



August 1, 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: PBM2022-02 - Request for Public Comments on the Applicability of Insurance Law Article 29 and Public Health Law § 280-a to Pharmacy Benefit Managers Providing Services to Medicare Part D Plans

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 affordable, lifesaving medications at their local community pharmacy. APhA appreciates the opportunity to provide additional feedback to that which we provided to your first request for comment, and now on the department's second request for comment.

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.

APhA recognizes the need for a thoughtful approach to implement provisions set forth in IL Article 29 and PHL § 280-a related to PBMs providing pharmacy benefit management services to Medicare Part D plans. In North Dakota and Oklahoma, state laws were challenged by the Pharmaceutical Care Management Association (PCMA) with claims that they were preempted by the Employee Retirement Income Security

Act of 1974 (ERISA). The U.S. Court of Appeals for the Eighth Circuit in *PCMA v. Wehbi*¹, and the U.S. District Court for the Western District of Oklahoma in *PCMA v. Mulready*², affirmed the U.S. Supreme Court's decision on *Rutledge v. PCMA*³, that ERISA was not preempted. However, the U.S. Court of Appeals for the Eighth Circuit and U.S. District Court for the Western District of Oklahoma ruled that sections of both state laws were preempted as applied to Medicare Part D plans. When determining how to implement provisions set forth in IL Article 29 and PHL § 280-a related to PBMs providing pharmacy benefit management services to Medicare Part D plans, APhA recommends referring to the decisions made in North Dakota and Oklahoma to ensure that the provisions are not preempted as applied to Medicare Part D plans. For the Department's reference, the sections of code in North Dakota that are preempted by Medicare Part D, and those that are not, are included below:

Sections Preempted by Medicare Part D

North Dakota Century Code sections 19-02.1-16.1

2. A pharmacy benefits manager or third-party payer may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim:
 - a. That is not apparent at the time of claim processing;
 - b. That is not reported on the remittance advice of an adjudicated claim; or
 - c. After the initial claim is adjudicated at the point of sale.
3. Pharmacy performance measures or pay for performance pharmacy networks shall utilize the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.
 - a. A pharmacy benefits manager or third-party payer may not collect a fee from a pharmacy if the pharmacy's performance scores or metrics fall within the criteria identified by the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.
 - b. If a pharmacy benefits manager or third-party payer imposes a fee upon a pharmacy for scores or metrics or both scores and metrics that do not meet those established by the electronic quality improvement platform for plans and pharmacies or other nationally recognized entity aiding in improving pharmacy performance measures, a pharmacy benefits manager or third-party payer is limited to applying the fee to the professional dispensing fee outlined in the pharmacy contract.

¹ *PCMA v. Wehbi*. U.S. Court of Appeals for the Eighth Circuit. Available at <https://ecf.ca8.uscourts.gov/opndir/21/11/182926P.pdf>

² *PCMA v. Mulready*. U.S. District Court for the Western District of Oklahoma. Available at https://www.oag.ok.gov/sites/g/files/gmc766/f/district_courts_opinion.pdf

³ *Rutledge v. PCMA*. U.S. Supreme Court. Available at https://www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf

c. A pharmacy benefits manager or third-party payer may not impose a fee relating to performance metrics on the cost of goods sold by a pharmacy.

5. . . . A pharmacy or pharmacist may disclose to the plan sponsor or to the patient information regarding the adjudicated reimbursement paid to the pharmacy which is compliant under the federal Health Insurance Portability and Accountability Act of 1996 [Pub. L. 104- 191; 110 Stat. 1936; 29 U.S.C. 1181 et seq.].

7. A pharmacy or pharmacist may provide relevant information to a patient if the patient is acquiring prescription drugs. This information may include the cost and clinical efficacy of a more affordable alternative drug if one is available. Gag orders of such a nature placed on a pharmacy or pharmacist are prohibited.

North Dakota Century Code sections 19-02.1-16.2

2. If requested by a plan sponsor contracted payer, a pharmacy benefits manager or third-party payer that has an ownership interest, either directly or through an affiliate or subsidiary, in a pharmacy shall disclose to the plan sponsor contracted payer any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor contracted payer.

Sections NOT Preempted by Medicare Part D

North Dakota Century Code sections 19-02.1-16.1

4. . . . If a patient pays a copayment, the dispensing provider or pharmacy shall retain the adjudicated cost and the pharmacy benefits manager or third-party payer may not redact the adjudicated cost.

8. A pharmacy or pharmacist may mail or deliver drugs to a patient as an ancillary service of a pharmacy.

9. A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered.

10. Upon request, a pharmacy benefits manager or third-party payer shall provide a pharmacy or pharmacist with the processor control number, bank identification number, and group number for each pharmacy network established or administered by a pharmacy benefits manager to enable the pharmacy to make an informed contracting decision.

11. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state.

North Dakota Century Code sections 19-02.1-16.2

3. A pharmacy benefits manager or a pharmacy benefits manager's affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefits manager, affiliate, or subsidiary agrees to not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty.
4. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state.
5. A licensed pharmacy or pharmacist may dispense any and all drugs allowed under that license.

In Oklahoma, the court ruled that Medicare Part D was preempted with respect to “Promotional Materials Provision, Cost Sharing Discount Provision, Retail-Only Pharmacy Access Standards, Service Fee Prohibition, Affiliated Pharmacy Price Match, and Post-Sale Price Reduction Prohibition” and Medicare Part D was not preempted with respect to “Any Willing Provider Provision, Affiliated Pharmacy Prohibition, Network Provider Restriction, Probation-Based Pharmacy Limitation Prohibition, Termination Payment Requirement, and Contract Approval Rule”.⁴

The regulations the Department is promulgating are focused around the authority of the Department to gather information from PBMs and licensing PBMs, including the following:

- “methods and procedures for facilitating and verifying compliance with the requirements of Article 29 and such other regulations as necessary to enforce the provisions of Article 29, including but not limited to requiring examinations of PBMs as often as the Department may deem it necessary”
- “require the filing of annual reports, and quarterly or other statements by PBMs, and address to any PBM any inquiry in relation to its provision of pharmacy benefit management services or any matter connected therewith”
- “minimum standards for the issuance of a license to a PBM, including both prerequisites for the issuance of a license and requirements for maintenance of a license”
- “defining, limiting, and relating to the duties, obligations, requirements and other provisions relating to PBMs under PHL 280-a(2), which provisions require PBMs to disclose and report certain information to New York health plans, and to hold certain funds in trust for the health plans”

As discussed in the *PCMA v. Mulready* opinion, “Medicare Part D incorporates the express preemption provision contained in Medicare Part C. See 42 U.S.C. § 1395w-112(g). Part C’s preemption provision provides: The standards established under this part shall supersede any State law or regulation (**other than State licensing laws** or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.” Given the inclusion of the bolded text, one could make the argument that state licensure laws of PBMs would not be preempted by Medicare Part D. APhA recommends the requirement of licensure of PBMs providing pharmacy benefit management services to Medicare Part D

⁴ *PCMA v. Mulready*. U.S. District Court for the Western District of Oklahoma. Available at https://www.oag.ok.gov/sites/g/files/gmc766/f/district_courts_opinion.pdf

plans in New York along with the authority of the Department to fine the PBM or revoke their license if infractions are identified.

In the North Dakota case, *PCMA v. Wehbi*, the court affirmed the district court's ruling that a plan sponsor contracted payer requesting a PBM with an affiliation to a pharmacy to disclose "any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor contracted payer" was preempted by Medicare Part D. In the U.S. District Court for the District of North Dakota decision on *PCMA v. Tufte*⁵, the court ruled Medicare Part D has federal standards on "setting forth annual disclosure obligations plan sponsors must provide to plan enrollees", "requiring PBMs to disclose information regarding drug sales and pricing to CMS", and "detailing reporting requirements for pharmacy benefits manager data to plan sponsors and CMS". APhA recommends the Department consult with legal counsel to review federal standards and ensure that the promulgation of rules on the following authorities of the Department are not preempted by Medicare Part D:

- "methods and procedures for facilitating and verifying compliance with the requirements of Article 29 and such other regulations as necessary to enforce the provisions of Article 29, including but not limited to requiring examinations of PBMs as often as the Department may deem it necessary"
- "require the filing of annual reports, and quarterly or other statements by PBMs, and address to any PBM any inquiry in relation to its provision of pharmacy benefit management services or any matter connected therewith"
- "defining, limiting, and relating to the duties, obligations, requirements and other provisions relating to PBMs under PHL 280-a(2), which provisions require PBMs to disclose and report certain information to New York health plans, and to hold certain funds in trust for the health plans"

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,



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

cc: The Honorable Governor Kathy Hochul

⁵ Pharm. Care Mgmt. Ass'n v. Tufte, 326 F. Supp. 3d 873
[Pharm. Care Mgmt. Ass'n v. Tufte, 326 F. Supp. 3d 873, 878, 2018 U.S. Dist. LEXIS 150655, *1, 2018 WL 4222870 \(D.N.D. September 5, 2018\)](#)