December 13, 2021

Commissioner John F. King
Office of Insurance and Safety Fire Commissioner
Administrative Procedure Division
Two Martin Luther King, Jr. Drive
704 West Tower, Floyd Building
Atlanta, Georgia 30334

Re: Pharmacy Benefits Managers Regulation

Dear Commissioner King,

We write to you regarding a pattern of large-scale non-compliance with Georgia's PBM laws found in Chapter 64 of Title 33 in the commercial market.

Georgia PBM laws are sweeping in scope, with significant time and effort being invested by the Georgia General Assembly to protect patients, payors, and providers from abusive PBM practices. Importantly, Georgia law affords you with significant enforcement powers to ensure patients, payors, and providers are protected including but not limited to the ability to conduct financial examinations and compliance audits, impose fines payable to the state, insureds, and dispensers, issue cease and desist orders, probation, and license revocation.

Nonetheless, and as you are likely aware, many of the large PBMs in Georgia have long taken the position that the Employee Retirement Income Security Act (ERISA) preempts Georgia's PBM laws and regulations and as such, they fail to comply with Georgia's law in the commercial market broadly or at a minimum Georgia's self-funded commercial market. In support of their position, PBMs have largely relied on a string of Eighth Circuit Court of Appeals cases striking down PBM regulations in Arkansas and in North Dakota.

While Georgia's PBM laws set forth in Chapter 64 of Title 33 and PBM regulations promulgated by your office in late 2020 and implemented in 2021 are written with broad applicability, the undersigned are unaware of any instances in which Georgia's PBM laws have been enforced by your office in the self-funded commercial market. In addition, the webpage for consumer complaints states that there is no jurisdiction for, amongst other things, self-insured employer plans. Note your office's provider complaint form also provides that fully insured and self-insured claims are not subject to the jurisdiction of your office.

In light of the U.S. Supreme Court decision in Rutledge v. Pharmaceutical Care Management Association (PBM trade association hereinafter referred to as "PCMA"), and the Eight Circuit Court of Appeals decision in PCMA v. Wehbi, we are asking that you make protecting Georgia's patients from PBM abuses a priority of your office.

More specifically, we are asking that you (1) provide immediate notice to PBMs of your intent to enforce Georgia's PBM laws across the commercial market including the fully insured and self-funded markets; (2) direct your investigators to reopen any complaints previously closed in which no action was taken due to the claims being fully insured or self-funded; (3) clarify on your website and complaint forms that Georgia's PBM laws will be enforced in the fully insured and self-funded market; (4) develop PBM provider and consumer complaint forms in coordination with the undersigned; and (5) pursue investigations into, amongst other things, patient steering of patients on specialty medications including oncology patients in the commercial market as well as the State Health Benefit Plan and Medicaid Managed Care.

For your convenience, set forth below is a more detailed summary of the recent cases ruling in favor of state regulations of PBMs with the cases themselves attached.

Rutledge v PCMA

In Rutledge v. PCMA, PCMA had asserted, amongst other things, that Arkansas' PBM generic pricing law was preempted by ERISA. The 8th Circuit agreed with PCMA but the U.S. Supreme Court overturned the 8th Circuit's decision holding that Arkansas' PBM MAC pricing law was not preempted by ERISA and that state cost regulations of PBMs is permissible including in the ERISA market. In that decision the U.S. Supreme Court drew clear limits to ERISA's preemptive reach:

> ERISA's preemptive reach is limited to a plan's internal functions and remedies related to those functions—for example, who is eligible for benefits, what benefits are available, what information must be reported and disclosed to beneficiaries, and what duties the plan owes its beneficiaries.

In Georgia, this holding has huge significance as Georgia has a variety of PBM laws which seek to protect patients, payors, and providers but that do not force plans to adopt "any particular scheme of substantive coverage." These laws include but are not limited to:

- Multisource generic drug pricing (O.C.G.A. 33-64-9);
- Prohibition of copay claw-backs (O.C.G.A. 33-64-11(a)(3));
- Prohibition of patient steering (O.C.G.A. 33-64-11(a)(7));
- Prohibition of point of sale and retroactive fees (O.C.G.A. 33-64-9.1(b)(2));
- Prohibition of reimbursement of a drug being tied to patient outcomes, scores, or metrics (O.C.G.A. 33-64-9.1(b)(2));
- Prohibition of PBM restrictions on pharmacies offering delivery services to patients (O.C.G.A. 33-64-11(a)(2));

- Prohibition of PBMs charging pharmacies and other dispensers fees for network enrollment (O.C.G.A. 33-64-11(a)(10));
- Prohibition of PBMs imposing accreditation standards for specialty dispensing in excess of standards imposed by the Georgia Board of Pharmacy(O.C.G.A. 33-64-11(a)(10));
- Prohibition of PBM imposed gag clauses restricting pharmacies and other dispensers from informing patients of cheaper alternatives (O.C.G.A. 33-64-11(a)(1)); and
- Imposing a surcharge on PBMs that continue to steer or impose point of sale or retroactive fees (O.C.G.A. 33-64-12).

Note, with regard to the surcharge, the U.S. Supreme Court in Rutledge v. PCMA relied heavily on New York State Blue Cross Plans v. Travelers (see attached) which was a case in which the U.S. Supreme Court upheld a surcharge instituted by the state of New York.

Because the foregoing laws do not limit plan internal functions and remedies, these laws are not preempted by ERISA and therefore PBMs should comply with these laws in the commercial market including the fully insured and self-funded market.

PCMA v. Wehbi

In PCMA v. Wehbi, the Eighth Circuit Court of Appeals considered the issue of ERISA preemption in connection with a set of North Dakota PBM laws that are strikingly similar to Georgia's laws set forth above. Notably, this case was before the court after the Eighth Circuit's previous holding in PCMA v. Tufte, finding North Dakota's PBM laws were preempted by ERISA, was vacated.

In PCMA v. Wehbi, PCMA withdrew its ERISA preemption challenge to the following North Dakota laws:

- Prohibiting fees after a claim is adjudicated;
- Restrictions on pharmacy performance measures including a prohibition on imposing a fee relating to performance metrics on the cost of goods sold by a pharmacy; and
- Prohibition on Copay clawbacks.

This is incredibly significant when it comes to Georgia enforcement as several of these laws bear similarities to Georgia's laws.

While PCMA withdrew its ERISA preemption challenge of the above referenced North Dakota laws, it continued to argue several other provisions of North Dakota's laws were preempted. The Eighth Circuit Court of Appeals disagreed holding the laws set forth below were not preempted:

- Prohibition of PBM restricting a pharmacy from disclosing information to a plan sponsor;
- Prohibition of PBM imposed pharmacy gag clauses;
- Prohibition of PBM restricting a pharmacy from mailing or delivering drug to a patient as an ancillary service;

- Prohibition of a PBM from requiring accreditation standards inconsistent with or more stringent than state requirements;
- Require PBM to make certain disclosures to plan sponsors and pharmacies; and
- Prohibition of PBM from owning or having an ownership interest in a mail order or specialty pharmacy unless the affiliate agrees to certain standards of conduct.

With regard to the foregoing laws, the Eighth Circuit Court of Appeals found that they did not relate to ERISA as they were, at most, regulating noncentral matters of plan administration with de minimis economic effects and impact on plan administration.

As previously indicated, just as North Dakota's laws are not preempted by ERISA as they at most regulate noncentral matters of plan administration, Georgia's laws also are not preempted because they at most regulate noncentral matters of plan administration.

Conclusion

In light of U.S. Supreme Court precedent and guidance from the Eighth Circuit Court of Appeals, you should feel empowered, and we hope compelled to enforce Georgia's PBM laws across the commercial market and to protect Georgia's patients, payers, and providers. Every day that Georgia's laws go unenforced, patients are steered away from oncology and pharmacy practices and to PBM owned and affiliated pharmacies. This issue is gaining national attention and it is worth noting that Georgia Attorney General Chris Carr joined other state attorney generals in briefs in both cases arguing for state rights to enforce PBM laws in the commercial market.

Finally, we again ask that you (1) provide immediate notice to PBMs of your intent to enforce Georgia's PBM laws across the commercial market; (2) direct your investigators to reopen any complaints previously closed in which no action was taken due to the claims being fully insured or self-funded; (3) clarify on your website and complaint forms that Georgia's PBM laws will be enforced in the fully insured and self-funded market; (4) Develop PBM provider and consumer complaint forms in coordination with the undersigned; and (5) pursue investigations into, amongst other things, patient steering of patients on specialty medications including oncology patients in the commercial market as well as the State Health Benefit Plan and Medicaid Managed care.

Thank you for your support, leadership, and attention to this important issue.

Sincerely,

American Pharmacy Cooperative, Inc.
Georgia Pharmacy Association
Georgia Society of Clinical Oncology