MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
October 27 & 28, 2010

Hilton Garden Inn Spectrum - Boise, Idaho

This meeting of the Board is held to conduct regular board business.

Chairman Holly Henggeler, Pharm D, called the meeting to order on October 27, 2010 at 1:00 p.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D; and Rich de Blaquiere, Pharm D; Mark Johnston, R.Ph., executive director; Jenifer Marcus, DAG; Fred Collings, Chief Investigator; Jan Atkinson, Senior Compliance Officer; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Wendy Hatten, and Ellen Mitchell. Ms. Gurnsey was unable to attend.

The minutes from the August 12, 2010 Board Meeting were reviewed. Dr. Chopski motioned to approve the minutes of August 12, 2010, with a minor correction. Mr. Fraser seconded. The motion carried unanimously.

Dr Chopski motioned to approve the minutes of the September 30, 2010 meeting with minor corrections. Dr. de Blaquiere seconded. The motion carried unanimously.

Mr. Johnston attended at a treasure valley mayors meeting, at which he had been invited to present on the temporary rule scheduling the known active ingredients in products collectively known as Spice. Mr. Johnston shared with the Board details of what has been experienced since the temporary rule went into effect, such as the Governor allowing a period of time before signing the temporary rule, the closure of stores that sold said products solely, and the charging of a store owner in Meridian, who continued to sell said products.

Mr. Johnston attended a Board of Medicine meeting and reported that their Board was supportive of the changes to proposed rule 469, as well as future movements to further regulate the delivery of legend drugs by practitioners. Some members of the Board of Medicine were hesitant to support pharmacist limited prescriptive authority.

In the matter of Public comment regarding proposed rule changes, Mr. Johnston introduced Chad Dwyer who is a 4th year pharmacy student of ISU.

Mr. Dwyer suggested the following changes to proposed language on Immunizations.

- 166.02: Qualifications
    - b.3: suggested ‘recommended’ be changed to either ‘most recent’ or ‘current’.
    - b.5: suggested ‘informed consent’ be changed to ‘language understandable to the patient or the patient’s agent.’ Dr. Chopski commented that that is what ‘informed consent’ means.
    - c: regarding CE instruction, are there already immunization CEs in place and is the requirement a live or online version? Dr. Henggeler commented that the Board didn’t want to specify the type of CE, and that there are several immunization CEs currently available. Dr Henggeler also reiterated that this additional, proposed requirement is part of the existing 15 CE requirement and not in addition to.

    - e: Mr. Dwyer requested clarification of the definition of ‘used contaminated supplies’. Mr. Fraser commented that there should be procedures in place for anything that is considered contaminated verses just throwing it in the normal trash.

- 166.05: Record Keeping
    - c: suggested also including the ‘type of vaccine’
    - e: suggested including which dose in the series the vaccine is, if applicable

- 166.05: (suggested addition to list)
    - completed informed consent forms
    - refrigerator and freezer temperature logs
    - according to CDC, for OSHA, there’s a requirement to keep a log on file that is signed and dated, of any declination of Hepatitis B injections. Dr. de Blaquiere clarified that the ‘declination of the Hepatitis B injection requirement’ applies to when someone at risk is offered the Hepatitis B injection and they declined it, resulting in a file at a place of employment, not at the pharmacy. Of course, it would be good practice for declining, immunizing pharmacist’s employers to keep such a file, but mandating it goes beyond the scope of this proposed rule.
    - immunization training record for pharmacists, including CEs, when trained and follow up training

- 166.02.b.ii: There are a couple of different levels of CPR training and the rule should specify CPR for healthcare workers verses layperson. Mr. Johnston pointed out to Dr. Henggeler that he has received similar public comment from a different entity, and that there would be a review of written comment on this subject from George Turgoose, ISU Pharmacy D candidate, tomorrow as well.

- 166.06: Emergencies
    - b: the CDC recommends injectable diphenhydramine, or oral diphenhydramine, also be in the kit.

Mr. Dwyer inquired about collaborative practice agreements. The Board and Mr. Johnston explained that the purpose of this rule promulgation is to establish education and recording keeping requirements. Not addressing how a pharmacist obtains authority to administer these RX items was purposeful, as the Board eventually hopes to request prescriptive authority from the legislature.

Mr. Dwyer’s final comment was on blood glucose or cholesterol screenings and the requirement to keep a clinical laboratory improvements amendments certificate of waiver, realizing CLIA Waivers are not required for the administration of vaccinations. Mr. Johnston commented that the said screenings are an allowed practice that is unregulated, but it’s too late to address for changes in 2011, as per the Administrative Procedures Act.

Mr. Johnston commented that Mr. Dwyer had given him a copy of his notes and that he noticed Mr. Dwyer had skipped one comment that he felt might have some value.

- 166.02.b.3: indicates that the recommended immunization schedule should be ‘most current’ the ‘VIS’ should also be ‘most current’

The next public comment on the proposed immunization rule was by Dr. Paul Cady, Dean of ISU, who spoke on behalf of suggestions that he received via email from Dr. Cathy Cashmore, Associate Dean of ISU. Dr. Cashmore provides instruction on the ISU vaccination program;

- 166.02.ii: Qualifications: change 'United States Public Health Service' to state 'CDC'

- 166.02.b.8: Immunization Reporting and Records Management: Dr. Cady asked Mr. Johnston for clarification of who the pharmacist would be responsible to report to. In response Mr. Johnston reported that Rep. Rusche would be giving oral public comment concerning the requirement for Idaho practitioners and nurses to report to IRIS and that Rep. Rusche would like to see pharmacist held to the same standard. Dr. Cady commented that wording should stay vague because pharmacist reporting requirements could change.

- 166.02.b.ii: suggested that current certification for CPR state that the type of training be for 'healthcare providers' verses the CPR provided for laymen, and should include 'AED (automated electronic defibrillator) training. Also Dr. Cady recommended that pharmacists be trained in pediatric and infant CPR.

- 166.05: Record keeping: should include reporting adverse reactions to VAERS (Vaccine Adverse Event Reporting System).

- 166.06.b: Emergencies: add 'injectable diphenhydramine or oral diphendydramine'.

The Board thanked Mr. Dwyer and Dr. Cady and explained that their comment would be considered at tomorrow's meeting.

The next agenda item was the Institutional Rules and Review Committee Report, as presented by Mr. Johnston, Dr. Kurt Vanden Bosch, from Saint Luke's Magic Valley Regional Medical Center and, Mr. Taylor Neilson, from West Valley Medical Center. Mr. Johnston began by stating that the committee had been meeting for nearly a half a year and were presenting a near finalized draft, which is drastically updated and the same number of pages as the current institutional rules section. Mr. Johnston explained that the committee had worked on individual topics and that Board had previously approved drafts of such. Now, many of the individual rules have been combined, considerably condensing the draft. Mr. Johnston presented the changes since the last Board meeting and asked the Board for certain guidance. After deliberation and input from Dr. Vanden Bosch and Mr. Neilson, the Board decided:

- Whenever an admitted patient brings drugs into a hospital a pharmacist (only) must visually evaluate (not assure) the quantity and quality. Said drugs may be disposed after (not within) a reasonable number of days following discharge or death.
- The institutional facility (not the appropriate committee) notifies the pharmacy of the prescribers authorized to issue drug orders.
- RX delivery from an ER must occur only pursuant to a valid drug order and must be documented as required in a pharmacist absence.
- The pharmacist absence section was separated into a section concerning the absence from the institutional facility and a section concerning the absence from the pharmacy while still working within the institutional facility.
- "out-patients receiving emergency treatment" was removed from a section entitled "emergency drug supply preparation and monitoring", as these two are not similar enough to combine.
- 'First expiring drug' was added to the labeling requirement of an emergency kit or crash cart, replacing 'expiration date'.

- Provisions were made to recognize electronic verification, as opposed to requiring signatures.
- ‘Prepackaged’ was changed to ‘unit dose’ clarifying labeling requirements for drugs dispensed to patients, intended to be used within facility.
- Separating ‘outsourcing’ into ‘tele-pharmacy’ and ‘other forms of centralized prescription drug ordering and filling’.
- To change ‘tech-check-tech’ to ‘verification technician’, eliminating the pilot status.

Lynette Berggren, Board consultant, presented changes to the proposed rules since the last Board meeting:

- The Board approved of the draft language changes to the unlawful conduct rule, unchanged.
- Proposed rule 065: Compounding: revised 02.b. per Mr. Johnston’s request, and added “’or be FDA approved’, to 03 in the first sentence. That was revised due to an oversight that the Board previously instructed be corrected.
- Proposed rule 570: Drug Products Storage: revised the language to improve clarity and enable Ms. Berggren to eliminate redundancy language in other sections. The Board directed that ‘authorized personnel’ verbiage be removed. Ms. Berggren suggested changing ‘must be stored in accordance with USP/NF requirements’, to ‘must be stored in an area secured appropriately to safeguard product integrity and protect against product theft or diversion’. The Board approved of the draft language.
- Proposed rule 600.02: Board Approval of Drug Outlet: revised wording slightly to improve clarity. The Board approved of the draft language, with the addition: ‘prior to opening or reopening’.
- Proposed rule 600.03: Space & Fixture: combined both subsections a & b. The Board approved of the draft language, unchanged.
- Proposed rule 600.06: Product Inventory: reworked language to separate provisions applicable to institutional pharmacies and improve clarity. There was much discussion by Board members. The Board approved of the draft language, unchanged.
- Proposed rule 600.07.a: Security: added ‘or an alternative designated storage area within an institutional facility’. The Board approved of the draft language, unchanged.
- Proposed rule 600.08.c: Operating Hours: slight wordsmithing. The Board approved of the draft language, unchanged.

Board chair Dr. Henggeler pointed out that within 600.08.d: ‘Approval’ should be ‘Notification’. The Board approved of said change.

Representative Dr. John Rusche presented a Power Point on the Patient Protection and Accountable Care Act (PPACA) aka Health Care Reform Bill. After presenting overall changes, Rep. Rusche elaborated on the potential for pharmacist cognitive service advancements and his view of how pharmacy might change in the future. This involves pharmaceutical care across state lines, but the Board was not supportive of expanding non-resident pharmacy and pharmacist registration at this time.

Mr. Johnston discussed the following updated proposed statute changes:

- 37-2725(7) struck, as outdated language.
- 54-1705: within the definition of drug order, un-striking language thus limiting the use of drug orders to institutional facilities and adding language that states the Board can define additional use in rule (first dose pharmacies in rule #257). Additionally, the definition of practitioner has been altered as per Dr. Chopski’s

prior request, and the reference in 54-1729(5) is corrected as per Dr Henggeler's prior direction.

- Updated CS Schedules: The DEA struck two substances that they had listed temporarily. These substances were structurally similar to other schedule I substances, but when studies were completed, they were not pharmacologically similar. Also, our addition to schedule II, as per the DEA, has been re-formatted.

RPh limited prescriptive authority: 'as defined by the rules of the board' has been added, as per LSO's wishes, and the prescriptive authority is now limited to just CV, liquid, codeine product.

The prospective drug review & counseling statute has been relocated, as per research performed after the last Board meeting. In 1994 several additions to Idaho Code were made to recognize and mandate counseling. At the time, the out of state mail pharmacy licensure act was the last set of statutes in the pharmacy practice act with a severability clause placed at the end: 54-1749. In 1994 when the new statute (prospective drug review and counseling) was added at the end of the pharmacy practice act, 54-1749 was chosen and the severability act was moved to the new end: 54-1750. Unfortunately, the severability clause, now located at 54-1750, is for the mail service act, and not the whole pharmacy practice act. The pharmacy practice act severability clause still remains at 54-1739. In addition, all of the statues enacted after 54-1750 were placed to the end of the pharmacy practice act, so all statutes after 54-1750 are not covered by such a clause. The result is that the current prospective drug review and counseling statute lies within the mail service act and not in the pharmacy practice act. Thus, one could argue that it pertains to mail service pharmacy only. Therefore, 54-1739 is struck and 54-1749 (with "on new medications") is moved to 54-1739 and 54-1750 is moved to the end of the pharmacy practice act. A discussion on counseling was tabled for a 10/28/10 discussion.

Glenn Luke presented the fiscal report through October 15, 2010. 3 subjects were discussed;

- Expenses & revenue year to date. The report covers July through October 18 of this year. The Board is right on line for fiscal year budget.

- License renewal results indicate that 75% were completed online. Those numbers are expected to go up.

- Fiscal Year 2012 budget request: We are requesting $1,311,100.00, slightly lower than the prior year. Requested expenses include $24,000.00 to replace a vehicle, $45,000.00 for conversion of old documents to an electronic format, and ongoing funds of $10,800.00 for maintenance on new software just purchased, $2,200.00 for data line changes and $10,000.00 for maintenance of the controlled substance database.

During Inspector Q&A, Mike Brown thanked Dr. Henggeler for recommending the CLEAR conference. Mike Brown, Regina Knittel and Lisa Culley attended the conference, and they are now 'CLEAR' certified. Mr. Brown pointed out that the conference would be beneficial to the Board members and some staff to attend in the future.

Mr. Fraser motioned to enter executive session, pursuant to Idaho Code Section 67-2345(1)(f). Dr Henggeler called for a roll call, and the vote was unanimous to enter executive session at 5:17p.m. Dr. de Blaquiere motioned to end executive session, Dr. Chopski seconded. The executive session adjourned at 5:22 p.m.

Mr. Fraser motioned to adjourn, Dr. Chopski seconded. Motion carried unanimously. Meeting adjourned at 5:22 p.m.

October 28, 2010

Chairman Holly Henggeler, Pharm D, called the meeting to order on October 28, 2010 at 8:00 a.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D; Rich de Blaquiere, Pharm D; Mark Johnston, R.Ph. Executive Director; Jenifer Marcus, DAG; Fred Collings, Chief Investigator; Jan Atkinson, Senior Compliance Officer; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Wendy Hatten, and Ellen Mitchell. Ms. Gurnsey was unable to attend.

Randy Lewis, manager of compliance and regulatory affairs for MWI Veterinary Supply Company, and James Culpepper R.Ph. and Vice President of purchasing for MWI Veterinary Supply Company, also a licensed Idaho pharmacist, presented a proposed change to the Wholesale Drug Distribution Act, statute 54-1752, which would exempt the following from the definition of wholesale drug distribution, as well as define "veterinary pharmacy": MWI is registered as a wholesaler, and Animal RX Pharmacy is registered as a pharmacy. Legend drugs are wholesaled to Animal RX Pharmacy, but invoiced to the veterinarian. Animal RX Pharmacy dispenses drugs directly to the end user pursuant to a valid prescription drug order, and the veterinarian bills the end user. There was a lengthy discussion by the Board. Dr. Chopski motioned to support MWI's proposed change. Mr. Fraser seconded. The motion carried unanimously.

George Turgoose, ISU Pharm D Candidate, presented the compilation of public comment on proposed rule changes. The first public comment was from NACDS concerning rule159: Prescription Drug Order Minimum Requirements. There was much discussion that included all of the Board members, Ms. Marcus and Mr. Johnston concerning prescription label requirements. Dr. Chopski motioned to accept rule change; there was no second, and the motion died. Mr. Fraser motioned to strike 'a label with' from 159.02. Dr. de Blaquiere seconded. Dr. Fraser amended his original motion to also strike159.02.g. Dr. Chopski seconded; the motion carried 2-1 with Dr. de Blaquiere abstaining.

Mr. Turgoose continued with the public comment compilation presentation for the proposed Immunization rule. NACDS submitted 2 comments:

- 166.02.a: define 'compromised patient'.
- 166.03: add 'other qualified government authorities'.

Dr. Henggeler lead a discussion considering all public comment received regarding the proposed immunization rule. The Board decided via unanimous consent to:

- replace 'United States Health Service' with 'CDS's'
- add 'current' to 'recommended immunization schedules'
- list VAERS and IRIS specifically in the reporting section
- add definitions of relative and absolute contraindication
- require live, basic life support health care professionals including AED
- recognize 'other qualified government authorities' who issue immunization recommendations
- add 'dose in series, if applicable', 'product name', and 'informed consent' to the record keeping requirements.

Via unanimous consent the Board approved rule 358, and rule 469 as written, as no public comment was received.

Mr. Ron Lavigne R.Ph. and Co-President of ISPA presented his comments in opposition of the proposed striking of the requirement of the offer to counsel from 54-1749, which currently resides within the out-of-state mail service pharmacy licensing act, as he believes the requirements should apply to mail order pharmacies.

Dennis McAllister, Director of Regulatory Affairs for Medco Health Solutions, presented his comments in defense of Mr. Lavigne's testimony, as well as presenting how Medco utilizes clinical pharmacists.

Sam Hoagland, R.Ph. presented his opposition to the proposed changes to 54-1749, specifically the addition of 'on new medications'.

Mr. Fraser and Mr. Johnston explained that the reason these proposed changes are necessary is because of testimony heard at the Senate Health & Welfare committee, regarding the 'Epilepsy Act' where pharmacists, student pharmacists, doctors, and patients testified concerning the lack of pharmacist counseling. Mr. Johnston was pulled aside by Senator Charles Coiner and was told to come back next year with stronger language regarding counseling. The Board's current policy is to mandate counseling on all new medications, which is stronger than the old policy that left the decision to counsel up to the pharmacist, when deemed appropriate. The current statute can be read to mandate counseling on all prescriptions, creating confusion.

There was a great deal of discussion between the Board members, Mr. Johnson, Mr. Hoagland and Ms. Marcus. There was concern over how other states have previously passed stringent counseling laws and had to reverse their decision recently. Mr. Hoagland commented that a double standard regarding Medicaid could be created, due to OBRA '90. Mr. Fraser said that if the Board doesn't act they run the risk of the legislature acting on their own.

Mr. Fraser motioned that the Board approve the suggestion made by Ms. Marcus to change the first sentence of 54-1749 to state "When filing a prescription a pharmacist shall complete a prospective drug review and then offer to counsel the patient or caregiver, on all new medications and on all other medications as deemed required by the pharmacist, face to face when possible or appropriate." Dr. Chopski seconded, so long as this change would have to apply to everybody. Further discussion commenced regarding the location of the statute and which types of pharmacy practices that it applies to. Dr Henggeler clarified the motion and then called for a vote: 1 in favor, 2 opposed. The motion died.

Dr. Chopski motioned that there be no change to 54-1749 and to explain to legislature "The Board changed their interpretation, so there is no need to change the statute." The motion died due to lack of a second.

Mr. Johnston clarified that the rules approved during this meeting would be printed in the next official Idaho Bulletin, then the pending rule will be presented to the legislature for the opportunity to approve, disapprove, not act or strike. The legislature doesn't have ability to add to pending rules, so rarely do they strike. They usually approve and sometimes disapprove. There is no opportunity for us to change proposed rule language after today because we can't give the public proper notification. Statutes are editable up to the time of the presentation, however, by the Board solely, just through 12/3/10. Mr. Johnston can request an edit of the statute be sent to amending order by a representative or a senator, after 12/3/10. There is also the option to rescind the order. Rules are typically heard before statutes, so realistically statutes won't be heard until the beginning of February.

Dr. Chopski motioned to table the decision on counseling until the Board's next meeting, Mr. Fraser seconded. The motion passed unanimously.

Karin Magnelli, DAG presented the diversion case regarding Alan Maxwell. Mr. Maxwell has voluntarily attended a 72 hour in-patient evaluation and joined the Pharmacist Recovery Network (PRN). Mr. Fraser motioned to accept the stipulated order as written, mandating that Mr. Maxwell remain in PRN for 10 years. Dr. de Blaquiere seconded. The motion carried 2-1 with Dr. Chopski abstaining.

Ms. Magnelli presented the Bruce Reeder case involving the dispensing of controlled substances without a prescription and failing to strictly follow the instructions of a practitioner. Mr. Fraser motioned to accept the stipulated order as written, whereby Mr. Reeder's license is placed on probation for 1 year, Mr. Reeder must submit a written plan of action, and pay $4325.00 in fees and fines. Dr. de Blaquiere seconded. The motion carried 2-1 with Dr. Chopski opposed.

Ms. Magnelli introduced Andrew Snook of the Idaho Department of Juvenile Corrections who will be representing the Board after Thanksgiving.

In the case regarding Steven Streeper's suspension for violations of his Board order, Mr. F. Michael Burkett Jr. presented as Mr. Streeper's attorney. Ms. Magnelli present on behalf of the Board. After opening comments by Mr. Burkett and Ms. Magnelli, the Board questioned Mr. Streeper. Mrs. Streeper testified on behalf of Mr. Streeper. Ashley Gouchner, senior compliance monitor for Southworth Associates, who is contracted to administrator the Board's Pharmacists Recovery Network, was questioned by Ms. Magnelli, Mr. Burkett, and the Board. Mr. Burkett, Ms. Magnelli and Mr. Streeper each made closing comments. Dr. Chopski motioned to accept the Board Staff's recommendation, as supported by Southworth Associates: Mr. Streeper is to be allowed to return to the practice of pharmacy after he submits to a 72 hour in-patient evaluation. Mr. Fraser seconded. The motion carried unanimously.

Ms. Magnelli presented the case regarding Charles Davis's PRN violation. Mr. Davis presented his case. Ms. Magnelli and the Board questioned Mr. Davis. William (Bill) Hofstra, compliance monitor for Southworth Associates, was questioned by Ms. Magnelli, Mr. Davis, and the Board. Mr. Fraser motioned to accept Board staff and PRN recommendation. Dr. de Blaquiere seconded. Dr. Chopski abstained. The vote: 2 opposed and 1 for. The motion failed. Dr. Chopski motioned to increase urinalysis to 2 times a month. Mr. Fraser seconded for discussion. Dr. Chopski amended her motion to add that non-compliance will result in an immediate suspension of Mr. Davis's license and controlled substance registration. Dr. de Blaquiere seconded. Dr. Henggeler asked for a vote: 2-1, with Mr. Fraser opposed. The motion passed.

Ms. Marcus pointed out for the record that we have a quorum for purposes of a meeting, considering the absence of Ms. Gurnsey. However, action by the Board must have a majority vote. There were 3 instances where only 2 members voted, due to Board members abstaining. The Board Chairman, Dr. Henggeler subsequently voted in favor of the motions concerning Alan Maxwell, Charles Davis, and rule #159.

In the matter of Ms. Annie Koberstein's appeal to the Board, the Board licensing staff had denied Ms. Koberstein's application to register as a Pharmacy Technician in Training, due to the fact that Ms. Koberstein's FBI background check results indicated a criminal history. Mr. Collings requested Board direction concerning an applicant's criminal history. Dr. Henggeler stated that the Board would like to review these applications on a case by case basis. The Board questioned Ms. Koberstein whose responses included not thoroughly reading the application litigation questions before answering, believing that her age at the time of the offense was a consideration, and that her technician training school did not explain the impact of her offenses. Mr. Johnston presented a letter from Southworth Associates that indicated they are capable of tailoring a one year monitoring contract for such technician applicants. Mr. Fraser

motioned to deny the application. Dr. de Blaquiere seconded. The motion carried unanimously. Ms. Atkinson noted that she presents to these schools concerning ramifications of criminal violations in the application process. A representative of a local technician school commented that applicants for admittance to their school are also informed of the ramifications.

In the matter of the Medication Review application, Mr. Johnston and Ms. Atkinson presented that the Board staff incorrectly registered Medication Review as a telepharmacy across state lines. Mr. Johnston found that they did not meet the criteria so their registration was cancelled. Medication Review is now considering opening an office in Idaho and would like the Board to consider registering them as a limited service pharmacy, but the Board's staff believes that their pharmacist might be able to utilize the new independent practice of pharmacy rule, without the need for facility registration. Mr. Johnston and Dr. de Blaquiere exited the meeting. The Board agrees that the facility doesn't need to be licensed as long as the individual pharmacists are licensed in Idaho, but the Board would like to see future legislation allowing registration of such a facility.

Of note, In the matter of Charles Davis, Ms. Magnelli noted that there were 2 exhibit C's and one should have been labeled exhibit D.

With Mr. Johnston and Dr de Blaquiere in attendance telephonically, the date of the next meeting was scheduled for 1/6/11. Dr de Blaquiere motioned to adjourn. Dr. Chopski seconded. The motion carried unanimously. Meeting adjourned at 4:19 p.m.