

June 19, 2017

Via: Hand-Delivery

The Honorable Jeff Landry Attorney General P.O. Box 94005 Baton Rouge, LA 70804

RE: Request for an opinion on the inappropriateness for the Board of Pharmacy to regulate PBMs

Dear Attorney General Landry:

I am writing, respectfully, in response to Representative Robert Johnson (D) request "for an attorney general opinion as to whether pharmacy benefit managers (PBMs) are subject to regulation by the Louisiana Pharmacy Board." As background, PCMA is the national trade association representing America's pharmacy benefit managers ("PBMs"), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D.

Employers and health insurers contract with PBMs to manage prescription drug benefits for their employees or enrollees. In addition to negotiating price concessions with pharmacies and drug manufacturers, PBMs handle a range of administrative functions including verifying eligibility, processing pharmacy claims, administering prior authorization and utilization review programs, auditing pharmacies for fraud and abuse, suggesting drug formularies to clients and handling grievances and appeals when requested to by the client. Since PBM benefit management supports health plans, they are required to comply with state insurance laws and regulations on behalf of their clients.

Federal Trade Commission (FTC) Opines Board of Pharmacy Regulation of PBMs is Anti-Competitive and Could Raise Drug Costs

In 2011, Mississippi Representative Mark Formby (R) received a letter from the FTC regarding legislation granting the Mississippi Board of Pharmacy regulatory oversight of PBMs. The FTC warned that, "If pharmaceutical manufacturers, pharmacists, and pharmacies gain access to whatever information the Pharmacy Board requires the PBMs to produce, they could have access to competitively sensitive information, potentially facilitate collusion, and increase prescription drug prices." The FTC further cautioned Representative Formby that the regulation of PBMs by the Board of Pharmacy would contribute to anti-competitive practices, because "pharmacists, who negotiate retail prescription drug prices with PBMs and compete against PBM-owned mail-order pharmacies, would now be regulating PBMs." PBMs negotiate rates for prescription drugs with pharmacies and, later, audit pharmacies for activities such as fraud, waste and abuse.

Consequently, a Board of Pharmacy which is composed of pharmacists cannot impartially regulate PBMs. The FTC concluded that "pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy

¹ The Honorable Robert Johnson letter to Attorney General Jeff Landry, May 15, 2017 Re: Request for an attorney general opinion as to whether pharmacy benefit managers are subject to regulation by the Louisiana Pharmacy Board.

² FTC letter to Representative Mark Formby (R-MS), March 22, 2011 https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippipbm.pdf.

³ Ibid



board. Indeed, the antitrust laws recognize that there is a real danger that regulatory boards composed of market participants may pursue their own interests rather than those of the state."

Additionally, the Supreme Court of the United States ruled in *North Carolina Board of Dental Examiners vs. Federal Trade Commission*⁵ that "when a controlling number of the decision makers on a state licensing board are active marketplace participants in the occupation the board regulates, the board can invoke state-action immunity only if it is subject to active supervision by the state." The FTC has recently filed a complaint against the Louisiana Real Estate Appraisers Board for violating the Supreme Court's ruling in the North Carolina Board of Dental Examiners decision.

PCMA strongly believes, given the FTC's comments in Mississippi, their recent complaint against the Louisiana Real Estate Appraisers Board, and the guidance found in North Carolina Board of Dental Examiners the Louisiana Board of Pharmacy regulating PBMs without the appropriate active supervision of the state could run afoul of the FTC. It is foreseeable that a situation could arise where the Board of Pharmacy, ostensibly acting in the best interests of the consumers of this state, promulgates a regulation perceived by the FTC as favoring pharmacists at the expense of PBMs.

The Louisiana Pharmacy Practice Act Does Not Give the Board of Pharmacy Regulatory Authority of PBMs

The Louisiana Revised Statutes, Title 37, Chapter 14 – Pharmacy Practice Act (Act), Part A. General Provisions, commences with the legislative declaration and the statement of purpose that provide guidance to the entirety of the Act and the stated purpose and role of the Board of Pharmacy.

§1162. Legislative declaration

The practice of pharmacy in the state of Louisiana is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. Therefore, *any rule or regulation adopted relative to pharmacists and the operations of pharmacies*, including any amendment, modification, or repeal thereof, shall be adopted as provided by the Administrative Procedure Act and shall be effective only upon approval by the respective oversight committees *having jurisdiction over matters relative to pharmacists and the operation of pharmacies*. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this Chapter, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy. This Chapter shall be liberally construed to carry out these objectives and purposes.

§1163. Statement of purpose

It is the purpose of this Chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; and the licensure, permitting, certification, registration, control, and regulation of all persons or sites, in or out of this state that sell drugs or devices to consumers and/or patients or assist in the practice of pharmacy, within the state.

⁴ Ibid

North Carolina Board of Dental Examiners v. FTC available at https://www.supremecourt.gov/opinions/14pdf/13-534_19m2.pdf

⁶ United States of America Before the Federal Trade Commission in the matter of Louisiana Real Estate Appraisers Board, Respondent, Docket No. 9374



These provisions specifies that the Board of Pharmacy is limited to regulating pharmacists and pharmacies, and specifically limits in the "Statement of Purpose" the areas of regulation to include the licensure of pharmacists, pharmacies and other pharmacy personnel that sell drugs or devices to consumers or patients. PBMs are not involved in the practice of pharmacy, with the exception of mail-service pharmacies or specialty pharmacies operated by PBMs which are already licensed as out-of-state pharmacies. The legislature has not deemed it in the public interest to bestow upon this Board this regulatory authority. Furthermore, in light of the guidance in North Carolina Board of Dental Examiners v FTC the legislature has not made the findings and created the framework to displace competition or provide the "active supervision" that governing federal law requires in this area.

Board of Pharmacy Regulation of PBMs is Inappropriate and Unnecessary

- **PBMs** are not acting as pharmacies with respect to their benefits management functions. PBMs are standing in the place of employers and health plans *payers* of pharmacy services when they determine an enrollee's eligibility and cost-sharing, process claims, conduct prior authorization and utilization review, and negotiate rates with pharmacies. PBMs clearly are not providing pharmacy services when they undertake these benefits management functions.
- Health plan subcontractors are regulated by state insurance departments. Health plans and employers contract with a variety of vendors for carved-out services, which, in addition to prescription drug management, may include behavioral health, imaging, and disease management. The services PBMs provide for prescription drug benefits are the same types of services health plans contract for with PPOs, utilization review companies, and third party administrators with respect to medical benefits.
- State insurance departments are best situated to protect consumers. Oversight of health plan subcontractors is best undertaken by the state agency tasked with ensuring that consumers receive the benefits they have been promised, which is the insurance department. State boards of pharmacy oversee the practice of pharmacy, which involves delivery of care. The insurance commissioner oversees delivery of promised coverage.
- **PBMs comply with state laws applicable to health insurance.** As subcontractors, PBMs in their benefit management capacity must comply with the same state laws designed to protect consumers rather than health care service providers as their health plan clients.

In conclusion, the regulation of PBMs by the Board of Pharmacy is akin to the Board of Medicine regulating health insurance plans. PCMA respectfully requests that the Office of the Attorney General offer an opinion that the Board of Pharmacy does not have the authority, under the Pharmacy Practice Act, to regulate PBMs. We appreciate your consideration of our concerns and if you have any questions, please feel free to contact me at lrowley@pcmanet.org, or Rob Rieger, Esq., Adams and Reese, LLP at Robert.Rieger@arlaw.com.

Sincerely,

Lauren Rowley

Vice President, State Affairs