

**MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
June 2, 2016**

**Coeur d'Alene Resort
Coeur d'Alene, Idaho**

This meeting of the Board was held to conduct regular Board business.

Chairman Rich de Blaquiere, PharmD, called the meeting to order at 8:00 a.m. In attendance were Vice Chairman Kristina Jonas, PharmD; Board members Nicki Chopski, PharmD; Holly Henggeler, PharmD; and Ed Sperry, Public Member creating a quorum. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Lisa Culley, CPhT, Jaime Sommer and Wendy Shiell, Compliance Officers; Andy Snook, Deputy Attorney General; Carl Withroe, Deputy Attorney General; Ellen Mitchell, Program Information Coordinator; Timothy P. Frost, pharmacy student on rotation with the Board from the University of Toledo; and several members of the public.

Dr. Henggeler motioned to approve the minutes of the April 7-8, 2016 meeting. Dr. Jonas seconded, the motion carried unanimously.

The Board took up the matter of the Consent Agenda, which contained the following matters:

- Board Performance Dashboard
- Financial Report
- Travel Calendar
- Exercises of Delegated Authority

Dr. Jonas motioned to approve the Financial Report and the Travel Calendar. Dr. Chopski seconded, the motion carried unanimously.

Dr. Adams reviewed the Board Performance Dashboard indicating strong internal performance across all measure domains. Dr. Adams indicated that complaints are being processed more quickly, averaging 42 days in the current performance period, down from 18-24 months from when he started. Dr. Adams indicated there are a few cases that have been outstanding for over 180 days because they are sequenced for hearing officers. Board compliance officers are continuing to exceed the inspection goals for pharmacies and prescriber drug outlets. There has been little movement in Prescription Monitoring Program (PMP) enrollment despite extensive Board staff outreach in the intervening time period. Dr. Adams indicated that Board staff has been surprised at the vigor with which some pharmacists oppose registering for the PMP despite the fact it takes only a few minutes and is free to enroll. The Board is appreciative of the information and suggested adding a column to explain any outlier results in order for the Dashboard to be included in the consent agenda.

Dr. Adams reviewed the Exercises of Delegated Authority (DA) to apprise the Board of how staff is using the authority the Board has entrusted to staff. Without the staff's ability to exercise DA, the Board would see many more disciplinary cases as 67 instances were resolved during this time period. Example cases include cancellation of technician-in-training registrations or controlled substance registrations, and resolution of continuing education violations. Board staff will continue to refine its internal processes to document all instances of DA for the Board to review at each regularly scheduled meeting.

The Board took up the matter of the Consent Agenda: Stipulation and Consent Orders, which contained the following matters:

- BioMed PA, Inc dba Soleo Health – Submitted an address change in September 2014 and failed to provide the required documentation, and did not respond to multiple requests from board staff. Following expiration of their mail service pharmacy registration on June 30, 2015, they continued to ship prescription medication into Idaho. By signing the Consent Order they have agreed to pay a \$4,000 administrative fine.
- Jeffery Koudelka, PharmD – Is the pharmacist-in-charge (PIC) at Ridley's Food & Drug in Gooding, Idaho. During routine inspections on December 9, 2014 and January 20, 2016 the Board's compliance officer identified outdated products on the stock shelves in the pharmacy in violation of Board Rules 261.01 and 500.10. By signing the Consent Order he is agreeing to pay a \$500 administrative fine.
- Jeanna Young, Technician in Training
- Chad Jungert, RPh

Dr. Jonas motioned to accept the Stipulation and Consent Orders of BioMed and Jeffery Koudelka, PharmD. Dr. Henggeler seconded, the motion carried unanimously.

The Board took up the matter of Jeanna Young, Technician-in-Training. Ms. Young did not attend the meeting. Mr. Withroe explained Omnicare provides pharmacy services to an assisted living facility where the patient was living. Ms. Young chose the wrong patient during the filling process, resulting in an error cascade that reportedly reduced kidney function in the patient. The pharmacist involved is also being proposed discipline by way of Delegated Authority. After extensive discussion Dr. Jonas motioned to accept the stipulation. Mr. Sperry seconded. After further discussion the motion carried with Dr. Henggeler opposed.

The Board took up the matter of Chad Jungert, RPh. Mr. Jungert did not attend the meeting. Stephen McCrea attended the meeting, representing Mr. Jungert. Mr. McCrea

indicated Mr. Jungert had installed new pharmacy software in his pharmacy that purportedly meets the requirements of the Board and indicated his belief that at least 20 other pharmacies are using the same software. Mr. McCrea indicated Mr. Jungert was in the system merely to adjust prices when his initials appeared on a prescription due to a system error; thus Mr. McCrea testified that Mr. Jungert was not actively practicing pharmacy, but fulfilling his duties as a business owner. Dr. de Blaquiere indicated he would like to see a report generated from the new system, though Mr. McCrea didn't have one available. After further discussion Dr. Chopski motioned to accept the stipulation. Dr. Jonas seconded, the motion carried unanimously.

Dr. de Blaquiere called on Dr. Adams to lead the agenda topic Legislation & Rule Review. Dr. Adams noted that he had submitted the current concepts in the Board's workbook to the Division of Financial Management and has received the requisite approval for the Board to move forward with rulemaking. The Board is still at an early stage; any concept that continues to move forward will be discussed publicly on the July 11th conference call, at the August 4th negotiated rulemaking session, and October 27th proposed rulemaking session. Thus, Dr. Adams' goal is to get the draft rules in strong shape for public posting. He indicated that he has met informally with diverse stakeholder groups to solicit initial input. He also indicated that a notice of intent to promulgate rules was officially published in the June 1, 2016 Administrative Bulletin.

Board members had been assigned to review initial rule drafts prior to the meeting. Each provided beneficial feedback that had been engrossed into the drafts circulated for the meeting. Further, Dr. de Blaquiere invited public comment following the discussion of each individual rule.

The Board provided directional feedback on the following rule drafts:

- Medication Synchronization – remove the specific days' supply restriction and replace it with language allowing for extension of a limited quantity sufficient to synchronize a patient's medications. Provide a definition of "medication synchronization program."
- Medication Error Reporting for Fatalities – amend to allow for a brief notification within two business days, followed by the submission of a report that is synchronized with existing reporting requirements for accrediting bodies or other government agencies.
- Emergency Room dispensing – no changes requested at this time.

The Board turned to its rule docket on pharmacy technicians, which was previously discussed in conceptual detail at the April strategic planning meeting. The spirit of the rule docket is to free up pharmacists for higher order care by allowing the delegation of routine and technical tasks to appropriately trained certified technicians, thus improving patient safety and care.

Prior to discussion on this rule docket, Ken Baker, formerly of Pharmacists Mutual Insurance Company, attended the meeting telephonically to address liability concerns

regarding expanded technician roles. Mr. Baker indicated that most of the concepts the Board is proposing are routine in other states, and that liability insurers have not found such activities to alter pharmacist liability or rates because of the demonstrated safety of such activities over time. As an example, rates for facilities do not differ in Illinois despite the expanded technician duties having been permissible for nearly 40 years. The Board discussed with Mr. Baker liability under a technician verification program; it was discussed that a pharmacist who fulfills programmatic requirements such as quality assurance and oversight would not have responsibility for individual doses checked in an otherwise compliant program as long as the Board rules explicitly allow technicians to perform this type of activity.

The Board discussed the following updates to the draft rules for certified technicians:

- Remove the requirement that the transferring and receiving pharmacy must document the credential of the transferring individual;
- Allow student pharmacists to participate fully in a technician verification program;
- Expand the taking of verbal prescriptions by certified technicians to all practice settings, not just institutional settings;
- No changes were requested with respect to the ability of technicians to clarify orders with prescribers at the pharmacist's direction
- Require cardiopulmonary resuscitation (CPR) and automated electronic defibrillator (AED) training for supervised technicians in order to administer medications at the direction of a pharmacist. Require technicians to further undergo training on appropriate intramuscular, subcutaneous, and intranasal technique;
- Clean up the technician verification language as it relates to students. Remove the requirement that only the verification technician can complete the barcode scan; and
- No changes were proposed at this point for remote data entry by technicians.

The Board received indications of support for the direction of the technician rule docket by groups in attendance. Donald Smith, RPh, inquired about the use of a technician verification program with respect to innovative packaging programs. Dr. Adams indicated he would research how this model has been adopted in other states. Nick Lyon, RPh, discussed the technician role expansion in the military, and cautioned against removing the pharmacist from the process for economic reasons; the Board reiterated that a pharmacist must perform prospective drug utilization review on each fill, and reiterated that each task could be performed only at the discretion of the supervising pharmacist. Thus, pharmacists are given the flexibility to delegate or not, depending on their confidence level with their technician support staff.

The Board provided directional feedback on the following draft rule updates:

- PIC Qualifications – remove the vague language around “substantial” time. Instead, allow pharmacists to serve as the PIC at no more than two pharmacies.
- PMP delegates – no requested changes at this time.

The Board tabled the remaining rule discussions until the afternoon.

Following the lunch break the Board took up the matter of Michael Gilbert, PharmD. Dr. Gilbert attended the meeting without legal counsel to appeal Board staff’s denial of his reciprocity application as the discussion was tabled at the April meeting. Carmen Catizone, Executive Director of the National Associations of Boards of Pharmacy (NABP) joined the meeting telephonically to discuss NABP’s Model Act with respect to reciprocity of pharmacist licenses. Mr. Catizone indicated the original intent of the NABP model language was not to prohibit pharmacists with disciplinary action from reciprocating, but to ensure they didn’t ‘escape’ discipline by going to another state. Mr. Catizone testified that a pharmacist who has current discipline traditionally triggers an appeals process that gives the Board the option to either deny the application based on the severity of the case, or alternatively the Board could create an order mirroring the stipulations in the pharmacist’s home state.

Dr. Gilbert indicated he has accepted a job in Idaho and is currently under stipulation with the Oregon Board of Pharmacy for failing to keep adequate controlled substance dispensing records at the hospital where he was employed. He is again asking the Board to allow him to practice in Idaho with the same restrictions imposed by Oregon. The restrictions are to not act as preceptor and if he is the PIC of a pharmacy he must identify a qualified individual to provide a quarterly report to the Oregon Board of Pharmacy. Following discussion Dr. Henggeler motioned to deny the application at this time. Dr. Jonas seconded for the sake of discussion, the motion failed with Dr. Henggeler in favor of the motion to deny. Following additional discussion, in which the Board recognized the inconsistency between the statutes and rules governing reciprocity and the eligibility of applicants with current discipline in another state, Dr. Chopski motioned to accept Dr. Gilbert’s application for reciprocity with a mirroring order that includes the same restrictions as the Oregon Board of Pharmacy, the quarterly report sent to Oregon will also be sent to the Idaho Board and he will maintain his Oregon pharmacist license at least until the completion of his Oregon stipulation. Mr. Sperry seconded, the motion carried with Dr. Henggeler opposed. Following further discussion, the Board directed Dr. Adams to draft changes to the statute and rules related to reciprocity that will clarify the eligibility of applicants with current discipline in another state.

Jim Stevenson, RPh attended the meeting telephonically to request a waiver to Board Rule 503 Prescription Delivery Restrictions to allow his pharmacy to deliver controlled substance medications to the patient’s physician versus a patient’s home in cases of intrathecal pain pumps. Mr. Stevenson believes delivering the medication to the

physician is critical as the medications are compounded and must be stored in a clean, refrigerated environment.

Dr. Adams was separately contacted by Linden Barber, an attorney at Quarles and Brady who spent 12 years in compliance at DEA. Mr. Barber now represents Advanced Infusion Solutions and attended the meeting. He stated his belief that federal and state delivery restrictions were generally not intended to be applied to CS products for direct administration. As evidence of this, Mr. Barber forwarded an email from Ruth Carter, Chief Liaison & Policy Section in the Office of Diversion Control at DEA. The email follows:

“ODL [Office of Diversion Control Liaison and Policy Section] has said that AIS may deliver intrathecal spinal pumps which were dispensed pursuant to a prescription, to whatever address the patient specifies.”

Following discussion Dr. Henggeler motioned to approve the waiver request for delivery of intrathecal medications to the physician’s office, with the understanding the pharmacy obtain patient consent in a manner similar to what Medicine Shoppe submitted. The Board authorized its Executive Director, Alex Adams, to grant the same waiver to other entities if properly requested until the end of May 2017. Mr. Sperry seconded. Following further discussion the motion carried unanimously. Dr. Adams will draft changes to the rules related to delivery restrictions and positive identification requirements for Board review.

Brady Dowding, Pharmacist-in-Charge of State Hospital South attended the meeting telephonically to request a waiver regarding Rule 410 Verification Technician Program. Dr. Dowding is specifically asking the Board to waive the requirement that a verification program may only be located in an ‘acute care hospital’. State Hospital South Pharmacy is part of an institutional psychiatric hospital, allowing the waiver would allow their facility to expand their technicians’ role in the unit dose distribution system allowing the pharmacist more clinical time. Dr. Adams noted that the waiver request is consistent with the Board’s draft rule to expand technician verification programs. Following a brief discussion over the potential value of the research data being presented at the October proposed rulemaking session, Dr. Chopski motioned to grant the waiver until the end of the 2017 legislative session. Dr. Jonas seconded, the motion carried unanimously.

Dr. Adams presented a memo regarding the agenda item Inspector Q&A. Dr. Adams asked for the Board’s desired outcomes from the Q&A session, as many of the questions that arise seem to fit better in other agenda items, such as the rules discussion or as waiver requests. Dr. Adams submitted that it would be most efficient for Board staff to receive bidirectional queries and present them to the Board with a well-researched brief in advance of the meeting, as opposed to the traditional on-the-spot questions and gut reactions. The Board is supportive of this approach, though expressed its desire that the compliance officers continue to attend Board meetings.

Following a discussion of election of officers for fiscal year 2017, Dr. Henggeler motioned for Dr. Jonas to serve as Chairperson beginning July 1, 2016. Dr. Chopski seconded and the motion carried with Dr. Jonas abstaining. Dr. Jonas motioned for Dr. Chopski to serve as Vice Chairperson beginning July 1, 2016. Dr. Henggeler seconded, the motion carried with Dr. Chopski abstaining.

The Board returned to the agenda item of Legislation & Rule Review. The Board discussed legislative concepts for the 2017 legislative session. Dr. Adams reviewed previously discussed concepts:

- Updating the qualifications of licensure by reciprocity in light of the recent appeal by a candidate; and
- Enhancing the PMP by requiring one-time pharmacist registration for the free PMP in a manner similar to what all prescribers, except veterinarians, have had to complete for several years. Dr. Adams also discussed setting a 5-year requirement on how long the Board must retain PMP data; currently there is no end date listed in statute, and a 5-year timeline would coincide with that for the statute of limitations for felonies. Dr. Adams also raised a suggestion that other groups have made regarding the reporting of opioid antagonists to the PMP. The Board wondered if this addition would be consistent with the statutory purpose of the PMP and Dr. Adams will assemble additional research on other states that have explored this.

Dr. Henggeler raised a concept for legislation that she saw in a presentation at the recent NABP Annual Meeting regarding the ability of pharmacists to furnish chemoprophylactic products for close contacts of an individual with diagnoses of pertussis. Dr. Henggeler provided an example she has experienced in which such authority would be in the best interest of public health and patient care. The Board tasked Dr. Adams with exploring this concept and other instances of chemoprophylaxis, and he noted he would meet with relevant stakeholder groups to assess this.

The Board provided directional feedback on the following draft rules:

- Centralized Pharmacy Services – no edits at this point;
- Pharmacist Work Activity During Breaks – the Board decided not to pursue a rule change at this time, as the rule currently provides an opportunity for appropriate work activity to continue during a pharmacist's brief absence from the pharmacy;
- Pharmacy Security Rules – no requested changes at this time;
- Substantially Constructed Cabinet – the Board made the decision to not add a definition of a substantially constructed cabinet given the direction from the federal Drug Enforcement Agency (DEA). The DEA notes that a definition is context-dependent and that it is influenced by other security provisions present at the pharmacy, the area's crime rate, and various other factors. Thus, the Board believed it would be at odds with federal law to attempt a one-size-fits-all definition;

- Collaborative Practice Agreements (CPA) – Dr. Adams will research the language; as written, it may not appropriately cover how services are delegated under a CPA as prescribers, not facilities, delegate services;
- Emergency Kits at Infusion Clinics – no edits at this point;
- Prescription Drug Labeling - no edits at this point;
- Prepackaged Drug Labeling - no edits at this point;
- NAPLEX Retake Requirements – edit the requirement of 30 continuing education hours to after the third attempt at the exam, instead of the second attempt as previously drafted;
- Pharmacy References - no edits at this point; and
- Legend Drug Donation Act – allow an exception against strict record verification for entities that donate product to themselves in accordance with Idaho Code.

Dr. Chopski motioned to adjourn, Dr. Henggeler seconded, meeting adjourned at 4:59 p.m.

APPROVED