

August 1, 2022

Pharmacy Benefits Bureau
New York State Department of Financial Services
1 State Street
New York, NY 10004

RE: NCPA response to RFI PBM 2022-02

To whom it may concern:

I am writing on behalf of the National Community Pharmacists Association (NCPA) in response to the request for information on the applicability of Insurance Law Article 29 and Public Health Law Section 280-a to pharmacy benefit managers (PBMs) providing services to Medicare Part D plans. 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 2,561 independent community pharmacies in New York. These New York pharmacies filled over 142 million prescriptions last year, impacting the lives of thousands of patients in your state.

Federal laws governing Medicare Part D do not preclude New York State from applying Insurance Law Article 29 or Public Health Law Section 280-a to PBMs providing services to Part D plans. The Part D preemption clause states, "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 [Part D plans] which are offered by [Part D sponsors] under this part."¹ Interpreting that statute, federal courts have ruled that Medicare Part D preempts state laws "when (1) Congress or [CMS] has established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to' those standards."² For example, the Eighth Circuit used this test to evaluate Part D preemption challenges to North Dakota's PBM regulations, many of which are similar to New York's laws, and ruled that most of the provisions are not preempted.³ Similarly, most, if not all, of the provisions in Insurance Law Article 29 and Public Health Law Section 280-a do not "act 'with respect to'" federally established "standards" and are not preempted.

Insurance Law Article 29

Insurance Law Article 29 generally imposes two obligations on pharmacy benefit managers operating in the state: (1) an obligation to obtain a license, and (2) the obligation to submit an annual report to the Superintendent. Federal law does not establish licensing requirements for PBMs that provide services for Part D plans. Additionally, federal law does not establish a requirement that PBMs serving Part D plans submit reports to state agencies.

¹ 42 U.S.C. § 1395w-26(b)(3).

² *PCMA v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018).

³ *PCMA v. Wehbi*, 18 F.4th 956 (8th Cir. 2021).

Therefore, neither of Article 29's obligations act with respect to federally established Part D standards, and those obligations can be applied to PBMs providing services to Part D plans.

Public Health Law Section 280-a

Section 280-a(2) governs a PBM's duty and obligation of fair dealing to the plan sponsor, covered individuals, and contracted pharmacies. Federal standards address the contents of the contracts between PBMs and other parties, such as Part D plan sponsors, beneficiaries, and pharmacies. However, those federal standards do not address the manner in which a PBM must fulfill its contractual obligations. Therefore, this state provision does not act with respect to a federally established standard, and it may be applied to PBMs providing services to Part D plans.

Section 280-a(4) requires PBMs to establish a "reasonable process to appeal, investigate and resolve disputes regarding multi-source generic drug pricing." Federal law establishes standards regarding the price "the part D sponsor (or other intermediary contracting organization) [such as a PBM] and the network dispensing pharmacy have negotiated as the amount such network entity will receive, in total, for a particular drug."⁴ However, the standards addressing the negotiated price do not address disputes regarding that price or the manner in which those disputes are resolved. Federal preemption requires the existence of a specific federal standard and overlap between state regulations and that federal standard, and that overlap does not exist here. For Part D plans, federal law governs the price agreed upon between the PBM and pharmacy but is silent regarding subsequent disputes between the parties over that price. Therefore, Section 280-a(4) does not act with respect to a federally established standard, and the provision can be applied to PBMs providing services to Part D plans.

Section 280-a(5)(b) allows pharmacies to retain the adjudicated cost of dispensed drugs and prohibits PBMs from recouping the adjudicated cost. CMS has established some cost-sharing obligations.⁵ However, those obligations do not specify which entity is entitled to retain copayment amounts. Therefore, there is no specific federal standard where the state regulation overlaps. As a result, Section 280-a(5)(b) does not act with respect to a federally established standard, and the provision can be applied to PBMs providing services to Part D plans.

Thank you for your time and consideration. If you have any questions about the information in these comments, please do not hesitate to contact me at anne.cassity@ncpa.org.

Sincerely,



Anne Cassity, JD
Vice President, Federal and State Government Affairs
National Community Pharmacists Association

⁴ 42 U.S.C. § 1395w-102.

⁵ 42 C.F.R. 423.104(d)(2)(i)-(iii).