

Madam President (or President Gutierrez), Members

Richard Mazzone representing the Pharmaceutical Care Management Association, the trade association representing the PBM industry. I am a licensed pharmacist in California, former member and president of this Board, and current chairman of the New Mexico Board of Pharmacy. While PCMA has a number of objections to this bill. I'm going to address only one aspect – that this board is not the appropriate regulator for PBMs.

As you know, in the North Carolina Dental Board decision, the Supreme Court sided with the Federal Trade Commission when it held that state licensing boards are not subject to immunity from anti-trust litigation if those boards are controlled by active market participants and are creating regulations that limit competition.

More recently, Maureen Ohlhausen, the acting Chair of the FTC, announced last month the creation of the Economic Liberty Task Force which will identify problematic licensing laws. Although this task force is mostly meant to be an advisory resource, it will have the ability to take legal action against licensing boards engaged in anti-competitive behavior.

And we know that the FTC already has a problem with BOP regulation of PBMs. When the state of Mississippi was considering this idea, the FTC wrote that “because pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBM's may create tensions and conflicts of interest for the pharmacy board. Indeed the anti-trust 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.”

The FTC has made it clear that this type of regulatory scheme could be anti-competitive. At the same time, they are increasing the scrutiny of boards like this one. You could end up in a situation where this board – ostensibly acting in the best interests of the consumers of this state – promulgates a regulation that is seen by the FTC as favoring pharmacists at the expense of PBMs. The result could be that this board and the pharmacists on this board lose their immunity for anti-trust litigation.

At the Senate Business & Professions Committee informational hearing on PBMs last week, pharmacists and their representatives argued that pharmacists were the best advocates for the consumers. But because of the scrutiny of the FTC, your

legal team will have to review every proposed rule to keep you out of trouble and as a result, this board may actually be precluded from enacting what you think is the right policy.

The other problem with this Board regulating PBMs is that much of what PBMs do is already regulated by the Department of Managed Health Care and the Department of Insurance. Regulations from this board could easily contradict existing laws, regulations or previous DMHC approvals of a health plan's pharmacy benefits.

At the Senate hearing, one of the documents provided by the staff to the committee was this one that is being handed out. It is a list of the statutes that PBMs must comply with. You'll note that these laws deal with coverage issues, medical necessity, prior authorization, step therapy, formularies, and even an entity unique to PBMs – Pharmacy & Therapeutics (P&T) Committees.

DMHC and DOI enforce laws on health care plans and health insurers. In the case of DMHC, they have promulgated regulations to require that the PBMs comply with these requirements – California Code of Regulations 1300.67.24 requires PBM contracts “include provisions, terms and conditions sufficient to ensure the standards” of DMHC regulations are met. Where the P&T committee decisions affect Medicare beneficiaries, the Centers for Medicare and Medicaid Services (CMS) also exert regulatory oversight to assure compliance with federal laws.

When the plans and insurers contract with PBMs, the plans and insurers require that the PBMs comply with all these laws, as well as the regulations that have been promulgated from those laws. If the PBM violates those laws, the PBM is in breach of contract. Yes, the PBMs are not directly regulated by DMHC, DOI and CMS, but their activities are. Consumers are protected by DMHC, DOI and CMS. So when a consumer is unhappy with the result, they can call their plan or insurer, and if they get no satisfaction, they can and do call DMHC, DOI or CMS.

Given the broad range of existing laws and regulations that apply to PBMs and the concerns with PBMs that the Board has expressed, it appears likely that the Board will delve into the same issues. The result could be contradictory regulations or applications of regulations through enforcement. More likely it will be different interpretations. But the result will be a regulatory nightmare. Our concern is that the Board of Pharmacy may promulgate regulations or reach decisions that says a PBMs practices are unacceptable – even though those same practices are

acceptable to DMHC and DOI. The plans and insurers will be caught in the middle.

For these reasons, PCMA would respectfully request the Board take a neutral or oppose position on AB315.