

**MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
February 8, 2018**

**Board of Pharmacy Office
Boise, Idaho**

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

Chairman Nicole Chopski, PharmD, called the meeting to order at 8:00 a.m. In attendance were Vice Chairman, Holly Henggeler, PharmD; board members Rich de Blaquiére, PharmD; Kristina Jonas, PharmD; and Ed Sperry, Public Member. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Fred Collings, Chief Investigator; Jaime Thompson and Wendy Shiell, Compliance Officers; Andy Snook, Deputy Attorney General; Steven Olsen, Deputy Attorney General; Misty Lawrence, Management Assistant; Ellen Mitchell, Program Information Coordinator; and several members of the public.

Dr. Jonas motioned to approve the October 25-26, 2017 minutes with minor corrections. Dr. Henggeler seconded, and the motion carried unanimously.

Dr. Henggeler motioned to approve the November 3, 2017 minutes as written. Dr. Jonas seconded, and the motion carried unanimously.

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

- Board Performance Dashboard
- Travel Calendar
- Exercises of Delegated Authority
- Director's Expenses
- Remote Dispensing Site Update

Dr. Jonas motioned to approve the Consent Agenda and have a brief discussion about the Travel Calendar. Dr. de Blaquiére seconded. During discussion Dr. Jonas indicated she would not be able to attend the NABP District 6-8 Meeting in October. Dr. Henggeler indicated she would attend the NABP meeting. Dr. Henggeler also expressed her appreciation of the travel summaries that are submitted by Board members and staff, following meetings they have attended. Following discussion, Dr. Chopski called for the vote. The motion carried unanimously.

Mr. Fraser shared that the Dashboard numbers for inspections is low due to the large number of new stores and remodels that have re-directed compliance officer time during the measured time-period. He also informed the Board that Lisa Culley had announced her retirement effective February 11, 2018. At that time, the Board will have 2 open positions. Theresa Arnold, currently in the Customer Service Representative (CSR) position, has accepted the position in licensing that was vacated when Sharon Treese retired. Mrs. Lawrence is currently reviewing resumes for the CSR position. The announcement for the south western Idaho Compliance Officer position will be completed soon. Staff will notify the Board when it is posted.

Dr. Adams expressed his appreciation to the Board members that were able to attend the legislative hearings on the proposed rules. The rules passed unanimously in the House and Senate Health & Welfare committees. The legislative review yielded a suggestion that the Board revert to its original, broader language on statins. Dr. Adams provided the Board with proposed language for a temporary rule to honor the Legislature's request. Mr. Snook explained that Dennis Stevenson, Administrative Rules Coordinator, asked for the rule to be published with an effective date of July 1.

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

- URM Stores Inc. – The facility was shipping over-the-counter medications to Idaho non-pharmacy drug outlets that were not properly licensed to carry the products. URM Stores was previously instructed by the Board to determine if facilities were properly

licensed before selling and shipping products. By signing the Stipulation and Consent Order, URM Stores agreed to pay a \$2,000 administrative fine.

- KJ's Pharmacy – During a routine inspection the Board's compliance officer found vials of liquid with no labeling and no expiration dates. Several compounded drugs lacked proper labeling, and no documentation of testing of compounded products could be located. An extensive amount of expired drug products and compounding bulk products were on the pharmacy shelves, in the refrigerator, and in the compounding area. It was also noted the pharmacy was in violation of the monthly reporting requirement of controlled substances to the Board's prescription monitoring program. By signing the Stipulation and Consent Order, KJ's Pharmacy agreed to pay a \$2,000 administrative fine.
- Timothy D. Brown – As the PIC of KJ's Pharmacy, he bears the responsibility for the above violations. By signing the Stipulation and Consent Order he has agreed to pay a \$500 administrative fine.
- Albert Middleton, RPh – PIC of Ridley's Pharmacy, failed to conduct an annual controlled substances inventory in the required manner for years 2013, 2014, 2015, and 2016. By signing the Stipulation and Consent Order he has agreed to pay a \$2,000 administrative fine.
- Pamela Goodliffe, DMD – Failed to conduct an annual controlled substances inventory as required, maintained outdated controlled substances in the office, dispensed outdated controlled substances to patients, and dispensed controlled substances to herself. She also failed to obtain a Prescriber Drug Outlet registration as required. By signing the Stipulation and Consent Order she has agreed to pay a \$4,000 administrative fine.
- Elanco – The facility shipped medication into Idaho for over a year without obtaining the proper licensure. By signing the Stipulation and Consent Order they have agreed to pay a \$40,000 administrative fine.
- Walgreens 06863 Coeur d'Alene – Failed to notify the public and Board office of a change in hours of operation as required. By signing the Stipulation and Consent Order they have agreed to pay a \$2,000 administrative fine.
- Walgreens 05648 Nampa - Failed to notify the public and Board office of a change in hours of operation as required. By signing the Stipulation and Consent Order they have agreed to pay a \$2,000 administrative fine.
- Walgreens 12503 Moscow – Failed to pay an administrative fine assessed by the Board in a previous matter. By signing the Stipulation and Consent Order they have agreed to pay a \$2,000 administrative fine, in addition to the \$2,000 administrative fine assessed previously for a total of \$4,000. Fine to be paid within 30 days.
- R & R Pharmacy – Non-compliance issues noted during inspections in 2014, 2016, and 2017. Issues include failure to conduct daily verification of electronic recordkeeping system, failure to include audit requirements for compounded drug products, ventilated cabinet not provided for compounding, and expired compounding bulk ingredients in the compounding room. By signing the Stipulation and Consent Order they have agreed to pay a \$2,000 administrative fine.
- Peter A. Gibbons, PharmD – As PIC of R & R Pharmacy, he bears the responsibility for the violations above. By signing the Stipulation and Consent Order he has agreed to pay a \$500 administrative fine.

Dr. Henggeler motioned to approve the Consent Agenda: Stipulation and Consent Orders except for R & R Pharmacy/Tim Brown, KJ's Pharmacy/Peter Gibbons, and Albert Middleton, Dr. Jonas seconded, and the motion carried unanimously.

Dr. Henggeler started the discussion regarding KJ's Pharmacy. Previously the Board did not discipline on the first violation. However, due to increased scrutiny on compounding and

compounded medications the presence of expired bulk product brought this matter before the Board.

The Board took up the case of Albert Middleton, RPh. Mr. Fraser explained the issues with Mr. Middleton have been going on since 2013, Concern was shown regarding this taking too long to rise to the level of discipline. Mr. Fraser explained the current method was to try and educate before discipline. Going forward the new licensing software will track inspection violations and follow-up requirements. He also explained they are putting more onus on the facility instead of the pharmacist-in-charge as the owner of the facility has the power to make quicker changes. Dr. Chopski requested the process of acting on violations be reviewed to ensure greater consistency.

Dr. Henggeler has the same concerns with R & R Pharmacy as she does with KJ's Pharmacy. Following a brief discussion, Dr. Henggeler motioned to accept KJ's, Middleton, and R & R's Stipulation and Consent Orders. Dr. de Blaquiere seconded and the motion carried unanimously.

Mr. Sperry thanked Steve Olsen for his hard work on the cases presented today.

Christopher Erb, pharmacist applicant, attended the meeting with his wife to provide the required annual update. He recently sat for the NAPLEX, though he doesn't have the results yet. He has the MPJE scheduled for next week. The Board thanked him for attending and looks forward to receiving his exam scores.

The Board took up the matter of John Bronsell, PharmD, who attended the meeting without legal counsel. Dr. Bronsell is seeking release from a Board order requiring monitoring by Southworth Associates. Following Dr. Bronsell's presentation and discussion, Dr. Jonas motioned to table the discussion until Tiffany East, Senior Compliance Monitor from Southworth Associates is available. Mr. Sperry seconded and the motion carried unanimously.

The Board took up the matter of Lindsey Schofield, Pharmacy Technician in Training applicant. Board staff was unable to approve the application as it falls outside the parameters of delegated authority. Following Ms. Schofield's presentation and Board discussion, Mr. Sperry motioned to approve the application. Dr. de Blaquiere seconded, and the motion carried unanimously.

The Board revisited the matter of Dr. Bronsell. Tiffany East attended the meeting telephonically to answer questions from the Board. Following a brief discussion Mr. Sperry motioned to release Dr. Bronsell from his current stipulation on August 6, 2018, he must remain compliant with the current Stipulation and his current contract with Southworth until that time. Dr. Adams may execute the Order releasing Dr. Bronsell and he does not need to reappear prior to being released. Dr. Jonas seconded. The Board discussion reiterated this case does not set precedent for future cases as this case has unique circumstances. Dr. Chopski called for the vote and the motion carried unanimously.

Dr. Adams introduced the Board Discussion agenda item. The first topic is the Licensing System Update and goes hand in hand with the topic of Spring Renewals. Dr. Adams asked Misty Lawrence present these topics.

Mrs. Lawrence presented an overview of MyLicense Suite which is produced by System Automation and is currently in development, it will replace GL Solutions as the board's licensing software. The software is slated to go live at the end of the spring renewal season on July 5-6, 2018. Staff will not have the ability to process late renewals or applications from July 1-6, prompting staff to seek Board approval to start renewal season two weeks earlier than normal to allow additional time for renewals to be processed prior to July 1. Since the change in renewal and expiration dates goes into effect at the same time, Mrs. Lawrence presented the following implementation plan:

Implementation Plan - The renewal will cover licenses that will be issued from July 1, 2018 to June 30, 2019. Board staff intends to implement as follows:

- For the licenses/registrations that are eliminated under the new rules taking effect July 1, 2018, renewals will not be required as they currently expire June 30, 2018. This includes Pharmacist Controlled Substance, Distributor Controlled Substance, Non-

Pharmacy Drug Outlets, Institutional Drug Outlets, Veterinary Drug Outlets, and Veterinary Drug Technicians.

- Licenses/registrations with fee changes effective July 1, 2018 will be charged the new fee during this renewal period as the license/registrations are issued for the period of July 1, 2018 through June 30, 2019
- Individuals that renew in the spring of 2018 will expire June 30, 2019, and the first birth month renewal for those individuals will occur in the spring of 2019. Practitioner/Researcher Controlled Substance registrations will expire December 2018, and the first birth month renewals for those individuals will occur in the fall of 2018.
- Facilities renewing in the spring of 2018 will be charged the full annual renewal fee and will expire December 31, 2018 (6 months). They will renew again in fall of 2018, at which time they will be charged 50% of the annual renewal fee and will expire December 31, 2019 (12 months). This format is being requested due to current system capabilities not allowing for a prorated fee, though the new system will.
- Technician-in-training registrations will not have a renewal process in the new system. Current active registrations will not renew this spring and will have the expiration date extended to the final expiration date allowed by current rule. If they have 1 renewal left they will expire 6/30/2019 and those with 2 renewals left will expire 6/30/2020. All technician-in-training registrations issued between now and June 30, 2018 will be given a June 30, 2020 expiration. Registrations issued July 1, 2018 and beyond will expire 2 years from issue date according to new rules.
- Transition to a birth month renewal will be completed using a prorated fee based on quarters in the registration period. This creates the least amount of work for registrants and less of a one-time loss across fiscal years.

o Example Chart:

Current Expiration Date	New Expiration Date	Quarters	% of year	Cost
12/31/2018	7/30/2019	3	75%	\$45.00
12/31/2018	8/31/2019	3	75%	\$45.00
12/31/2018	9/30/2019	3	75%	\$45.00
12/31/2018	10/31/2019	4	100%	\$60.00
12/31/2018	11/30/2019	4	100%	\$60.00
12/31/2018	12/31/2019	4	100%	\$60.00
12/31/2018	1/30/2020	5	125%	\$75.00
12/31/2018	2/28/2020	5	125%	\$75.00
12/31/2018	3/31/2020	5	125%	\$75.00
12/31/2018	4/30/2020	6	150%	\$90.00
12/31/2018	5/31/2020	6	150%	\$90.00
12/31/2018	6/30/2020	6	150%	\$90.00

- A similar chart will be used in spring of 2019 to transition the remainder of the affected individuals to birth month renewal.

Staff is specifically asking Board approval to

- Extend the Spring Renewal period from 10 weeks to 12 weeks, for a start date of April 9, 2018,
- Extension of Rule 017.05 Exemption from 10 weeks to 12 weeks, and
- Acceptance of the implementation plan proposed by board staff.

Approval of these requests would allow the renewal process to begin two weeks earlier in preparation for the launch of the new licensing software. A temporary fee rule will be discussed via conference call, in March for a change to the fee for the non-resident pharmacist registrations as described in the October 2017 Idaho Administrative bulletin. Dr.

Adams will submit the Administrative Rules Form following the passage of House Bill 351, as outlined in the October Idaho Administrative bulletin.

Following discussion Dr. Jonas motioned to adopt the Licensing Implementation Plan with minor corrections. Dr. Henggeler seconded and the motion carried unanimously

Dr. Chopski asked Dr. Adams to frame the discussion regarding Pharmacist-In-Charge (PIC) Qualifications. The Board received a waiver requesting the maximum number of locations that a PIC can oversee be increased. Dr. Adams provided the Board with information regarding a handful of states to generate discussion. Following the discussion Dr. Chopski asked Dr. Adams to review recent cases in Idaho related to Idaho PICs.

Following a lunch break the Board took up the matter of the Multistate Pharmacy Jurisprudence Examination® (MPJE). With the re-writing of the law book and a 'standard of care' approach to regulation, Dr. Adams doesn't believe Idaho has enough material to create the number of questions required for the test to be psychometrically sound. Research conducted by Board staff discovered the Idaho Board of Medicine doesn't require a law exam, nor does the Idaho Board of Nursing. The Idaho Board of Dentistry requires an open book exam. After a lengthy discussion, the Board agreed that an alternative to the MPJE was needed. This topic will be discussed during the March conference call.

Dr. Chopski asked Dr. Adams to frame the discussion regarding Rules Governing DME, Manufacturing, and Distribution. Dr. Adams indicated the rules contained in this section of the law are addressed in other parts of the law book. He suggested incorporating the non-duplicative provisions to the appropriate locations in other rule chapters. The Board granted unanimous consent to move forward.

Dr. Henggeler recused herself for the topic of Sav-On's waiver request.

Laura Churns, PharmD, Sav-On Pharmacy Legislative and Regulatory Affairs director presented her company's request for a waiver of Board Rules 011.11 and 310.01. Their request is from the date of approval until June 30, 2018. The Board requested a report of findings be presented at the June meeting.

Jason Bailey, PharmD, owner of Teton Pharmacy telepharmacy sites, submitted a waiver request asking the Board to grant him an exemption from rule 710.03.a. Dr. Bailey attended the meeting telephonically. He is currently the PIC of two of his locations and is requesting he be allowed to be the PIC of the third location as well. He believes the technology he uses decreases errors and increases safety. He is currently fulfilling the monthly reporting and self-inspection requirements for two locations, and there would be no detriment to adding one more location. Following discussion Mr. Sperry motioned to grant Dr. Bailey's request with an end date of June 30, 2019, Dr. Jonas seconded. Following further discussion Dr. Chopski called for the vote. Mr. Sperry and Dr. Jonas voted in favor of the motion, Dr. Henggeler was opposed, and Dr. de Blaquiere abstained. The motion carried allowing Dr. Bailey to be PIC for his three telepharmacy locations.

Dr. Henggeler recused herself for the topic of Broulim's waiver request.

Marcus Hurst, PharmD, Broulim's Pharmacy Supervisor, attended the meeting telephonically to present his company's waiver request of Board Rules 011.13 and 310.

Following the discussion of the Sav-On's and Broulim's waivers, Dr. Jonas motioned to allow a pilot project that allows pharmacies to enter into a Memorandum of Understanding (MOU) to include the following criteria:

- May not start until Board protocols are complete
- MOU must be signed by applicant
- MOU expires June 30, 2018
- Board inspection and data to be presented at the June 2018 Board meeting to determine if any tweaks are needed to protocols
- All applications to be submitted to Dr. Adams for approval

Dr. de Blaquiere seconded, and the motion carried. Sav-On's and Broulim's have applied and have been approved.

Mrs. Lawrence presented the Board financial information. Expenditures and receipts are on track for this time of year. The fiscal year is 50% expended with 42% of the budget expended.

- Personnel Costs are 49.37% expended with approximately \$7,300 in one-time salary savings
- Operating Expenses are 35% expended
- Capital Outlay is 32% expended, the purchase of new laptops has been completed, and the first payment to System Automation for project planning and system admin training has been made.
- The beginning cash fund balance was \$2,610,200. Disbursements were exceeding receipts by \$265,195 or 106% on the last report. Disbursements now exceed receipts by \$162,830 or 20.5%. Receipts to disbursements continue to stabilize. There will likely be another dip over the next few months until renewals start in April.
- Budget trend comparison shows expenditures are on target for the first half of the year and in line with the appropriation at 42% expended. The DHW project expenditures and revenues were removed for this comparison.
 - Revenues were trending down 28%, or \$58,700 in the 1st Qtr. As of 12/31 revenues have stabilized but are still trending down about 3% or \$24,700. This is also shown in the decrease of new applications, in the 1st quarter, with 143 fewer applications and at half the year, down 153 applications.
- Monthly cash flow charts show August with a significant increase in expenditures. The SWCAP (Governmental Overhead) annual payment of \$62,900 and an Appriss payment in the amount of \$97,240 for Gateway and NarxCare licenses issued through the DHW contract. The payment Appriss was reimbursed by DHW, though the revenue was not received until September.
 - When removing the reimbursement, September revenue was actually \$32,460, making the September variance -\$69,270.
 - The significant increase of receipts in November and December are due to practitioner controlled substance renewal. The renewal period was successful with 95% renewed. 7,809 renewed on time with an additional 111 renewing late. 125 moved out of state and/or retired leaving 3.66% (305) not renewed.
- Cumulative monthly cash flow show the Board in the red by \$162,900, this trend will likely continue as the Board was appropriated \$250,000 in one time monies. This will skew the cash flow to regular expenditure numbers.

Personnel Update

- Sharon Treese officially retired December 31, 2017
- Over the last 3 years the licensing team has been cross training so all staff can process and issue any license. One licensing position was classified as a TRSI and two positions as TRSII. Board staff was able to work with DHR to successfully re-class the TRSI position to a TRSII position.
- Staff is in the process of hiring for the Customer Service Rep position.

FY18 Budget/Appropriation Budget Update (Supplemental)

- JFAC budget hearing was held January 11, 2018 and the supplemental for \$37,200 was approved.
- The final appropriation for FY18 will be \$2,336,500. The appropriation bill has passed the House and was sent on to the Senate.

FY19 Budget request – Update

- The Board's budget request for FY 19 is \$2,007,700
- The Governor's Recommendation is \$2,028,700, which includes a 3% CEC merit based increase for regular employees.
- The budget hearing was Feb 8th, and there were no questions or concerns. The budget setting hearing is scheduled for March 1st.

Hearing no further business, Dr. Jonas motioned to adjourn. Dr. de Blaquiere seconded, and the motion carried. Meeting adjourned at 3:23 p.m.