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July 8, 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 (PCMA) regarding the proposed changes to Rule 61-04-12 regarding patient consultation requirements and 61-08-01-10 regarding patient counseling services.

PCMA is the national trade 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.

Thank you for considering suggestions from PCMA and other PBMs regarding 61-04-12, the patient consultation regulation proposal. We appreciate the amendments that were made from the prior draft. Unfortunately, we remain concerned regarding 61-08-01-10 relating to counseling services provided by Out-of-State Pharmacies.

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 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 is concerned that the proposed regulations unfairly hinder out-of-state mail order pharmacy practice. 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 is not only unnecessary, it unfairly burdens mail order pharmacies and will cause delays in getting patients their necessary treatments.

Plan enrollees are provided all information regarding the delivery of pharmacy benefits in member handbooks and other enrollment materials. In addition, when the patient is prescribed a medication, one of two things generally occurs: (1) the patient sends a physical prescription to a mail order pharmacy him or herself, or (2) more often than not these days, the prescriber’s office sends an electronic prescription to the mail order facility after discussing with the patient (typically while the patient is in the office) where the prescription is to be dispensed. The patient has already had the opportunity to tell the physician where he or she prefers the prescription to be dispensed. In addition, there are times when a patient contacts a mail order facility directly and requests that the pharmacy contact his or her physician to obtain the prescription. In all of these cases, the patient is aware of the fact or even requested that the medication is to be dispensed by mail, and any additional requirement on the mail order facility to obtain patient consent is a time-consuming process that will delay access to the medication.

This proposed regulation is clearly designed to handicap mail order facilities that are competitors to retail pharmacies. The proposal does not contain a similar requirement for a retail pharmacy to assure the patient chooses to receive prescriptions in a retail setting as opposed to what could be their preference—if so informed—for a more affordable, convenient option to receive prescriptions by mail. This section clearly discriminates against mail order pharmacies.

Because of these proposed requirements, PCMA remains concerned that the proposed rules are intended to have an unreasonable and burdensome impact on the ability of mail order facilities to compete in the North Dakota pharmacy marketplace. These types of barriers to competition are prohibited by federal law.

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

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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 restrict or hamper out of state competitors in the marketplace. Such board members and their actions are subject to federal lawsuits to insure boards do not unfairly take advantage of their power to limit or disadvantage out of state competitors. Any state action to approve or allow such methods must also undertake a comprehensive review of the substance and procedures followed by the local board. This rule was articulated in the U.S. Supreme Court decision upon which the North Carolina Dental decision was based. See, *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980), finding that California's retail wine pricing system was invalid in violation of the Sherman Antitrust Act.

PCMA appreciates the opportunity to provide comment on the proposed rule and asks that your board kindly take these concerns 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. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick J. Ward". The signature is written in a cursive, flowing style.

Patrick J. Ward