

The 2021 Board Member retreat was held at the Carolina Inn, Chapel Hill, NC November 8 – 9, 2021. The Board conducted required training on November 8. President William (Bill) Mixon called the Board business meeting to order at 9 am on Tuesday, November 9. All Board Members – President Mixon, Vice President Wallace Nelson, Ashley Duggins, Keith Vance, Andy Bowman, and Mischelle Corbin – were in attendance. Members of the staff were present. Due to the COVID-19 public health emergency, members of the public attended via teleconference.

Ethics Statement & Welcome

President Mixon read the Ethics Statement regarding conflicts of interest. No conflicts were noted by Board members.

Consideration of September 14th, 2021 Meeting Minutes

The members received the September 14th, 2021 meeting minutes for review prior to the meeting. Dr. Bowman moved to approve the minutes. Mr. Nelson seconded. The motion passed with no dissenting votes.

Financial Report

Monthly Financial Report (*Brown*)

The members received the monthly financial report prior to this meeting. The members reviewed and discussed the report.

FY 2020-2021 Financial Audit

The annual financial audit report was received in early October, in time for inclusion in the Chapter 93B Annual Report due on October 31. At the September Board meeting, the members delegated to the Budget & Finance Committee the responsibility and authority to review and, if appropriate, accept the FY2020-21 Audited Financial Report on behalf of the full Board. The Budget and Finance Committee convened on Tuesday, October 19, 2021 to receive and review the report. The Board's auditors at Bernard Robinson & Company reviewed the report with the members. The auditors reported a clean audit. The Committee voted to accept the report as presented. The report was included in the Board's Chapter 93B FY2020-21 Annual Report filed on October 29, 2021 and available here: http://www.ncbop.org/about/AnnualReport2020_21.pdf

Licensing Report

2021 Renewal Season (*Betz*)

Director of Licensing Missy Betz provided a briefing on the 2021 license/permit/registration renewal season, noting that as of yet there were not as many emails and calls concerning lost/forgotten usernames and passwords due to the new procedures put in place.

FY2020-21 Chapter 93B Annual Report Filed

N.C.G.S. Chapter 93-B, which governs occupational licensing boards, requires each board to submit an annual report by October 31 of each year. The required contents of the report are set forth in detail by the statute, and are composed primarily of various data on licensees, registrants, and permittees. It must also include audited financial reports for the preceding year. Board staff filed the report with all required agencies and other entities on October 29, 2021. It is available here: http://www.ncbop.org/about/AnnualReport2020_21.pdf Mr. Campbell thanked the staff for their diligence in compiling the annual report.

Board Member Elections for Northern and Western District Seats (*Moore*)

Elections to select Board members from the Northern and Western Districts are underway. As detailed in Section .2100 of the Boards rules, the election is conducted by electronic balloting and runs concurrently with the license renewal period – November 1, 2021 through March 1, 2022. The successful candidates will be commissioned to five-year terms on the Board commencing May 1, 2022.

NABP District III Annual Meeting Overview (*Campbell*)

Mr. Campbell praised Traci Collier, NABP District III Chair and Executive Director of the SC Board of Pharmacy, and the members of the South Carolina Board for a successful and informative event. COVID-19 pandemic restrictions forced several reschedules. Board Enforcement Specialist Cindy Parham once again performed exemplary work as NABP District III Secretary/Treasurer.

MALTAGON Overview (*Kohler*)

Mr. Kohler thanked the Alabama Board of Pharmacy for its hosting a successful and informative annual MALTAGON meeting, and he briefed the members on the meeting's discussion topics.

Rulemaking

Proposed Publication of Proposed Amendments to 21 NCAC 46.1606 and .1607, North Carolina Specific Education for Permit Applicants and Out-Of-State Pharmacies

The Permit Meeting/Pharmacist Manager Education Committee met on October 19, 2021. During the meeting, the committee members and staff viewed the draft video/education module produced by Third Wheel Media. The committee provided feedback, and Board staff are incorporating that into the final version of the educational video.

Board Counsel Clint Pinyan discussed proposed amendments to Rules .1606 and .1607 to implement the Committee's recommendations. The current rules require the pharmacist-manager for each permit applicant to meet personally with Board staff before the Board will grant a permit. These meetings have traditionally been a means of imparting knowledge about North Carolina pharmacy law and Board procedures. These meetings are an inefficient way to provide that information, and the result of that burden has been that out-of-state permit applicants often have not named their actual pharmacist-manager as the pharmacist-manager on their North Carolina applications, thereby creating a disconnect between the person who is legally responsible for their compliance with North Carolina law and the person who actually supervises the pharmacy. The principal purposes of the proposed changes are to substitute an online educational module in place of the in-person meeting, and to require that the pharmacist-manager on the North Carolina permit match the pharmacist-manager in the pharmacy's home state. In addition, Rule .1607 concerning out-of-state pharmacy permits has not been revised in 15 years. The Board has proposed general updates to that Rule largely in order to (a) clarify and emphasize certain matters that have been subject to periodic questions from the regulated entities, (b) more accurately reflect modern Board procedures and practices, (c) remove repetitive requirements contained elsewhere, and (d) refer to other laws and rules covering certain matters, rather than attempting to restate them, which has resulted in incomplete, inconsistent and confusing descriptions of those laws.

Dr. Bowman moved to publish the proposed amendments for notice and comment. Ms. Corbin Second. The motion passed unanimously.

Proposed Publication of Proposed Amendments to 21 NCAC 46.1503, Experience in Pharmacy and Pharmacy Internship

The Pharmacy Intern Registration Committee met by teleconference on June 28 and recommended that the Board create a registration system through which pharmacies/pharmacists can confirm that a putative pharmacy student is, in fact, eligible for "pharmacy intern" status. The Committee also recommended that the Board replace the

current, paper-based method pharmacy interns use to document non-curricular experiential hours with an on-line system integrated into a pharmacy intern registration system.

Board Counsel Clint Pinyan discussed proposed amendments to Rules. .1503, .1612, .1613, and .1615 to implement the Committee's recommendations. The Pharmacy Practice Act requires all applicants for initial licensure and certain reinstatement and reciprocity candidates to complete practical experience in order to be licensed, and further requires the Board of Pharmacy to adopt regulations to "assure that the person successfully completing the program will have gained practical experience that will enable him to safely and properly practice pharmacy." NCGS 90-85.14. Those gaining practical experience are regularly and collectively referred to as "pharmacy interns." The Board has proposed to amend Rule .1503 to provide for a uniform system by which those gaining practical experience can sign up with the Board and can easily document and verify their practical experience hours through an on-line system. Moreover, in recent years, a handful of individuals have falsely claimed to be pharmacy students or recent graduates who were entitled to work as pharmacy interns, who are allowed to engage in all acts constituting the practice of pharmacy under the supervision of pharmacists. These individuals who lacked pharmacy educational training thereby created a risk of harm to the public safety, health and welfare in order to defraud their employers. This was made easier because, previously, in order to verify whether an individual was entitled to work as a pharmacy intern, that individual's prospective employer would have to contact pharmacy schools directly. The new uniform system will make it easier to ensure that only those who are entitled to work as pharmacy interns are able to do so. In addition to amending Rule .1503, the Board has proposed to adopt conforming amendments to other rules in addition to appropriately reference and account for the changes to Rule .1503.

Dr. Duggins moved to publish the proposed amendments for notice and comment. Dr. Bowman seconded. The motion passed unanimously.

The Board then took a short break.

Proposed Adoption of Proposed Repeal of 21 NCAC 46.1417, Remote Medication Order Processing Services, and Amendments to 21 NCAC 46.1816, Procedures for Centralized Processing of Prescription Orders

Board Counsel Clint Pinyan and Board members reviewed the public comments received on the proposed repeal of Rule .1417 and amendments to Rule .1816. The Board's Telepharmacy Committee met several times between July 2021 and this meeting to review each of the comments received in detail and to discuss whether and to what extent changes to the proposed repeal and amendments should be made in light of those comments. The Committee produced a detailed memorandum discussing each of the comments and recommended responses. All Board members received this memo well in advance of this

meeting. Board staff obtained an opinion from Staff Counsel at the North Carolina Rules Review Commission that none of the comment-responsive changes were substantive, and thus that republication of the proposal was not required. Each of the proposed changes eliminated requirements that commenters found problematic or replaced requirements with simpler, easier-to-administer options. In particular, and in response to comments, the revised rule eliminates the requirement that out-of-state pharmacy technicians providing inter-pharmacy remote medication order entry services be individually registered in North Carolina. The revised rule also provides an alternative to individual licensure in North Carolina for out-of-state pharmacists performing inter-pharmacy remote medication order entry services through a continuous monitoring service administered by the National Association of Boards of Pharmacy.

Board Counsel Clint Pinyan also reviewed with Board members proposed new Rule .2515 to implement the Telepharmacy Committee's recommendation that the Board authorized intra-pharmacy remote operations (the proposed repeal of Rule .1417 and amendment to Rule .1816 would broaden inter-pharmacy remote operation authorization from health-system pharmacies to all pharmacy practice types). During the COVID public health emergency, North Carolina pharmacy personnel have been able to perform certain work outside the pharmacy under a Board of Pharmacy Emergency Services Waiver. Further, some other states' laws permit pharmacy personnel to perform remote work. During a recent notice and comment period for other Board rules, many commenters requested that the Board adopt the proposed rule, in order to provide for permitted pharmacy locations in North Carolina to allow remote work (other than physical acts in the dispensing process) on a permanent basis and to approve out-of-state permitted pharmacy locations to provide similar services for North Carolina patients to the extent permitted by their home states. The Board believes that the proposed rule will permit alternative work environments while ensuring processes and systems for patient safety.

Mr. Nelson moved to adopt the repeal of Rule .1417 and amendments to Rule .1816, as well as to publish proposed Rule .2515 for notice and comment. Dr. Duggins seconded. The motion passed unanimously.

Consent Agenda

The following items were approved with Mr. Mixon abstaining.

Consent Orders of Discipline/Reinstatement

- RPh. Jamie Lane Foy, License #22440
- RPh. Glen Damon McDonald, License #19109
- RPh. Megan Riley Hairr, License #25603

Staff Issued Letters of Warning

- Walgreens Pharmacy, Permit #13661
- RPh. Rebecca Adams, License #23384
- RPh. Kitchawa Roulac, License #22671
- Technician Jennifer Best, Registration #25257

Reciprocity Candidates

License Number	First Name	Last Name	License Type	License Status	Licensed Date	Licensure Method
30881	Harriet	Kneece	Pharmacist	Active	9/16/2021	Reciprocity
30884	Rachel	Wiechert	Pharmacist	Active	9/16/2021	Reciprocity
30883	Dil Sagar	Sharma	Pharmacist	Active	9/16/2021	Reciprocity
30880	Krystal	Flaherty	Pharmacist	Active	9/16/2021	Reciprocity
30882	Vidien	Nguyen	Pharmacist	Active	9/16/2021	Reciprocity
30898	Pauline	Lee	Pharmacist	Active	9/23/2021	Reciprocity
30897	Joshua	Dynda	Pharmacist	Active	9/23/2021	Reciprocity
30918	Jacintha	Cauffield	Pharmacist	Active	9/30/2021	Reciprocity
30920	Nicole	Martoia	Pharmacist	Active	9/30/2021	Reciprocity
30915	Martha	Charles	Pharmacist	Active	9/30/2021	Reciprocity
30928	Scott	Strassels	Pharmacist	Active	10/7/2021	Reciprocity
30923	Radhika	Engineer	Pharmacist	Active	10/7/2021	Reciprocity
30922	Aubrey	Dean	Pharmacist	Active	10/7/2021	Reciprocity
30927	Megan	Serley	Pharmacist	Active	10/7/2021	Reciprocity
30925	Virginia	McQueen	Pharmacist	Active	10/7/2021	Reciprocity

30926	Reema	Rifaie	Pharmacist	Active	10/7/2021	Reciprocity
30924	Vu	Luong	Pharmacist	Active	10/7/2021	Reciprocity
30921	Andrew	Bartz	Pharmacist	Active	10/7/2021	Reciprocity
30939	Lili	Lin	Pharmacist	Active	10/14/2021	Reciprocity
30940	Atit	Thakar	Pharmacist	Active	10/14/2021	Reciprocity
30936	Devki	Gajera	Pharmacist	Active	10/14/2021	Reciprocity
30938	Courtney	King	Pharmacist	Active	10/14/2021	Reciprocity
30937	Larissa	Himmeger	Pharmacist	Active	10/14/2021	Reciprocity
30935	Eti	Ebong	Pharmacist	Active	10/14/2021	Reciprocity
30949	Kiana	King	Pharmacist	Active	10/21/2021	Reciprocity
30950	Jolly	Kuriakose	Pharmacist	Active	10/21/2021	Reciprocity
30951	Katherine	Logan	Pharmacist	Active	10/21/2021	Reciprocity
30948	Ilya	Gaykov	Pharmacist	Active	10/21/2021	Reciprocity
30953	Barbara	Pereira	Pharmacist	Active	10/21/2021	Reciprocity
30954	Michael	Tauss	Pharmacist	Active	10/21/2021	Reciprocity
30955	Kelaysia	Weaver	Pharmacist	Active	10/21/2021	Reciprocity
30952	Rachel	Norton	Pharmacist	Active	10/21/2021	Reciprocity
30947	Lori	Delossantos	Pharmacist	Active	10/21/2021	Reciprocity
30968	Amy	D'Silva	Pharmacist	Active	10/28/2021	Reciprocity
30969	Crystal	Mounce	Pharmacist	Active	10/28/2021	Reciprocity
30967	Allison	Cronin	Pharmacist	Active	10/28/2021	Reciprocity
30975	Jennifer	Yourich	Pharmacist	Active	10/28/2021	Reciprocity
30972	Ross	Rosenberg	Pharmacist	Active	10/28/2021	Reciprocity

30973	Lydia	Taylor	Pharmacist	Active	10/28/2021	Reciprocity
30971	Allison	Powell	Pharmacist	Active	10/28/2021	Reciprocity
30966	David	Bui	Pharmacist	Active	10/28/2021	Reciprocity
30970	Justin	Nierengarten	Pharmacist	Active	10/28/2021	Reciprocity
30974	Valerie	Woods	Pharmacist	Active	10/28/2021	Reciprocity
30985	Stacy	Rogers	Pharmacist	Active	11/4/2021	Reciprocity
30984	Twillow	Rhodes	Pharmacist	Active	11/4/2021	Reciprocity
30981	Enitan	Ekwotafia	Pharmacist	Active	11/4/2021	Reciprocity
30980	Carolyn	Clark	Pharmacist	Active	11/4/2021	Reciprocity
30987	Joseph	Scotfield	Pharmacist	Active	11/4/2021	Reciprocity
30983	Rachelle	Kelley	Pharmacist	Active	11/4/2021	Reciprocity
30989	Ariel	Zlich	Pharmacist	Active	11/4/2021	Reciprocity
30988	Connie	Zhang	Pharmacist	Active	11/4/2021	Reciprocity
30986	Michael	Salrin	Pharmacist	Active	11/4/2021	Reciprocity
30982	Jessica	Hay	Pharmacist	Active	11/4/2021	Reciprocity

CPP Candidates

License Number	First Name	Last Name	License Type	License Status	Licensed Date
700319	Danijela	Stefanovic	Clinical Pharmacist Practitioner	Active	9/16/2021
700321	Alexandria	Taylor	Clinical Pharmacist Practitioner	Active	9/28/2021
700320	Anne	Misher	Clinical Pharmacist Practitioner	Active	9/28/2021
700322	Thomas	Henry	Clinical Pharmacist Practitioner	Active	9/28/2021

700324	Jennifer	Reagan	Clinical Pharmacist Practitioner	Active	9/28/2021
700323	Janna	Beavers	Clinical Pharmacist Practitioner	Active	9/28/2021
700326	Mary	Chandran	Clinical Pharmacist Practitioner	Active	9/29/2021
700327	Keesha	Kline	Clinical Pharmacist Practitioner	Active	9/29/2021
700325	Alice	Pan	Clinical Pharmacist Practitioner	Active	9/29/2021
700328	Deirdre	Kaan	Clinical Pharmacist Practitioner	Active	10/4/2021
700332	Saleena	Brownell	Clinical Pharmacist Practitioner	Active	11/4/2021
700331	Lauren	Garner	Clinical Pharmacist Practitioner	Active	11/4/2021
700333	Adam	Furr	Clinical Pharmacist Practitioner	Active	11/4/2021
700329	Catherine	Dunton	Clinical Pharmacist Practitioner	Active	11/4/2021
700330	Emily	Owens	Clinical Pharmacist Practitioner	Active	11/4/2021
700334	Angela	Perhac	Clinical Pharmacist Practitioner	Active	11/4/2021

Increase in Pharmacist to Technicians Ratio

License Number	License Type	Process Type	Status	Complete Date	PTRatio
13948	Pharmacy	PT Ratio Change	Complete	9/15/2021	1:5
11964	Pharmacy	PT Ratio Change	Complete	9/20/2021	1:4
11945	Pharmacy	PT Ratio Change	Complete	9/20/2021	1:3
8101	Pharmacy	PT Ratio Change	Complete	9/21/2021	1:4
13607	Pharmacy	PT Ratio Change	Complete	9/21/2021	1:4
13609	Pharmacy	PT Ratio Change	Complete	9/27/2021	1:4

12990	Pharmacy	PT Ratio Change	Complete	10/4/2021	1:4
10285	Pharmacy	PT Ratio Change	Complete	10/5/2021	1:4
13406	Pharmacy	PT Ratio Change	Complete	10/6/2021	1:3
10489	Pharmacy	PT Ratio Change	Complete	10/6/2021	1:3
5395	Pharmacy	PT Ratio Change	Complete	10/8/2021	1:4
10262	Pharmacy	PT Ratio Change	Complete	10/11/2021	1:4
13478	Pharmacy	PT Ratio Change	Complete	10/11/2021	1:3
13549	Pharmacy	PT Ratio Change	Complete	10/11/2021	1:3
13767	Pharmacy	PT Ratio Change	Complete	10/13/2021	1:4
10849	Pharmacy	PT Ratio Change	Complete	10/14/2021	1:4
10270	Pharmacy	PT Ratio Change	Complete	10/14/2021	1:3
7675	Pharmacy	PT Ratio Change	Complete	10/27/2021	1:3
13679	Pharmacy	PT Ratio Change	Complete	10/27/2021	1:3
11905	Pharmacy	PT Ratio Change	Complete	11/3/2021	1:3
10966	Pharmacy	PT Ratio Change	Complete	11/3/2021	1:4
11912	Pharmacy	PT Ratio Change	Complete	11/3/2021	1:4
14556	Pharmacy	PT Ratio Change	Complete	11/5/2021	1:3
10946	Pharmacy	PT Ratio Change	Complete	11/7/2021	1:3

Closed Session

No closed session was necessary today. Ms. Corbin moved to adjourn. Mr. Mixon seconded. The motion passed with no dissenting votes.

After lunch the Board convened its annual planning retreat at 12:45 pm.

Board Retreat

Board Operations

- *NABP Testing Eligibility Determinations* – Director of Licensing Missy Betz discussed potential changes to pharmacy application review process, specifically potential use of NABP resources to make initial testing eligibility determination. This change would not require a rule change. In brief, the Board would (of course) retain all authority to determine licensure eligibility. But the license application process would be altered such that NABP made the initial determination of eligibility to sit for the licensing exams. A candidate eligible to sit for the licensure exams would immediately receive an authorization to test and, upon successful completion of the examinations, the score(s) would be directly reported to the Board. Board staff would then complete review of the licensure application, obtain any additional information or documents needed, and determine eligibility for licensure. This process would eliminate the need for the Board to collect certificates of graduation (NABP collects qualifying transcripts for all examination candidates) and should materially speed the licensure process. After discussion, it was the consensus of the Board to authorize staff to pursue and implement these revisions to the licensure process.
- *Pharmacist-Manager Change Policy* – Director of Licensing Missy Betz introduced a staff recommendation that current processes be altered such that a pharmacist-manager change request only be submitted by the incoming pharmacist-manager. Currently, anyone associated with a pharmacy may submit a pharmacist-manager change request. Under North Carolina law, the pharmacist-manager is responsible for the permit, and part of the responsibility is to ensure that they are properly listed as the pharmacist-manager. Under the current process, errors in the designated pharmacist-manager are not uncommon. This change in process would also require the incoming pharmacist-manager to attest to knowledge of the permit, such as the approved pharmacist:technician ratio. After discussion, it was the consensus of the Board to authorize staff to implement these revisions to the pharmacist-manager change process.
- *New Member Onboarding* – The Board discussed new member onboarding – specifically methods to improve new member orientation/education. All agreed that the onboarding staff presentations are informative and helpful. The members recommended consolidating a new member manual and scheduling at appropriate intervals a seminar-type training event on effective Board service.
- *Review of USP chapter <795> and <797> revision process* – Director of Inspections Krystal Stefanyk presented a reset overview of the USP chapter <795> and <797>

revision process. The members asked about the ability to attend Critical Point sterile compounding training. Board staff stated that was absolutely an appropriate and useful training for members and that they would work with any interested members to make the arrangements. Director Stefanyk also reminded members of USP's on-line training modules.

- *Pharmacy Technician Ratio Enforcement Policy* – Director Stefanyk presented the Investigation & Inspection Department's policy for inspecting for, and enforcing, technician ratio requirements. If a pharmacy is cited for a PT ratio violation of any kind, the pharmacy will automatically be issued a Corrective Action Plan (CAP) with a follow up in inspection in 90 days. If the pharmacy is still in violation when a follow up inspection is completed the pharmacy will be scheduled for pre-hearing conference. The Board member will then be able to take disciplinary action, including revocation of any previously granted ratio allowance. The members discussed the policy, and it was the consensus of the Board that this policy is an appropriate approach.

Policy Discussions

- *Pharmacist:Technician Ratio Requests* – The Board reviewed the PT ratio request process revisions implemented after the February 2021 retreat. The members discussed staffing issues, recent legislative changes conferring additional authority on pharmacy technicians, and the patient safety factors that inform a PT ratio determination. After thorough discussion, it was the consensus of the Board to alter the PT ratio request process to allow Board staff to approve a PT ratio of up to 1:5, so long as the requesting pharmacist-manager employs sufficient certified technicians to meet the requirements of G.S. 90-85.15A(c). A PT ratio request of 1:6 or higher must come before the full Board for review and consideration. The members directed staff to communicate the changed policy to licensees.
- *S.L. 2021-110 (H96) Implementation* – The Board has appointed a S.L. 2021-110 Implementation Committee (Duggins, Vance, Corbin). The Committee members have met to review drafts of implementing rules. Once the Medical Board has appointed its three members of the statutorily designated Joint Committee, that body will meet to reach consensus on the implementing rules. The North Carolina Association of Pharmacists has taken the lead working with a broad range of stakeholders to develop statewide standing orders that the State Health Director must issue by February 1, 2022. The members discussed the new statutory authority and implementation process at length.
- *Automated Systems for Verification of Prescriptions* Board Rule .2502 states that a pharmacist must “physically review . . . the dispensed product before the product is

delivered to the patient” There are specific exemptions to this baseline requirement (*e.g.*, certain robotic systems in health care facilities). Board staff sought guidance from the members on whether “physical review” contemplates the use of technological adjuncts. After discussion, it was the consensus of the Board that physical review does not exclude the use of technological adjuncts. Pharmacists are, of course, ultimately responsible for the safety and accuracy of dispensed medications. When inspecting a pharmacy (or investigating a complaint) and technology is used in the product verification process, staff should focus on matters such as the type of technology, appropriate training of pharmacy personnel to employ the technology, policies and procedures governing its use (including quality assurance programs), and the pharmacists’ ability to adjust the technology’s use (or cease its use) as patient safety circumstances as determined in the pharmacists’ judgment dictates.

Dr. Bowman moved to adjourn. Dr. Duggins seconded. The motion passed with no dissenting votes.

William A. Mixon, President

Dr. Andy Bowman

Mischelle Corbin

Dr. Ashley Duggins

Wallace Nelson

Dr. Keith Vance