November 11, 2019

Andrew Kleinendorst
Minnesota Department of Commerce
Insurance Division
85 7th Place East, Suite 280
Saint Paul, MN 55101
Via email: PBM.Licensing@state.mn.us

Re: Request for Information Regarding Possible Rules Relating to Pharmacy Benefit Manager Licensing and Regulation; Revisor's ID R-04625

Dear Mr. Kleinendorst:

I am writing on behalf of the Pharmaceutical Care Management Association (PCMA) regarding the request for information published in the Sept. 30, 2019 register regarding the implementation of SF 278 (2019), the "Minnesota Pharmacy Benefit Manager Licensure and Regulation Act" and the possible rules to implement the new law. PCMA is the national trade association representing PBMs, which manage prescription drug benefits for large employers, health insurance carriers, labor trusts, government programs, and other payers. We appreciate the opportunity to provide a response to your request.

At the outset, we note that the Act is 21 pages long with an extraordinary level of detail for a PBM regulatory statute. The statute is very prescriptive, defining relevant terms for use in the statute and including such detail as the license procedures; fees; renewal procedures; and detailed reporting procedures between PBMs, their clients, and the commissioner, among other items. In addition, the commissioner has already implemented some of the requirements, including the network adequacy report.

PCMA members believe that due to the prescriptive nature of the statute, comprehensive regulations are not necessary at this time. PBMs have sufficient notice in the statute to comply except in the limited areas we listed below. Sec. 20 of the Act provides *permissive* authority to the commissioner of commerce to adopt rules for license application and renewal requirements, forms, procedures, network adequacy, and reporting procedures. The commissioner is not required to draft rules. We encourage the commissioner to refrain from drafting rules where not absolutely necessary.

On that note, our members are concerned about two areas of the law where we are seeking further informal guidance by the Department and one area of the regulatory notice we are seeking opportunity for additional input.

1. Section 6 (62W.06 – Pharmacy Benefit Manager Transparency) establishes data required to be reported by PBMs. Some of these data elements are straightforward, but others are less so. For example, "wholesale acquisition costs from a manufacturer or distributor…" (see Subdivision 2(a)(1)). Because PBMs, in their benefits administrator role, do not purchase drugs from manufacturers, this data element does not make

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

sense. PCMA seeks further guidance from the Department about what it would expect PBMs to provide in these situations.

2. Section 17 (62W.14) allows for an exemption from the requirement to deliver specialty drugs within 7-business days when there is a delay in shipment by the specialty drug manufacturer or wholesaler. PCMA members are concerned that, although rare in occurrence, there are legitimate reasons a delay in shipping from the specialty pharmacy (not the wholesaler or manufacturer) may occur. Shipping delays by the specialty pharmacy could be caused by the same problem as the cause of the shipping delay from the manufacturer or wholesaler. For example, inclement weather could cause shipment delays from the wholesaler or manufacturer, but also the specialty pharmacy, depending on where the weather event is. The Department should recognize these rare circumstances where an exception to the delivery deadlines is warranted.

3. In the Department's regulatory notice, there was mention of an advisory committee to be created. PCMA requests that PBMs, as regulated entities, should have representation on the committee so there is sufficient expertise on the committee to provide informed advice.

Finally, we understand that through the adoption of this law, the Department of Commerce has been charged with new, significant responsibilities in the area of PBM regulation. We are open to discuss these new responsibilities and are available to provide education about PBMs at a convenient time for the Department. Please contact Melodie Shrader, Assistant Vice President, State Affairs, at 270-454-1773, or me, at 202-756-5743 if you are interested in scheduling a discussion.

Thank you for the opportunity to provide feedback. We look forward to working with you in the future.

Sincerely,

April C. Alexander
Vice President, State Legislative and Regulatory Affairs

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