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May 19, 2016

Mark Hardy  
Executive Director  
North Dakota State Board of Pharmacy  
1906 East Broadway Ave.  
Bismarck, ND 58501

RE: Comment on Proposed Pharmacy Board Rules 61-04-12 and 61-08-01-10  
regarding patient counseling services and their impact on mail order pharmacies.

Dear Mr. Hardy:

I am writing on behalf of the Pharmacy Care Management Association regarding the proposed changes to Rule 61-04-12 regarding patient consultation requirements and 61-08-01-10 regarding patient counseling services.

The Pharmaceutical Care Management Association (PCMA) is a national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program, state government employees plans including North Dakota, managed Medicaid plans, and others. PBMs are key drivers in lowering prescription drug costs and increasing access.

As you know, many plans prefer mail order pharmacies as a convenient and efficient way to provide chronic care prescriptions to members enrolled in these health plans. To our knowledge, there have been no complaints from member consumers, providers or insurers about this valuable service, and in fact, patient surveys have repeatedly shown high satisfaction and high medication adherence rates with convenient home delivery of

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prescription drugs. Mail-order pharmacies provide with the dispensed medications a wealth of information about the medication, as well as a toll-free phone number to call if the patient has any questions or would like to speak with a pharmacist about the prescription.

PCMA member companies are concerned that the proposed regulations unfairly hinder out-of-state mail order pharmacy practice. For no clear reason, section 61-04-12(3) establishes a separate standard to “provide counseling” to patients who are “required by their insurance plan to use or [are] financially incentivized to use a pharmacy which provides mail-order prescription service.” There is no explanation of the difference between providing “consultation” and providing “counseling” in these circumstances, or what warrants a separate section for patients whose plans provide a financial incentive to use a lower-cost alternative delivery system.

In addition, proposed section 61-08-01-10 requires an out-of-state mail order pharmacy to contact a patient to “assure that the patient chooses to receive prescriptions from the pharmacy before fulfilling the prescription.” This requirement unfairly burdens mail order pharmacies and will cause delays in getting patients their necessary treatments. Furthermore, plan enrollees are provided all information regarding the delivery of pharmacy benefits in member handbooks and other enrollment materials. Finally, there is no similar requirement for a retail pharmacy to assure the patient chooses to receive prescriptions in a retail setting as opposed to what could be a more affordable, convenient option to receive prescriptions by mail. This section clearly discriminates against mail order pharmacies.

Because of these proposed requirements, PCMA member companies have concerns that the rules proposed are intended to or more indirectly could have an unreasonable and burdensome impact on their ability to compete in the North Dakota pharmacy marketplace.

You may be aware that, just last year the United States Supreme Court, in a case involving the North Carolina Dental Association, warned about state boards which are run by “active market participants,” (such as the North Dakota Board of Pharmacy which consists of five pharmacists out of seven members) using the power conferred on them by the state to pass rules or regulations which are, in effect, anti-competitive and restrain trade in violation of federal antitrust laws. The Court noted there is no state shield of immunity for such regulations and that the state must “actively supervise” such boards to insure that members are not using their position or power to restrain competition, impair interstate commerce, or gain a competitive advantage for in state market participants.

Any action your board takes on these measures must be fair and reasonable and not unduly attempt to restrict or hamper out of state competitors in the marketplace. We believe that the current practice of mail order pharmacy in providing customers with written or electronic materials and a toll free phone number accompanying the

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prescriptions to consult a pharmacist is a safe and sensible practice with regard to patient consultation.

We, therefore, suggest that if you are considering adopting any change or amendment to existing patient consultation requirements, you consider at a minimum, the suggestions proposed in the comment letter dated March 29, 2016, by Dennis McAllister of Express Scripts. His suggestion for proposed Rule 61-04-12 would be to add a subparagraph 5 which in essence provides as follows, "in a case in which the patient, spouse, or guardian is not available at the time of dispensing, the pharmacy must supply written or electronic materials and a toll free number for the patient, spouse or caregiver to contact the pharmacist."

We thank you for the opportunity to provide comment on the proposed rule and ask that your board kindly take these comments into consideration before proposing or adopting any final rule. I would also ask that you keep me in the loop as this process goes forward.

Sincerely,

Patrick J. Ward

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