MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
NOVEMBER 2, 2012
HOLIDAY INN – BOISE, IDAHO

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

Chairman Berk Fraser, R.Ph., called the meeting to order at 8:30 a.m. In attendance were Board members Rich de Blaquiere, Pharm D.; Nicole Chopski, Pharm D.; Holly Henggeler, Pharm D.; Ed Sperry, and Mark Johnston, R.Ph., Executive Director; Nicole McKay, DAG; Kathy Takasugi, DAG; Jan Atkinson, Senior Compliance Officer; Fred Collings, Chief Investigator; Compliance Officers Lisa Culley, Mike Brown and Gina Knittel, and Ellen Mitchell.

Dr. Chopski motioned to approve the minutes of August 21-22, 2012 with minor corrections. Dr. Henggeler seconded. Motion carried unanimously.

Mr. Johnston received a request from Nichelle Daigle, Pharm D to amend the minutes of the May 31, 2012 meeting to reflect '*Ms. Daigle received a withheld judgment for ~~two~~ one non-drug related felony while still in pharmacy school'*. Mr. Johnston confirmed that Ms. Daigle's request is valid. Dr. Chopski motioned to approve the amendment. Dr. de Blaquiere seconded. Motion carried unanimously.

Chairman Fraser asked Mr. Johnston to lead the agenda item entitled "Legislation and Rule Review". Mr. Johnston presented documentation from the Idaho State Legislature's Legislative Services Office confirming no objections to the Board's proposed rules will be filed. Mr. Johnston then presented written public comment on the Board's proposed rules received during the official public comment period.

- Mr. Edward Rickert, R.Ph., JD, representing InstyMeds, public comment requested the addition of "except self service ADS systems" to rule 292.03. Instead, the Board approved similar language drafted by Ms. McKay via unanimous consent.

- Ms. Chris Ciolko, representing Pipeline Healthcare, public comment led to changes drafted by Mr. Johnston and Ms. McKay to rule 320 that assist with the differentiation between pharmacist independent practice and centralized pharmacy services. The Board approved via unanimous consent.

- Pursuant to a Board decision at the August 2012 Board meeting, "verifiable shortage" was removed from draft changes to rule 130.03, and Nancy Kerr, publically commented that the Idaho Board of Medicine had no issue with the change.

- Mr. Dennis McAlliser, representing Express Scripts, appeared in person to support his written comments proposing striking language adding the requirement of a pharmacist's initials or their unique identifier to pharmacy label requirements in rule 140.13. The Board discussed pharmacy electronic record keeping systems that were grandfathered, as to not require such documentation electronically, and rejected Mr. McAllister's comment via unanimous consent.

- Mr. Johnston publically commented that “hospital without a pharmacy” should be struck from rule 021. After discussion, Dr. Henggeler motioned as such, Dr. Chopski seconded and the motion passed unanimously.

- Dr. de Blaquiere publically commented concerning extraneous and confusing language within proposed rule 291, and the Board accepted Mr. Johnston’s draft striking via unanimous consent.

- Dr Chopski publically commented that proposed rule 10.09.a-f should be struck as extraneous, formatting was incorrect in rule 013.01, that the CPE requirement in rule 330 should be added to rule 052 as purposeful redundancy, that “valid” should be added before “prescriber-patient relationship” in rule 110.01.e, and that “other authorized designee” should be added to rule 290.03. After discussion, the Board approved of such changes via unanimous consent.

- Idaho pharmacists Bill Wheeler, Jo Ann Wheeler and Laura Heitzman commented that a grandfathering clause should be added to 602.03, and the Board agreed via unanimous consent.

- Ms. McKay publically commented that proposed rule 035.03 should be struck as extraneous, and the Board agreed via unanimous consent.

- Mr. Johnston submitted non-substantive public comment to rule 610 and 293 and explained that the Idaho Department of Administration, Division of Rules has already corrected two typos that were contained within the proposed rule printing. The Board approved said changes via unanimous consent.

Mr. Roy Eiguren, representing Optimum Rx, with assistance from Mr. McAllister, clarified written comment that he submitted during the public comment period. In conjunction with additional public comment received by Ms. Ciolko, Mr. Johnston made the following suggestions to attempt to rectify the situation that Mr. Eiguren brought to the Board’s attention:

- Define ‘Remote Office Location’ in rule

- Develop clarifying changes to proposed rules 029 and 073 and existing rule 600 that include a reference to statutory exemptions, reinforce statutory requirements, and harmonize terminology.

- Add requirements to draft rule 610 that include private, encrypted connections, secured areas restricted to authorized personnel, and a mandate that centralized pharmacy services must be performed from a pharmacy, central drug outlet, or remote office location.

- Define central drug outlet, central pharmacist, centralized pharmacy services and PIC in statute.

- Combine draft 54-1721(b) and (c), add an employment relationship requirement, and strike references to the location that the practice of pharmacy is performed from.

The Board approved the conceptual changes and directed Mr. Johnston and Ms. McKay to draft such language which recognizes the practice of pharmacy from “home offices”, preserves the

exemption requirement if pharmacists working from such location are employed by a mail service pharmacy, establishes additional security parameters for such locations, and clarifies that centralized pharmacy services can only be performed outside of a drug outlet if from within such locations.

Mr. Johnston explained draft formatting changes to 54-1704 and the many changes to draft, non-resident drug outlet, statutory language penned by Mr. Johnston and Ms McKay, pursuant to the Board's direction during the August 23, 2012 meeting. Via unanimous consent, the Board approved the changes with the addition of one corrected reference, as identified by Dr. Chopski. Mr. Johnston detailed changes within the project to incorporate DEA controlled substance scheduling by reference, including the addition of "spice" language from temporary rule 210, which will expire Sine Die of the 2013 Idaho Legislature, necessitating an emergency clause within the bill; the Board approved via unanimous consent. There were no additional changes to draft 37-2730A since the Board's August 23, 2012 direction, the Board approved 37-2730A and all rules that contained no changes from the proposed to pending phase of rule promulgation via unanimous consent.

Mr. Rickert (InstyMeds) and Dorsie Sullenger, R.Ph. representing Madison Memorial Hospital (MMH) requested a waiver and/or variance from the Board regarding the use of ADS systems in MMH's emergency room. The specific rules related to their request were 290.11 b, c, d and e; 291 and 637. MMH would follow ADS pending rules instead. After discussion Mr. Sperry motioned to approve the request until Sine Die with inspector visits once or twice during the wavier period. Dr. Chopski seconded. After further discussion Mr. Sperry amended his motion to approve the waiver/variance until the end of the April 4, 2013 board meeting. Dr. Chopski seconded. Motion carried unanimously.

Mike Galloway and Gabe Zawaideh representing MatchRx joined the meeting by conference call. Mr. Galloway and Mr. Zawaideh presented their business model, which facilitates pharmacies distributing Rx items to other pharmacies via MatchRx's web site. Mr. Galloway and Mr. Zawaideh understood that such transactions are outside of the normal distribution channel and thus prohibited by the Idaho Wholesale Drug Distribution Act. Ms. Atkinson confirmed that this process is commonly referred to as 'virtual wholesaling'. The Board was interested in changes to the law that facilitate pharmacy inventory reduction, but was hesitant to support procedures that could create an avenue for counterfeit or adulterated drugs from entering the normal distribution channel. The Board thanked the presenters and requested that MatchRx provide the Board with any language that might be presented to the Idaho Legislature.

The hearing for BOP case 13-008 regarding Christopher LeBlanc, Pharmacy Technician-in-Training, was vacated as Mr. LeBlanc has voluntarily surrendered his registration.

For the reinstatement hearing of Dennis Beach Mr. Fraser recused himself due to his prior personal and professional relationship with Mr. Beach. Dr. Chopski called the hearing to order. Kathy Takasugi, DAG, presented information regarding Mr. Beach's previous Board actions. Dr. Henggeler motioned to enter into executive session to discuss health matters with Mr. Beach. Mr. Sperry seconded. Dr Chopski called for a roll call and all were in favor of the motion. The Board entered executive session at 2:09pm. Dr. Henggeler motioned to end executive session. Mr. Sperry seconded. Dr. Chopski called for a roll call, and all were in favor of the motion. Executive Session ended at 2:29pm. Mr. Sperry motioned to not grant licensure, to have Mr. Beach continue to work through the Board's Pharmacy Recovery Network (PRN), and for Mr. Beach to apply for reinstatement no earlier than one year from now. Dr. Henggeler seconded.

Mr. Sperry then clarified that his motion included denying Mr. Beach's request for reinstatement. The motion carried unanimously.

Ms. Takasugi presented the stipulation and consent order signed by Lisa Mathis, R.Ph. Ms Mathis is to execute an 18 month extension to her original PRN contract for non-compliance. Dr. Henggeler motioned to accept stipulation and consent order as written. Dr. de Blaquiere seconded. Dr. Chopski wants to know sooner of non-compliance with PRN.
Three voted in favor with Dr. Chopski opposed. The motion carried.

Ms. Takasugi presented the stipulation and consent order signed by Nichelle Daigle, Pharm D. Ms Daigle is to remain compliant with her PRN contract for one year. Dr. Henggeler motioned to accept the stipulation and consent order as written. Dr. de Blaquiere seconded. Motion carried unanimously.

Ms. Takasugi presented the stipulation and consent order signed by Brian Charles, D.D.S. Dr. Charles' controlled substance registration is to be reinstated pursuant to several restrictions. Dr. de Blaquiere motioned to accept the stipulation and consent order as written. Dr. Chopski seconded. The motion carried unanimously.

During the Inspector Q & A, the Board, Mr. Johnston and the inspectors discussed the New England Compounding Center (NECC) tragedy, the national landscape of pharmacy compounding, Idaho compounding law, and sterile compounding. Ms. Atkinson has requested NECC's voluntary surrender of their mail service pharmacy registration. Dr. de Blaquiere led a discussion of dispensing compounded product pursuant to patient specific prescription drug orders. The Board also discussed USP 797 standards and potential inspector training. The Board developed an action plan and instructed Mr. Johnston to hold a conference call with key Idaho compounders, schedule a negotiated rulemaking public meeting in conjunction with the Board's January 2013 open public meeting, consult with Representative Dr. John Rusche concerning the Idaho Legislature's desire to address this topic in 2013, research Idaho law pertaining to dispensing pursuant to patient specific prescription drug orders, provide the Board with USP 797 language, and research 'USP 797 like' language from other states.

Mr. Johnston presented the Board financials. 31.51% of the fiscal year has elapsed and the Board has spent 24.11% of their budget. Only 10.59% of the federal grant has been spent.

Mr. Johnston presented the Board's travel calendar and Dr. Henggeler, Dr. Chopski, and Chairman Fraser expressed interest in attending NABP's annual meeting in St. Louis.

Dr. Henggeler motioned to enter executive session as authorized by Idaho Code 67-2345(1)(a). Dr. de Blaquiere seconded. Chairman Fraser called for a roll call and the motion was approved unanimously. The Board entered executive session at 4:00 p.m. Dr. de Blaquiere motioned to end executive session. Dr. Chopski seconded. Chairman Fraser called for a roll call and the motion carried unanimously. The executive session adjourned 4:20 p.m.

Dr. Henggeler motioned to adjourn the meeting. Dr. Chopski seconded. The motion carried unanimously and the meeting adjourned at 4:21pm.