



Sept. 14, 2016

Mark Hardy
Executive Director
North Dakota 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 service pharmacies

Dear Mr. Hardy:

I am writing on behalf of the Pharmaceutical Care Management Association (PCMA) regarding the proposed changes to Rules 61-04-12 and 61-08-01-10, and their impact on mail service pharmacies.

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 plan 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 both lowering prescription drug costs and increasing access.

PCMA appreciates the opportunity to have participated in the Board's discussion of these proposed rules over the course of the last several months, and we appreciate the willingness of the Board to listen to our concerns. As mentioned in PCMA's two previous letters, many plans prefer mail order pharmacies as a convenient and efficient way to provide chronic care prescriptions to members enrolled in these plans, and patient surveys have repeatedly shown high satisfaction and high adherence rates with home delivery of prescription drugs. Mail service pharmacies provide a wealth of information with dispensed medications, including a toll-free phone number to call if the patient has any questions. Additionally, information about the use of mail service pharmacies is provided to plan members in enrollment and membership materials.

At the outset, PCMA would like to memorialize the discussion held at the July 2016 meeting, that the Board would strike subsection (3) of 61-04-12 relating to programs that provide a financial incentive to use a particular type of pharmacy. PCMA supports this deletion.



We remain concerned, however, that overall, the rules are designed to force mail service pharmacies into a regulatory scheme that is designed for a different delivery model: retail pharmacies. There has not been a clear foundation established for applying these rules to mail service pharmacies, making it appear that the rationale for the rule is simply to create a barrier to mail service pharmacies serving patients in North Dakota. Thus, PCMA remains concerned that there is discriminatory intent behind this proposal.

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 that there is no state shield of immunity for such regulations and that the state must “actively supervise” such boards to ensure that members are not using their positions 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 Board 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 comments on this proposal and we welcome the opportunity to have a dialogue about these changes. Please do not hesitate to contact me at 202-756-5743 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "April C. Alexander". The signature is written in a cursive, flowing style.

April C. Alexander
Senior Director, State Affairs