

President Ashley Duggins called the meeting to order at 10 am. Due to the COVID-19 state of emergency, the meeting was convened by teleconference. Board Members Ashley Duggins, Keith Vance, Andy Bowman, Wallace Nelson, Mischelle Corbin and Bill Mixon were in attendance. Members of the public also attended the meeting via teleconference.

Ethics Statement & Welcome

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

Consideration of January 2021 Meeting Minutes

The members received the January 19, 2021 meeting minutes for review prior to this meeting. It was moved by Ms. Corbin, seconded by Mr. Nelson, to approve both sets of minutes. The motion passed with no dissenting votes.

Licensing Report

2021 Renewal Season Update

Ms. Betz provided a briefing on the 2021 license/permit/registration renewal season and included a comparison with 2020 renewal season. Renewal trends are consistent with previous years and showed no apparent COVID-related drop-off.

Financials

February Financial Report

JP Brown, Accounting Manager, presented the February 2021 financial report to the Board, which included recommended FY2020-2021 budget adjustments from the Budget and Finance Committee. The Budget and Finance Committee determined that the COVID-19 pandemic had not affected Board revenues as adversely as predicted last spring. Accordingly, the Budget and Finance Committee recommended reinstating certain operational expenses that were deferred during the budgeting process last year. Mr. Mixon moved to accept the report and the Budget and Finance Committee's recommended adjustments to the FY2020-2021 budget. Dr. Bowman seconded. The motion passed with no dissenting votes.

Investigative Report

Docket Report

Joshua Kohler, Director of Investigation, presented the January 2021 investigations report.

Southeastern District Board Member Election Update

Kristin Moore, Director of Operations, presented an update on the Southeastern District Board Member Election and reminded the Board members of the March 2nd meeting at 10 am to review and certify election results.

Consent Agenda

The following items were approved.

Prehearing Conference**Consent Orders****Reciprocity Candidates**

License Number	First Name	Last Name	Licensed Date
29362	Kristen	Egert	1/23/2020
29364	Amie	Mizell	1/23/2020
29365	Brad	Petersen	1/23/2020
29363	Audra	Hecker	1/23/2020
29369	Nicklas	Armellino	1/30/2020
29374	Kristen	Roche	1/30/2020
29373	Jacob	Potts	1/30/2020
29371	Denise	Klinker	1/30/2020
29375	Jacquelyn	Rossi	1/30/2020
29372	Keisha	Moye	1/30/2020

29376	Tauseef	Salim	1/30/2020
29370	Helen	Cheong Xiao	1/30/2020
29228	Erik	Berg	2/6/2020
29382	Raymond	Nash	2/6/2020
29380	Jojo	Entsuah	2/6/2020
29381	Ashim	Ghosh	2/6/2020
29383	Kathryn	Petersen	2/6/2020
29391	Lauren	Thomas	2/13/2020
29390	Carl	Ndangoh	2/13/2020
29389	Margaret	McNamara	2/13/2020
29388	Sarah	Anderson	2/13/2020
29392	Erin	Williams	2/13/2020

CPP Candidates

License Number	First Name	LastName	License Date
700237	Daniel	Wolverton	1/31/2020
700236	Marina	Stamopoulos	1/31/2020
700235	Sarah	Russell	1/31/2020
700234	Leah	Edenfield	1/31/2020
700238	Catherine	Travis	2/4/2020
700239	Amber	Yopp	2/14/2020

Increase in Pharmacist to Technicians Ratio

LicenseNumber	Pharmacy Name	ProcessType	CompleteDate
13992	Vident Medical	PT Ratio Change 1:4	1/25/2021
14418	Cape Fear Discount Drug	PT Ratio Change 1:4	1/25/2021
7978	Wal-Mart	PT Ratio Change 1:4	1/27/2021
11979	Harris Teeter	PT Ratio Change 1:4	1/27/2021
12816	CVS	PT Ratio Change 1:4	1/27/2021
13324	C3 HealthCareRx	PT Ratio Change 1:4	2/1/2021
11539	Wal-Mart	PT Ratio Change 1:3	2/1/2021
7995	Wal-Mart	PT Ratio Change 1:4	2/1/2021
12207	Walgreens	PT Ratio Change 1:4	2/2/2021
11973	Harris Teeter	PT Ratio Change 1:3	2/2/2021
12322	Walgreens	PT Ratio Change 1:4	2/3/2021
11342	Wal-Mart	PT Ratio Change 1:4	2/3/2021
12372	Walgreens	PT Ratio Change 1:4	2/3/2021
12208	Walgreens	PT Ratio Change 1:4	2/3/2021
10415	Gate City Pharmacy	PT Ratio Change 1:4	2/5/2021
13563	Walgreens	PT Ratio Change 1:4	2/9/2021
12522	Walgreens	PT Ratio Change 1:4	2/9/2021
12332	Walgreens	PT Ratio Change 1:3	2/10/2021
12444	Walgreens	PT Ratio Change 1:4	2/10/2021
12402	Walgreens	PT Ratio Change 1:4	2/10/2021

12307	Walgreens	PT Ratio Change 1:4	2/10/2021
12457	Walgreens	PT Ratio Change 1:4	2/10/2021
13001	Community	PT Ratio Change 1:4	2/10/2021
12871	Walgreens	PT Ratio Change 1:4	2/11/2021
14266	Walgreens	PT Ratio Change 1:4	2/11/2021
12276	Walgreens	PT Ratio Change 1:3	2/12/2021
12279	Walgreens	PT Ratio Change 1:4	2/13/2021

On a motion from Dr. Vance, seconded by Mr. Mixon with no dissenting votes, the Board moved to approve the consent agenda.

Closed Session

On a motion from Dr. Bowman, seconded by Mr. Nelson with no dissenting votes, the Board moved into closed session to discuss possible summary suspensions.

When open session resumed on a motion from Dr. Vance, seconded by Mr. Mixon with no dissenting votes, President Duggins stated that the Board summarily suspended Technician Registration No. 60754 issued to Judith Stocks.

Board Retreat

Discussion of 21 NCAC 46.1606 Permit Meeting Rule

The members discussed 21 NCAC 46.1606, which provides: Prior to issuance of any original permit or device and medical equipment permit, the following persons must appear personally at the Board office on the first Monday of the month, the Monday before the monthly Board meeting, or such other time as scheduled with the Board's staff: (1) the pharmacist-manager for the applicant pharmacy; and (2) the person in charge of the facility applying for the device and medical equipment permit

In 2015, the Board contracted with NABP to perform an independent review of the Board's operations and systems and to identify areas where greater efficiencies and effectiveness might

be achieved. One resulting recommendation was that the Board consider amending the requirement that pharmacist-managers or persons-in-charge (for DME applicants) appear personally at the Board to obtain a permit.

After Governor Cooper declared the COVID public health emergency in March 2020 and the Board's emergency services waiver went into operation, the Executive Director cancelled in-person permit meetings until further notice. Board licensing staff have, of course, continued to review, process, and approve permit applications throughout the pandemic.

Given the now 10-month suspension of the in-person permit meeting requirement, the Board discussed the costs and benefits of that requirement and considered whether and how the requirement should be eliminated or altered. Director of Licensing Missy Betz presented several documents to facilitate discussion.

Mr. Campbell proposed forming a committee to consider amending Rule .1602 to eliminate the requirement of in-person meetings for permit issuance, consider development of on-line educational modules for permit applicants and pharmacist-managers, and make recommendations to the full Board. It was the consensus of the Board to do so. President Duggins deferred appointment of committee members to the conclusion of all retreat discussion items.

Temperature Sensitive Drug Delivery

In December 2020, NBC News aired a story regarding mail order delivery of prescription drugs. The principal focus was concern that temperature sensitive drugs shipped by mail may be exposed to conditions that reduce their efficacy.

In two separate provisions of the Pharmacy Practice Act, the General Assembly has prohibited the Board from adopting any special rules about the delivery of mail order drugs. The section governing out-of-state permits (N.C. Gen. Stat. § 90-85.21A) provides: "[T]he Board shall not adopt rules pertaining to the shipping, mailing or other manner of delivery of dispensed legend drugs by pharmacies required to register under this section that are more restrictive than federal statutes or regulations governing the delivery of prescription medications by mail or common carrier." Moreover, with respect to potentially regulating in-state mail order pharmacies, the section on mail or common-carrier delivery (N.C. Gen. Stat. § 90-85.32) provides: "[T]he Board shall not adopt rules pertaining to the shipment, mailing, or other manner of delivery of dispensed legend drugs that are more restrictive than federal statutes or regulations governing the delivery of prescription medications by mail or common carrier." Therefore, any requests to adopt specific mail order restrictions must be addressed to the General Assembly rather than the Board.

The Board can promulgate general restrictions that cover mail order delivery in the same fashion as other delivery methods. It could, for example, require all temperature sensitive drugs to be dispensed with strips to detect extreme temperatures, or to be dispensed in insulated packaging, regardless of whether dispensed by mail order, by personal delivery, or in the pharmacy. However, under the Administrative Procedures Act, any such proposed rule would have to be accompanied by a fiscal note showing the rules' costs and benefits – benefits that could be difficult to quantify, given the absence of any complaints about out-of-temperature-range dispensing.

The Board directed staff to assign a pharmacy student to research these matters at the first available opportunity.

The Board recessed for lunch at 12:06 pm and reconvened at 12:45 pm.

Review of Out-of-Practice Reinstatement Rule, Policy, and Operation

Board Rule .1602(c) states that the Board shall require a candidate for licensure without examination (i.e., a reinstatement or reciprocity candidate) “who has not practiced pharmacy within two years prior to application to obtain additional continuing education, practical pharmacy experience, successfully complete one or more parts of the Board’s licensure examination, or a combination of the foregoing, as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.”

The Board has long had a default policy concerning requirements under Rule .1602(c) for candidates seeking licensure without examination:

Out of practice up to two years – obtain 15 hours of continuing education for each year out of practice, 5 of which must be contact (live) and take the Multistate Pharmacy Jurisprudence Exam;

Out of practice up to five years – obtain 500 hours of internship, obtain 15 hours of continuing education for each year out of practice, 5 of which must be contact, and pass the Multistate Jurisprudence Exam;

Out of practice more than five years – obtain 1500 hours experience and pass NAPLEX and the Multistate Jurisprudence Exam (MPJE).

The members discussed that determining “out of practice” status is not difficult when a pharmacist has not been licensed as a pharmacist at all for a period of years. Where a pharmacist has continuously maintained a license to practice pharmacy in another state – and is seeking to reciprocate that license – however, determining “out of practice” status can become a

significantly more difficult exercise. Moreover, the members discussed, an applicant who has continuously maintained a license to practice pharmacy is deemed to satisfy the safety and competency requirements necessary to practice pharmacy at any time, regardless of whether the pharmacist has been “actively” practicing pharmacy in the interim.

The members directed Mr. Campbell to draft edits to the existing policy implementing Rule .1602(c) for discussion at the March 2021 Board meeting.

Review of Pharmacist:Technician Ratio Statute, Policy, and Operation

Mr. Campbell reviewed the current pharmacist:technician ratio requirements set forth in the Pharmacy Practice Act, as well as summaries of requests to the Board to increase the pharmacist:technician ratio to 5:1 or higher at a practice site submitted since April 2011.

The members discussed the continuing need to evaluate requests to increase the pharmacy:technician ratio to 5:1 on a case-by-case basis, with the focus on whether implementation is consistent with adequate protection of the public health. The members agreed that providing ratio increase applicants with guidelines to shape and focus presentations to the Board would be useful.

The Board directed staff to draft a guidance document along these lines for consideration at a future Board meeting.

The Board took a recess and resumed at 2:05 pm.

Review of Haywood Fund Operation and Potential Changes

Joe Jordan and Cindy Clark from the NC Professionals Health Program (NCPHP) joined the retreat to discuss the work of the L. Stanley Haywood Recovery Fund. The Fund provides financial support to qualifying pharmacists and pharmacy personnel in need of substance use assessment, treatment, and monitoring services.

The members discussed increasing the principal fund amount so that more earnings could become available to supply more financial support to qualifying pharmacists and pharmacy personnel. The members also discussed potential broadening of the eligibility criteria for pharmacy technicians.

By consensus, the members decided to appoint a committee to consider these issues and provide recommendations at the March 2021 Board meeting.

Consideration of FDA's Memorandum of Understanding Addressing
Certain Distribution of Compounded Human Drug Products

Board staff received three additional comments on the advisability of entering into the FDA's MOU. All came from North Carolina compounding pharmacists – Henry Herring (Medical Center Specialty Pharmacy in Wilmington) Jerry Beamer (Andrews Apothecary in Winston-Salem), and Doug Yoch (Stanley Specialty Pharmacy in Charlotte). All urged the Board to enter into the MOU. All stated that they provide compounded human drug product to patients in neighboring states and would not want that jeopardized by being subject to the “5% rule” in the DQSA.

The members discussed the pros and cons of the FDA's MOU in depth. It was the consensus of the members to sign on to the MOU, but the members agreed that participation in NABP's Information Sharing Network to collect and report required data under the MOU would significantly reduce the administrative costs and burdens of the MOU.

The members directed staff to draft a proposed rulemaking to require compounding pharmacies to report MOU-required data through the NABP Information Sharing Network annually, and to bring that proposal back for discussion at the March 2021 Board meeting.

The Board took a recess and reconvened at 3:25 pm.

Potential Rulemaking Concerning Limited Service Permit Eligibility
and Limited Service Permit Pharmacist Manager Responsibilities

The members received the report and recommendation of the Limited Service Permit Revision Committee. The Committee undertook a comprehensive review of the LSP census with an eye toward a potential rulemaking. The chief goals were clarifying what types of pharmacies may qualify for LSPs and clarifying pharmacist-manager responsibilities for an LSP.

The Committee recommends that Board rules be amended to specify that only certain types of pharmacy practices, detailed in the report, are eligible for an LSP. These pharmacy practices are ones in which the Committee believes that neither a lack of routine, proactive inspections nor a pharmacist-manager's division of time among multiple pharmacies creates an unacceptable risk of harm to the public health and safety.

The Committee's proposed revisions would have a negligible effect on existing pharmacy permits. But the revisions would add clarity for the Board and applicants.

The members discussed the Committee's report and recommendations in detail. They directed Board staff to prepare a draft rulemaking that reflects those recommendations and bring that back to the April 2021 Board meeting for further discussion.

Potential Registration System for Pharmacy Interns

In the past couple of years, the Board staff has investigated three cases of individuals fraudulently passing themselves off as pharmacy students in order to secure employment as pharmacy interns. Because pharmacy interns are not required to register with the Board, there is no ready Board-created resource to check their bona fides in the same way that one can with pharmacists and technicians.

The members discussed the possibility of creating a pharmacy intern registration system, as well as the Board's current statutory authority to manage pharmacy interns. The members' consensus view is that there is a public safety-protection need for an intern registration system. The members agreed to appoint a committee to study the matter further and make a report and recommendation to the full Board at a future meeting.

Qualified Pharmacy Technician Vaccination Post-COVID

Under the PREP Act, the United States Department of Health and Human Services has authorized technicians to administer vaccines under certain circumstances. The Board discussed the need and desirability authorizing properly trained pharmacy technicians to continue administering vaccines once the pandemic public emergency has ended and the PREP Act authorizations have expired. Board staff advised that doing so would require a legislative amendment to the Pharmacy Practice Act.

It was the consensus of the members that the Board have a positive position on any such legislative effort.

Update on Telepharmacy Committee Work

The Telepharmacy Committee reviewed with the full Board its efforts to date. The members agreed that the most pressing issue before the Committee is whether and under what circumstances 21 NCAC 46.1417, Remote Medication Order Processing Services, should be amended to authorize implementation of remote medication order processing services by pharmacies that are not health-care facility pharmacies.

Expanded RMOE services have been implemented in North Carolina and elsewhere under COVID-pandemic-based waivers. Providing guidance on if and how pharmacies that have done so may continue once the pandemic public health emergency has ended is needed.

The members tasked the Committee to make recommendations to the Board on this topic at the April 2021 Board meeting.

Board Meeting Schedule and Format

The members discussed the pros and cons of altering the Board's current meeting schedule and format (full Board meetings each month except August and December). The Board reached consensus that, beginning in September 2021, it would shift to full Board meetings every other month, with time reserved in the interim months for pre-hearing conferences and committee work. The members agreed that August and December should remain open months. The members directed staff to develop a proposed schedule for review and discussion at the March 2021 Board meeting.

Committees Formed

President Duggins appointed the following committees:

Limited Service Permit Revision Committee – *Mixon, Nelson* (members);
Campbell, Stefanyk, Bissell, Pinyan (staff)

Permit Meeting/Pharmacist Manager Education Committee – *Duggins, Vance* (members); *Betz, Watson, Kohler, Stefanyk* (staff)

Intern Registration System Committee – *Vance, Bowman* (members); *Betz, Campbell, Pinyan* (staff)

Haywood Fund Committee – *Bowman, Mixon, Corbin* (members) *Vick, Jones, Brown, Pinyan* (staff)

Discussion of Evaluation Process for Executive Director

In consultation with Rhonda Jones, Director of Finance and Human Resources, the Budget and Finance Committee approved an evaluation process for the Executive Director.

At 5:11 pm Dr. Bowman moved to adjourn. Ms. Corbin seconded. The motion passed with no dissenting votes.

Dr. Ashley Duggins, President

Wallace Nelson

William A. Mixon

Mischelle Corbin

Dr. Andy Bowman

Dr. Keith Vance