to restrict a pharmacy from dispensing a prescription drug covered by the covered individual's health plan found in Section 456.8(b)(2), we recommend the addition of PCN and IRX/Group to the proposal of RX BIN number.

NCPA also strongly supports the consumer protections found in Part 458 Insurance Regulation 228. In addition to our support of provisions pertaining to patient privacy protections, consumers will be especially well served by the language found in Section 458.2(c)(1) prohibiting marketing, advertising, and promotional activities that steer patients to pharmacies that are owned or affiliated with the PBM. With this proposed language, DFS joins many other policymaking entities across the nation in recognizing how not only consumers, but also taxpayers and pharmacies, are harmed by PBM conflicts of interest.

Patient steering is anticompetitive and hurts both consumers and local community pharmacy businesses in the state. It allows PBMs and their affiliated pharmacies to avoid competition with non-affiliated community pharmacies for consumers' business. According to a 2020 NCPA survey, 79% of respondents said their patients' prescriptions were transferred to another pharmacy in the previous six months without their patients' knowledge or consent.[4] Community pharmacies lost a median of 12 patients during that time period.[5]

The California Task Force on Pharmacy Benefit Management Reporting found that patient steering may create "misaligned incentives" that may lead a PBM to "favor an integrated pharmacy even if competing pharmacies have lower costs."[6] A similar task force in Minnesota came to the same conclusion, finding "these circumstances present obvious conflict-of-interest concerns" because "a PBM could engage in business practices that steer purchasers and payers to buy a drug from a

[3] https://www.wvinsurance.gov/LinkClick.aspx?fileticket=2-yH9776d-I%3d&tabid=915&portalid=0&mid=6681

[4] "Patient Steering a Massive Problem for Community Pharmacists, New Survey Shows," NCPA (Sept. 17, 2020) https://ncpa.org/newsroom/news-releases/2020/09/17/patient-steering-massive-problem-community-pharmacists-new-survey.
[5] Id.
[6] 3 California Department of Managed Health Care Task Force on Pharmacy Benefit Management Reporting, Report to the Legislature 6 (Feb. 2020), https://www.dmhc.ca.gov/Portals/0/Docs/DO/PharmacyBenefitManagementLegislativeReportAccessible.pdf.

pharmacy the PBM owns, even if the price of the drug is cheaper at a competing pharmacy."[7] A New York Senate committee determined "the strong possibility of a conflict of interest arises," giving PBMs the "opportunity to manipulate drug dispensing at their mail order pharmacies to enhance their own profits at the expense of plans and its members."[8] Finally, a Wisconsin task force also identified the inherent conflict of interest, finding that "when PBMs own pharmacies, they might favor their own pharmacies, even if other pharmacies have lower costs."[9]

The problem is particularly egregious when "specialty drugs" are involved because the practice is incredibly lucrative for PBMs. In 2021, the top four specialty pharmacies were all fully or partially owned by one of the largest PBMs.[10] Those four pharmacies accounted for 75% of total prescription revenues from pharmacy-dispensed specialty drugs.[11] The problem was made apparent in Florida by this Agency's audit, which found PBM-owned pharmacies were reimbursed at higher rates than non-affiliated pharmacies for dispensing the same specialty drugs.[12]

The solution for many states has been to open the pharmacy provider networks to all pharmacies that are willing to meet the terms and conditions of network participation and to allow consumers the opportunity to utilize the in-network pharmacy of their choice. This "any willing pharmacy" will make all pharmacies in the state compete for business, giving consumers the opportunity to choose the pharmacy that best meets their needs. While any willing pharmacy is not part of the DFS proposal, we appreciate the network adequacy standards found in Section 458.4, most notably provision a(2) that PBMs shall not use pharmacies that only provide mail order services to meet access standards. We ask DFS to include this language in the final rule.

Finally, NCPA supports the proposed requirements for audits and investigations of pharmacies found in Part 459 (Insurance Regulation 229). Of note, we commend DFS for the provision found in Section 459.2(a)(1)(ii) requiring PBMs to provide in advance a list of specific prescription numbers to be included in the audit or investigation. We ask DFS to include this provision in the final rule.

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[7] Report of the Minnesota Attorney General's Advisory Task Force on Lowering Pharmaceutical Drug Prices 44, (Feb. 2020), https://www.ag.state.mn.us/Office/Communications/2020/docs/DPTF_Feb2020Report.pdf.

[8] 5 New York Senate Committee on Investigations and Government Operations, Final Investigative Report: Pharmacy Benefit Managers in New York 22, (May 31, 2019), https://www.nysenate.gov/sites/default/files/article/attachment/final_investigatory_report_pharmacy_benefit_managers_in_new_york.pdf.

[9] 6 Report of the Governor's Task Force on Reducing Prescription Drug Prices 21, (Oct. 2020), https://oci.wi.gov/Documents/AboutOCI/RxTaskForceFinalReport.pdf.

[10] Adam J. Fein, "DCI's Top 15 Specialty Pharmacies of 2021 – and Three Factors that will Reshape 2022," DRUG CHANNELS (May 4, 2022) https://www.drugchannels.net/2022/05/dcis-top-15-specialty-pharmacies-of.html.

[11] *Id.*

[12] Milliman, Florida Agency for Health Care Administration: Pharmacy Benefit Manager Pricing Practices in Statewide Medicaid Managed Care Program (Dec. 2020).

Thank you for recognizing the need to regulate PBMs and for seeking public comment on these important issues. NCPA commends DFS for an excellent proposal and hopes our constructive recommendations will be incorporated in the final rule. If you have any questions, please do not hesitate to contact me at (703) 600-1186 or joel.kurzman@ncpa.org.

Sincerely,

Joel Kurzman
Director, State Government Affairs