December 17, 2019

Members of the WV Legislature's Rule-Making and Review Committee
State Capitol
Charleston, WV 25305

Via email

Re: Pharmacy Auditing Entities and Pharmacy Benefit Managers, 114 CSR 99 (CR)

Dear: Members of the WV Legislature's Rule-Making and Review Committee:

I am writing to provide the Pharmaceutical Care Management Association (PCMA) comments on the West Virginia Insurance Commission's revised proposed rule implementing SB 489 (2019) and its changes to the Pharmacy Audit Integrity Act (the "Act"), enacted earlier this year. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which manage prescription drug benefits for large employers, health insurance carriers, labor trusts, government programs, and other payers. While we appreciate that the Offices of the Insurance Commissioner (OIC) acceptance of many of our previously suggested amendments to the regulation (114CSR99), we continue to have concerns with some of the remaining provisions.

We believe that many of the provisions included in §114-99-6. Network adequacy and reporting requirements of the revised proposed rule go beyond the Act, establishing new policies and requirements not contemplated by the Legislature or authorized by the statute. In fact, the legislature purposely removed the inclusion of these types of provisions when it adopted a licensing structure for PBMs and restrictions on gag orders, fees, and audits.

The OIC's contention that the rebate provisions are authorized under the grant of rulemaking authority in W.Va. Code 33-51-8 and 33-51-10 to establish reporting requirements is without merit. The agency may not come up with reporting requirements on any topic it wishes. The reporting requirements must bear a reasonable relationship to the purpose and intent of the statute. See *Anderson v. Anderson Contractors, Inc. v. Latimer*, 162 W.Va. 803, 807-808 (1979)("the rules and regulations must be reasonable and conform to the laws enacted by the Legislature."); Syl. Pt. 4, State ex rel. *Callaghan v. W.Va. Civil Serv. Comm'n*, 166 W.Va. 117 (1980) ("[R]ules will only be upheld if they are reasonable and do not enlarge, amend or repeal" rights created by statute.). As noted above, the rebate provisions were specifically excluded from the statute. Accordingly, the agency's proposed provisions cannot be said to reasonably relate to the statute.

The OIC's contention that its authority to promulgate the rebate provisions flows from its statutory authority to regulate premiums for accident and sickness insurance is equally flawed. As the proposed rule itself states, [t]he purpose of this rule is to implement the Pharmacy Audit Integrity Act . . ." Likewise, the other provision relied upon by OIC to justify the rebate

provisions is W.Va. Code 33-51-10, authorizes it to promulgate rules to implement the provisions of Article 51 (i.e., the Act). As noted above, however, the purpose and intent of the Act is to allow for the regulation of pharmacy audits. The Act does address the regulation of accident and sickness insurance premiums. The regulation of such insurance premiums is authorized under Article 16 of Chapter 33. If the OIC wishes to promulgate rules regarding rebates so as further its regulation of insurance premiums, it must do so pursuant to its grant of rulemaking authority under that article. See W.Va. Code 33-16-17. To do otherwise, as OIC seeks to do here, would deprive the people of West Virginia the proper notice required to ensure that their government and its legislative process remain open, transparent and effective.

The OIC additionally claims that this information will assist them in evaluating insurance premium rates. We adamantly disagree with their premise that reporting of this rebate information will inform them on evaluating premium rates. Health plan MLR reporting already requires rebate information to assist the OIC in evaluating insurance premium rates. What a PBM retains in rebates is irrelevant to premium rates and as previously stated, not required by the Act.

Additionally, the proposed rule requires PBMs to report "both the amount paid by the covered entity and the PBM for pharmacist services itemized by pharmacy, product and by goods and services." Again, this is an area of regulation that the legislature considered and rejected in adopting the final version of SB 489. Not only is this a significant expansion of the statute, the type of information required is confidential, proprietary and competitively sensitive. We believe the OIC is not implementing the Pharmacy Audit Integrity Act with this provision, but rather is rewriting the statute, in violation of well-established precedent. Critically, rules and regulations will only be upheld if "they are reasonable and do not enlarge, amend or repeal substantive rights created by statute." *Hale,* 228 W.Va. at 786, 724 S.E.2ed at757(quoting Syl.Pt.4, *State ex rel.Callahan v W.Va. Civil Serv. Comm'n,* 166 W. Va. 117, 273 S.E.2d 72 (1980)) (emphasis added). Indeed, the Legislature considered the "spread" issues when it enacted the Act but rejected it. The agency cannot now seek now to have those provisions enacted through the rulemaking process.

Additionally, government agencies – including the Congressional Budget Office (CBO) and the Federal Trade Commission (FTC) – have long cautioned that the PBM disclosure mentioned about could raise the cost of prescription drug benefits.

Lastly, the proposed rule also requires PBMs to report the number of pharmacists (with whom PBMs do not contract) and the number of pharmacies that have terminated their network participation with a covered entity. The OIC did not provide a rationale for the requirement of pharmacy data – termination and reimbursements – which is also not included in the Act.

We therefore recommend striking §114-99-6.3 - 4 from the proposed regulation.

Thank you for the opportunity to our concerns. Please contact me at 202-756-5740, if you have any questions about our comments.

Sincerely,

Lauren Rowley
Senior Vice President, State Affairs