Because of inclement weather, the North Carolina Board of Pharmacy met, after proper notice to the public, by conference call on Tuesday, February 17, 2015. President Robert J. McLaughlin called the meeting to order at 10:00 am with Board Members Carol Yates Day, Gene Minton, Dr. Parker Chesson, and Bill Mixon present. Board Member Lazelle Marks was absent from the call. Also present were Executive Director Jay Campbell and Board Counsel Clint Pinyan. Present as visitors were: Valanda Nelson, NCPRN; Jenna Huggins, Mutual Drugs; and RPh. TJ Bruflat.

Ethics Statement

President McLaughlin read the Ethics Statement regarding any conflicts of interest and/or appearance of conflicts of interest of any Board member. No conflicts were noted by Board members.

Minutes of January 2015 Board Meeting

The members received the January 20, 2015 meeting minutes prior to this meeting for review. It was moved by Dr. Chesson, seconded by Mr. Mixon, to accept the minutes as submitted. The motion passed with no dissenting votes.

Application for Licensure – Timothy J. Bruflat

Mr. Timothy J. Bruflat appeared before the Board concerning his application for licensure as a pharmacist in North Carolina. On his licensure application, Mr. Bruflat answered "yes" to the question that asked if he has ever been addicted to drugs or alcohol or received treatment for substance abuse. Dr. Bruflat and Valanda Nelson, Executive Director of NCPRN, testified concerning Dr. Bruflat's application.

After presentation of evidence and testimony, on a motion from Mr. Mixon, seconded by Dr. Chesson with no dissenting votes, the Board moved to allow Mr. Bruflat to continue with the licensure process and if he is able to obtain his license as a pharmacist, it will be subject to conditions.

A copy of the Order Regarding Licensure can be found elsewhere in the Minutes and is incorporated by reference herein.

North Carolina Medical Board Draft Position Statement on "Physicians Compounding"

Board staff and counsel met with the North Carolina Medical Board in October 2014 to discuss physician compounding matters. Board staff and Medical Board staff discussed issues surrounding dispensing physician authority and the types of proactive, inspection-based policies and procedures necessary to effectively regulate compounding.

The Medical Board has since issued a draft policy statement concerning physician compounding. The Medical Board is accepting comments on the proposed draft through February 27, 2015. Mr. Campbell presented a proposed response letter for Board's approval.

After discussion, it was the consensus of the Board to approve the proposed letter and directed Mr. Campbell to send it to the Medical Board. A copy of that letter is attached to these minutes and incorporated by reference herein.

FDA Intergovernmental Meeting on Compounding Regulations, March 18-19, 2015

Mr. Campbell stated that he and Associate Executive Director Ellen Vick will attend the FDA Intergovernmental meeting on compounding regulations March 18-19, 2015.

Update on Proposed Amendments to 21 NCAC 46.3301 Governing Technician Registration

At the January 2015 meeting, The Board voted to publish proposed rule amendments to .3301(d) that would require a technician volunteering in a free clinic to register with the Board, but would waive the registration fee. The proposed rule also eliminates paragraph (c), which has been superseded by amendments to G.S. § 90-15.15A. The amendments have been published for notice and comment and Board staff has so far received positive comments for the amendments.

Appointment of Delegate to the NABP Annual Meeting, May 16-19, 2015

The National Association of Boards of Pharmacy will hold its annual meeting May 16-19, 2015 in New Orleans. The Board members discussed designating an official voting delegate and an alternate delegate for the meeting. The Board selected Mr. Mixon as the voting delegate with Mr. Campbell serving as the alternate.

Statements of Economic Interest Must be Filed with the North Carolina Ethics Commission by April 15, 2015

Mr. Campbell reminded Board Members that their Statement of Economic Interest must be filed with the Ethics Commission by April 15th.

Consideration of Proposal for Review of Board Operations by NABP

At the January 2015 meeting, the Board authorized Mr. Campbell to develop a contract with National Association of Boards of Pharmacy (NABP) for an operational review of the Board to be approved by the financel committee. The finance committee approved the contract and NABP will conduct the operational review March 9 – 13, 2015.

Consent Agenda

Following a review of the consent agenda, it was moved by Mr. Mixon, seconded by Dr. Chesson to approve the consent agenda as presented. The motion carried with no dissenting votes. The following items were approved.

Prehearing Conference

None

Increase in Pharmacists to Technician Ratio

1. Cape Fear Discount Drugs North, Fayetteville NC, Permit #10195, Elizabeth Hudson PM, Approved 02/11/2015
2. Margaret R. Pardee Memorial Hospital, Hendersonville NC, Permit #01309, Bess Reinhardt PM, Approved 02/11/2015
3. Pamlico Pharmacy, Grantsboro NC, Permit #10638, Holly Minnifield PM, Approved 01/30/2015
4. Robbinsville Pharmacy, Robbinsville NC, Permit #10886, Lindsay Jenkins PM, Approved 01/30/2015
5. Rx Care Pharmacy, Charlotte NC, Permit #11204, Aditya Parikh PM, Approved 01/3/2015
6. Walgreens, Belhaven NC, Permit #12400, Jessica Ambrose PM, Approved 01/30/2015
7. Walgreens, Louisburg NC, Permit #12337, Christopher Peoples PM, Approved 01/30/2015
8. Walgreens, Mebane NC, Permit #12278, Kasey O'Quinn PM, Approved 02/11/2015
9. Walgreens, Zebulon NC, Permit #12339, Hal Walrod PM, Approved 02/11/2015
10. Wal-Mart Neighborhood Market Pharmacy, Charlotte NC, Permit #11435, Mary Jo MdDowell PM, Approved 01/30/2015

CPP Candidates

RPH. Katherine Joyce Owens, License #19297
NC Heart and Vascular
Knightdale and Clayton NC

RPh. Charlene Rhinehart Williams, License #15022
UNC Asheville Health and Counseling Center
Ashville NC

Board Representative to 2015 Pharmacy Leaders' Forum Planning Committee

The 2015 Pharmacy Leaders' Forum (PLF) will be held Friday, September 25, 2015. At the January 2015 meeting, Bill Mixon agreed to serve on the planning committee with Michael Adams, incoming Dean of Campbell University College of Pharmacy and Ron Ragan, Dean of the High Point University School of Pharmacy. Mrs. Day stated that she would like to serve on the planning committee and would serve as an additional planning committee member.

There being no further business, on a motion from Mr. Mixon, seconded by Mrs. Day with no dissenting votes, the meeting adjourned at 11:00am.

_____

Robert J. McLaughlin, Jr, President

E. Lazelle Marks, Vice-President

J. Parker Chesson, Jr.

Gene Minton

Carol Yates Day

William A. Mixon

Jack W. Campbell, IV
Executive Director

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Legal Counsel

NORTH CAROLINA

BOARD OF PHARMACY

February 19, 2015

VIA ELECTRONIC MAIL (david.henderson@ncmedboard.org and compounding@ncmedboard.org) AND U.S. MAIL

David Henderson
Executive Director
North Carolina Medical Board
P.O. Box 20007
Raleigh, NC 27619

Dear David:

Thank you for the opportunity to comment on the Medical Board's proposed position statement entitled "Physician Compounding." The Board of Pharmacy has deep concerns with the policy as drafted, from the standpoint of both North Carolina law and appropriate public health and safety protection.

First, some background. As you know, in the fall of 2012, an outbreak of fungal meningitis sickened hundreds, and killed dozens, of patients across the United States – including patients in North Carolina. The outbreak was traced to contaminated vials of preservative-free methylprednisolone acetate produced by the Massachusetts-based New England Compounding Center ("NECC"). Virtually all of the affected patients received contaminated injections as part of office- or health-care-facility-based medical procedures. Appropriately, the NECC tragedy spurred a nation-wide reassessment of how the compounding of prescription drug products is, and should be, regulated.

Over the subsequent two years, the Board of Pharmacy expended massive effort in ensuring that the health, safety and welfare of patients were protected from North Carolina pharmacists who did not meet the high standards required for compounding drug products. Among other things, the Board of Pharmacy: performed an inspection "blitz" of all pharmacies in North Carolina that specialize in compounding (whether sterile or non-sterile products);

formalized a more frequent proactive inspection program for compounding pharmacies keyed to the type and risk level of compounding performed; hired expert compounding consultants to revamp the compounding inspection training curriculum for field staff; overhauled inspection tools and forms to better adhere to United States Pharmacopeia ("USP") chapter standards governing compounding; retooled Board databases to track the types of compounding activities performed at pharmacies at a more granular level; hired additional field staff to meet the challenges of an increased inspection workload; implemented a program of continuous training on compounding issues for field staff; and revamped all Board of Pharmacy rules governing compounding. This effort was enormous – in time, training, and expense – but necessary. And, fortunately, the North Carolina Board of Pharmacy was far ahead of most other boards in the country on these issues even prior to the NECC tragedy. Had the Board of Pharmacy been in a position of having to start from "square one," the costs in time, training, and expense would have been orders of magnitude higher.

Board of Pharmacy staff also is heavily involved with the Verified Pharmacy Program ("VPP") under development by the National Association of Boards of Pharmacy. VPP's creation was spurred by the NECC tragedy and is intended to assist boards of pharmacy nationwide with the design and implementation of a proactive, inspection-based program for regulatory and standard-of-care based compounding compliance.

And, as the draft position statement reflects, in November 2013, Congress passed and the President signed into law the Drug Quality and Security Act ("DQSA"). In pertinent part, the DQSA regulates prescription compounding at the federal level. Among other things, the DQSA prohibits prescription drug compounding except pursuant to an individual patient prescription. So-called "office use" compounding violates the federal Food Drug and Cosmetic Act unless performed at an "outsourcing facility" registered with the FDA and in compliance with a raft of manufacturing, labeling, and reporting standards. Moreover, even permissible patient-specific compounding must comply with a lengthy set of DQSA-based regulatory and technical standards, including: (as is true under North Carolina law) satisfying stringent USP standards; not compounding certain drugs designated by FDA as unsafe for compounding in any circumstance; not compounding what is "essentially" a copy of a commercially available product; and limitations on inter-state shipment or delivery of compounded drug products. The DQSA further posits a proactive, inspection-based program to ensure compliance. And the DQSA specifically charges state regulators to work proactively, and cooperatively, with the FDA to detect and resolve violations.

With that background, I turn to the Board of Pharmacy's concerns with the draft position statement.

North Carolina Law Prohibits Physician Compounding

The position statement flatly avers, without support, that the "practice of medicine includes compounding of prescription medications." The Medical Board appears to reach this conclusion from the fact that the Pharmacy Practice Act permits physicians to dispense prescription drugs to their patients for a fee or charge, if they are registered with the Board of Pharmacy. This is an unwarranted leap and misunderstanding, because compounding and dispensing are distinct concepts under North Carolina law.

It is correct that N.C.G.S. § 95-85.21(b) authorizes physicians "who dispense prescription drugs for a fee or other charge" to do so as long as the physician registers with the Board of Pharmacy and complies with laws governing the "distribution of drugs, including packaging, labeling, and recordkeeping." (emphases added).

Notably absent from this statutory provision, however, is any authorization for physician compounding. "Dispensing" and "compounding" are separately defined activities under the Pharmacy Practice Act. See N.C.G.S. §§ 90-85.3(c) & (f). Critically, "compounding" is not a lesser-included activity of "dispensing." Indeed, throughout the Pharmacy Practice Act, when a provision intends to refer to dispensing and compounding, it so states. See, e.g., N.C.G.S. §§ 90-85.3(q); 90-85.40(a). In contrast, while § 90-85.21(b) specifically grants an authority to physicians to "dispense," it does not grant a corresponding authority to "compound." Board staff has consistently advised inquirers accordingly. If the Medical Board's position is different (as it appears to be), then the Board of Pharmacy will explore an appropriate path for resolving that difference.

There is, however, one apparent point of agreement on North Carolina law. Even if the Medical Board were correct that physicians may compound drugs under North Carolina law, the Medical Board concedes that it is only the physician himself or herself who is permitted to perform the actual compounding. Nurses, physician assistants and other associated health professionals have neither any independent authority to compound prescription drugs nor an authority to do so under the supervision of a physician. So, a compounding physician would be required to conduct all compounding operations himself or herself. The Board of Pharmacy believes that this is highly unlikely to happen in practice. Therefore, there is a significant risk that the position statement will be misused by physicians to justify compounding activity by those under their supervision that is not permitted by law.

The Board of Pharmacy Cannot Enforce the Complex Web of Compounding Laws with Respect to Physician Compounding

As described at the outset of this letter and seemingly acknowledged in the position statement, the practice of compounding is highly regulated, both at the state and federal level, and is governed by highly detailed standards adopted by the United States Pharmacopoeia. And failure to follow those regulations and standards can be disastrous.

The Medical Board acknowledges that (even if compounding by physicians were permitted), those physicians must be registered as dispensing physicians with the Board of Pharmacy. However, that registration does not permit the Board of Pharmacy to regulate the safe compounding of drugs by physicians.

The requirement of registration does nothing more than provide a mechanism by which a list of dispensing physicians is compiled by the Board of Pharmacy. There is no dispensing-competency based prerequisite to registration by a physician, much less a compounding-specific competency prerequisite. Indeed, the statute clearly limits the Board of Pharmacy's ability even to inquire as to such matters – specifically prohibiting the Board of Pharmacy from doing more than collecting certain specified highly general pieces of information. N.C.G.S. § 90-85.21(b). In other words, even after registration, the Board of Pharmacy does not know – and has no statutory authority to know – which physicians would purport to compound, much less the type and risk level of compounding underway.

Reasonable people could debate whether § 90-85.21(b)'s cursory registration process is sufficient even for dispensing commercially-prepared prescription drug products. It certainly is difficult to imagine that the legislature could have thought it sufficient for the highly technical – and potentially dangerous – field of prescription drug compounding.

Moreover, as the position statement tacitly acknowledges, N.C.G.S. § 90-85.21(b) deprives the Board of Pharmacy of any enforcement authority over dispensing physicians who are registered with the Board. Enforcement and disciplinary authority for any violation of dispensing standards lies with "the licensing board having jurisdiction over the physician" – i.e., the Medical Board, not the Board of Pharmacy. Therefore, if § 90-85.21(b)'s grant of authority were found to include compounding, the Medical Board stands as the sole body with enforcement authority. For reasons discussed in more detail below, the position statement's contemplation of a reactive, complaint-based enforcement scheme for physician compounders is insufficient to protect the public, whether the compounding occurs purely "in house" for administration or whether the compounded products were dispensed, rather than administered, to the patient.

It bears mention that physicians are well aware that the Board of Pharmacy has no authority to enforce dispensing rules and standards where physicians are concerned. For example, in 2010, acting on a complaint that a dispensing physician was compounding prescription drug products under unsafe conditions, the Board of Pharmacy sought to inspect the physician's facility. The physician barred Board of Pharmacy staff from entering. Lacking other recourse, Board of Pharmacy staff referred the matter to the Medical Board. No action was taken by the Medical Board for over five years, and then only after the FDA issued a warning letter to the physician over compounding and manufacturing issues occurring in the physician's office. The physician was issued a private letter of concern by the Medical Board over the FDA matter and, as an aside, was cautioned that he must conform his practices to North Carolina law. This sort of approach – memorialized in the draft position statement – fails to grapple with the fundamental public health and safety issues at stake.

The Draft Position Statement Contemplates a Purely Reactive, Complaint-Based System of Enforcement That Is Incapable of Adequatley Protecting the Public Health and Safety.

Moreover, assuming solely for purposes of discussion that § 90-85.21(b) were determined to authorize physician compounding, that would not resolve the substantial weaknesses in the position statement's contemplated enforcement program by the Medical Board.

First, as noted above, notwithstanding the dispensing physician registration requirement, the Board of Pharmacy has no record of which physicians may wish to compound, and it has no statutory authority to create such a record. Therefore, if physician compounding were permitted by law, the Medical Board would need to build out a database to collect and categorize the information necessary to enforce the applicable laws. The proposed position statement does not contemplate any such data collection.

More fundamentally, the position statement contemplates that the Medical Board will carry out a purely reactive, complaint-based program of enforcing compounding standards. As events of the past couple of years (discussed above) have demonstrated, an enforcement program

unaccompanied by proactive, inspection-based efforts is one that does not – and cannot – protect the public health and safety adequately. The public and policymakers (at the federal and state levels) have demanded that enforcement of compounding standards be thorough and proactive.

The position statement does not contemplate a proactive enforcement program. It does not identify an inspection program, implement an inspection schedule, identify appropriately trained Medical Board personnel who can carry out a compounding inspection and enforcement program, or even place an obligation on a physician who is compounding to report the fact of compounding (much less the type and risk-level of compounding) to the Medical Board so that compliance can be monitored. If the law did permit physician compounding, the Medical Board would have to adopt the sort of multifaceted and proactive program that the Board of Pharmacy has adopted, as described at the outset of this letter.

The position statement makes a cursory reference to the language of the DQSA for physicians who are, or are contemplating, compounding. That reference provides no meaningful guidance to would-be physician compounders. Worse, it does not even direct would-be physician compounders to the numerous, strict, and highly technical USP chapter standards for safe prescription drug compounding.

This is not the stuff of which an appropriate prescription drug compounding enforcement program is made. The position statement amounts to an invitation for physician offices to become places where, intentionally or unintentionally, lesser compounding safety standards are followed. The risk to the public of such a program – as events have demonstrated – is unacceptable.

* * *

The Board of Pharmacy does not doubt that the proposed position statement is borne of good intentions and based on a sincere desire, shared by all occupational licensing boards, to protect the public health and safety. But the policy rests in significant part on, at best, a questionable reading of North Carolina law. Moreover, it contemplates an enforcement mechanism that has proven – tragically – incapable of serving a public safety protection mission.

Sincerely yours,

Jay Campbell
Executive Director