MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
October 24-25, 2018

Idaho State Capitol Building
Boise, Idaho

This meeting of the Board was held to conduct proposed rulemaking and other business.

Chairman Nicole Chopski, PharmD, called the meeting to order at 9:00 a.m. In addition to Dr. Chopski, those in attendance included Vice Chairman, Holly Henggeler, PharmD; Rich de Blaquiere, PharmD; Kristina Jonas, PharmD; Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Fred Collings, Chief Investigator; Andy Snook, DAG; Jaime Thompson, Wendy Shiell, and Amy Hickerson, CPhT, Compliance Officers; Misty Lawrence, Management Assistant; Ellen Mitchell, Program Information Coordinator and several members of the public.

Board staff sought approval for a late addition to the agenda. Dr. Jonas motioned to amend the agenda to include Wells Pharmacy to Action Item: Consent Agenda: Stipulation and Consent Orders, Dr. de Blaquiere seconded, and the motion carried unanimously.

Dr. Henggeler motioned to approve the minutes from the August 30, 2018 meeting as written, Dr. Jonas seconded, and the motion carried unanimously.

Dr. Jonas noted the Travel Calendar should indicate her travel to Chicago in September for NABP's Standards of Care Task Force was covered by NABP; Dr. Adams noted his attendance at the ACCP Annual Meeting.

Dr. Jonas motioned to accept the Consent Agenda, Dr. Henggeler seconded, and the motion carried unanimously.

The Board took up the action item Consent Agenda: Stipulation and Consent Orders which contained:

a) Bengal Pharmacy at Challis
b) Kurt's Pharmacy
c) Reddish Pharmacy
d) Machelle Siegel, CPhT
e) Star Pharmacy
f) Florida Discount Drugs
g) Falls Drug
h) Owl Pharmacy
i) Wells Pharmacy

Dr. Jonas motioned to remove items d, e, h, and i from the Consent Agenda: Stipulation and Consent Orders for discussion, Dr. Henggeler seconded and the motion carried.

Dr. Henggeler motioned to approve the remaining Stipulation and Consent Orders as written (items a, b, c, f, and g), Dr. Jonas seconded, and the motion carried unanimously.

Satish Poondi, SLV Pharmacy dba Valley Pharmacy, attended the meeting telephonically to request the Board consider their application for an Out of State Mail Service Pharmacy. Based on information submitted with the application, it did not meet the parameters of the staff's delegated authority. Following a brief discussion Dr. de Blaquiere motioned to approve the application, Dr. Henggeler seconded, and the motion carried.

The Board returned to the remaining Stipulation and Consent Orders, Steven Olsen, DAG attended to answer questions regarding the proposed Stipulations. Dr. Henggeler clarified in the case of Owl Pharmacies, the facility was being disciplined not the PIC. Mr. Collings cited Board direction from 2012 where the Board indicated discipline for the facility was appropriate when a loss was in excess of 5,000 dosage units. Dr. de Blaquiere motioned to approve the Owl Pharmacy Stipulation and Order as written, Dr. Henggeler seconded, and the motion carried unanimously.

Following the discussion, Dr. Henggeler motioned to approve the Machelle Siegel and Star Pharmacy Stipulation and Consent Orders as written, Dr. de Blaquiere seconded, and the motion carried unanimously,

Dr. Henggeler motioned to accept the Stipulation and Consent Order of Wells Pharmacy, Dr. de Blaquiere seconded, and the motion carried unanimously.

Following a break, Roy Thomas, PharmD, and Mark Hopmen, from DexCom Pharmaceuticals asked the Board for clarification of IDAPA 27.01.04.022.03 Pharmacist Prescribing of Devices, Diabetes Blood Sugar Testing Supplies. It was noted that the FDA uses the same classification for continuous glucose monitoring as finger stick testing. Following discussion the Board concurred, by unanimous consent, that the board's rule does not distinguish between methods of blood sugar testing.

Per direction from the Board at their August 2, 2018 meeting Dr. Adams presented staff research pertaining to the expungement of disciplinary records. At the time of the original request it was unclear if any regulatory boards had processes in place for expungement. While not widespread, staff has identified examples from other state boards of pharmacy, nursing, and medicine. Board staff feels the largest impediment to expungement is that neither the National Practitioner Data Bank nor the Healthcare Integrity and Protection Data Bank expunge disciplinary information, which would serve to undermine the primary purpose. Dr. Chopski noted that if enough states take similar action, it could force a federal policy change. Dr. Henggeler expressed her concerns with expungement but noted she would feel more comfortable if it was limited to minor cases and a 5-year window for expungement. Following a review of the research and the processes of the five identified boards, Dr. Jonas, and Dr. de Blaquiere were in favor of adopting an expungement process, while Dr. Henggeler was opposed. The Board chose to table the discussion until tomorrow. The earliest a statute could take effect would be 2020, and the Board would then need to promulgate rules.

The Board took up the matter of the U.S. Food and Drug Administration (FDA) Memorandum of Understanding (MOU) received by staff. The MOU was created to establish an agreement between the states and the FDA regarding the distribution of compounded human drug products. States that sign the MOU would provide information to the FDA regarding the amount of product being shipped out of state. Those states would also be allowed to have pharmacies ship more product than other states. One of the major concerns with signing the documents is determining who the legal entity would be and if the Board has the authority to sign.

Mark Johnston, RPh, expressed his concerns over the MOU as the FDA definition of distribute includes dispensing. He was also concerned with the term 'prescription' as it includes chart orders, though federal law often makes a distinction between the two. A letter from national pharmacy associations further encouraged state boards not to sign the MOU for various statutory reasons.

The Board discussed the time burden of providing forensic accounting of percentages shipped versus inspecting actual hoods. It was also noted that at the recent NABP forum, no states indicated they intended to sign the MOU. Following the discussion, the Board declined to sign the FDA MOU, by unanimous consent.

The Board took up the matter pertaining to the resale of 503B products from Prescriber Drug Outlets (PDO). In several recent inspections, compliance officers have identified practitioners dispensing compounded product initially provided to them from an outsourcing facility. This has led to the question of whether or not the act of a practitioner dispensing a drug from an outsourcing facility is allowed under Idaho law. Staff noted that there seems to be ambiguity in federal law regarding the "resale" of drugs obtained from outsourcing facilities. Dr. Chopski and compliance officer Wendy Shiell attended the recent FDA 50-State Compounding meeting and asked about this issue; an FDA attorney noted they are reviewing this matter, and thus there is not a definitive answer from FDA at this point. Following discussion, the Board directed staff to exercise enforcement discretion at the PDO level; PDOs are required to label appropriately. If FDA updates its guidance as it relates to PDOs, Board staff will enforce at that time.

Mr. Sperry arrived at 1:00 p.m.

Following the lunch break Dr. Chopski took up the final Public Comment Period for the 2019 Proposed Rule Making Session. The Board may make changes to the proposed rules and agency bills during this meeting. Any changes made will be incorporated into the proposed rule drafts which will be published in the December 5, 2018 Administrative Bulletin.

Following a review of each chapter, Dr. Chopski called for public comment. The Board also reviewed written comments submitted in advance of the meeting.

Rule Docket No. 27-0101-1801 – Chapter 1, General Provisions

No verbal comments were provided at the meeting, and Dr. Adams indicated that no written comments were received in advance of the meeting.

No changes were made to the docket.

Rule Docket No. 27-0102-1802 – Chapter 2, Rules Governing Licensure and Registration

Dr. Adams directed attention to Rule 035. Non-Resident PIC Registration to Practice Pharmacy into Idaho. He believes it is appropriate for the non-resident PIC to pay a higher application fee as they are the only responsible party between the pharmacy and the Board. Dr. Adams also requested the fingerprint background check be waived for those that are licensed pharmacists in Idaho serving as a PIC at a non-resident pharmacy and need to be registered versus licensed as it is only a parallel move.

Dr. Adams indicated that no written comments were received in advance of the meeting.

Rule Docket No. 27-0103-1802 – Chapter 3, Rules Governing Pharmacy Practice

Dr. Adams indicated he had received the following public comment from the Idaho Psychiatric Association (IPA) to remove psychotropic drugs from Prescriber-Authorized Substitution:

> "There is substantial scientific evidence demonstrating that psychotropic medications, in general, do not have "a substantially equivalent therapeutic effect" as one another, as no two medications are molecularly identical. Each medication has a unique therapeutic and side effect profile, causing wide variation in response from one person to another. Research has demonstrated that therapeutic substitution of medications used to treat serious mental illness creates significant downstream impacts and causes an elevated financial burden on the overall healthcare system. Because therapeutic substitution for psychotropic medications can cause physical and cognitive complications and prevent the individual from receiving effective treatment, individuals living with serious mental illness will require more emergency room visits, experience an increased risk of homelessness, and interact more frequently with the criminal justice system. These higher costs far outweigh any potential savings achieved through therapeutic substitution. Because of the lack of therapeutic equivalence between psychotropic molecules and formulations, the harm that therapeutic substitution can cause, and the costs that therapeutic substitution can incur, IPA urges the Idaho State Board of Pharmacy to remove this class of medications from the proposed rules to ensure that H.B. 339 does not negatively impact individuals with mental health conditions."

The Idaho Medical Association (IMA) submitted similar written comment in support of IPA's request.

Dr. Adams offered the following proposed language to address the concerns of IMA and IPA:

05. Prescriber-Authorized Substitution.
e. Prescriber-authorized substitution does not apply to biological products, ~~or~~ narrow therapeutic index drugs, or psychotropic drugs.

No verbal comment was offered at the meeting.

Rule Docket No. 27-0104-1802 – Chapter 4, Rules Governing Pharmacist Prescriptive Authority

Dr. Adams received three written public comments as follows:

Kimberly McKeirnan, PharmD, BCACP, Clinical Assistant Professor, Washington State University College of Pharmacy and Pharmaceutical Sciences, shared her research on pharmacist prescribing for allergic rhinitis, and a recent survey of physicians, patients, and pharmacists that indicated support for this service at pharmacies.

Deeb Eid, PharmD, Assistant Professor at Ferris State University shared his support for the prescribing rules, and shared research on physician perceptions supporting this expanded role.

Mark Johnston, writing on behalf of CVS Health, noted that it would be more appropriate to rename the header in rule 026.06 as follows:

> 026. PHARMACIST PRESCRIBING TO SUPPLEMENT AN INFUSION ORDER.
> 06. ~~Emergency Kit Drugs~~ Additional Supplemental Drugs. Methylprednisolone, hydrocortisone, diphenhydramine, epinephrine, and normal saline.

The Board received a verbal comment from Christal McKay, 4th year Pharmacy Student at Idaho State University. She expressed her support for the prescribing rules and noted the excitement of her fellow students, some of whom moved to Idaho to pursue practice in the state because of the rules. She hopes the Board will expand pharmacist prescribing to include moderate acne in the future, and that pharmacist's prescriptive authority is a vital step towards improving patient care.

Dr. Adams noted that he recently attending the Idaho Board of Medicine meeting and that they carefully reviewed the rules line-by-line and did not express any concerns.

Rule Docket No. 27-0105-1801 – Chapter 5, Rules Governing Drug Compounding

Dr. Adams presented proposed language to address a concern raised by a medical clinic as follows:

> 101. STERILE PRODUCT PREPARATION 05.d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet, or a comparable compounding area when authorized by USP 797.

Dr. Adams indicated that no written comments were received in advance of the meeting.

Rule Docket No. 27-0106-1801 – Chapter 6, Rules Governing DME, Manufacturing, and Distribution {Repeal}

No verbal comments were provided at the meeting, and Dr. Adams indicated that no written comments were received in advance of the meeting.

Dr. Adams summarized the changes discussed and posted a summary on the Board's website for stakeholder review prior to the morning rule finalization. In addition, the summary of proposed changes was sent to known stakeholders.

Dr. Chopski called on Dr. Adams to present the proposed agency bills for the 2019 legislation, drafts of which have been on the Board's website for review.

Controlled Substances Act – Legislative Proposal

No verbal comments were provided at the meeting, and Dr. Adams indicated that no written comments were received in advance of the meeting.

Dr. Adams presented the proposed language to add as required by Idaho Code 37-2702 as follows:

> 37-2713. SCHEDULE V. (e) Approved cannabidiol drugs. (1) A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

Pharmacy Practice Act – Legislative Proposal

Dr. Adams indicated that no written comments were received in advance of the meeting.

Ademola Are, pharmacy student at Idaho State University offered public comment in support of multi-state licensure for pharmacists, students, and technicians. He believes it would provide better patient care and encouraged the addition of interns to the draft.

Mark Johnston provided comments on behalf of CVS Health. On 54-1733.a.2.b – Transmission of Prescription Drug Orders, Mr. Johnston suggested striking 'institutional' to allow the transmission of prescription drug orders in other practice settings. Mr. Johnston expressed concern with the Board's draft language regarding nurses as agents at long-term care facilities. The Board noted that the striking was consistent with recent federal law changes, as Idaho's law is now arbitrarily more restrictive than federal law in terms of who can serve as an agent on behalf of a physician. Idaho's proposed update is consistent with NABP's recent report of recommendations for the regulation of long-term care facilities. Dr. Chopski encouraged Dr. Adams and Mr. Johnston to work on language to review for the morning session, and following brief discussion, a draft was posted online for review by interested stakeholders.

Dr. Chopski called for any remaining public comments on any agenda item, and no comments were offered.

Misty Lawrence presented the following Financial Report:

Fiscal Year Budget to Expenses

- Fiscal year 2019 budget status with 25% percent of the year elapsed and 23.25% of the budget expended.
    - Personnel Costs are 22.66% expended
    - Operating Expenditures are 27.87% expended
    - Operating Expenditures for DHW Contract is 0% expended

- Current Cash Balance
    - Cash Fund balance as of September 30, 2018 was $2,485,680. The fiscal year started the with a cash balance of $2,699,070. (Down $213,390 from the beginning of the fiscal year)

- Annual budget Trend Comparison FY16 - FY19 – July – September
    - Expenditures are slightly lower than in previous years but within the trend
    - Revenues are trending up 4% or $11,000, this is due to the change in renewal periods
    - Though the cash fund is decreasing, revenues are still trending up over the last few years
    - There was also a decrease in the Agency appropriation

- FY18 Monthly Cash Flow
    - The budget continues to be in the red for the first quarter of the fiscal year, this is a normal trend. Once the renewal transition is complete (FY20), this will level out.

- Accumulative Monthly Cash Flow
    - Cash flow is in the red by $213,400, compared to this time last year the Agency was in the red by $265,600. The difference is due to the change in renewal dates.

- Budget Request Comparison
    - FY19 there is a peak and then a drop in FY20, this is due to the estimated impact of the renewal transition. There is an estimated cash fund increase in FY19 as we are seeing both a decrease in estimated revenue and estimated expenditures.
    - There will be a one-time decrease in FY20 as only the CS registrants will renew in FY20. The revenue level off in FY21, currently estimated at $2,009,900.
    - The budget request was light this year, though we are in the process of a revision.
        - General inflation for IT support and credit card fees $7200
        - Contract Inflation for the building lease $2,500
        - Replacement computers for staff $18,800
        - Software upgrades for the new computers $12,000.

- 2 line item requests for ongoing monies
  - $4800 for annual Microsoft Office Suite licensing
  - $19,600 to cover the additional licensing system maintenance for the new system
- Current budget request was $2,124,100, though the SWCAP revision will decrease the amount by $9,100 bringing the total request to $2,115,000, a 4.2% decrease.

The Board thanked Mrs. Lawrence for her comprehensive update.

The Board set meeting dates for 2019 as follows:

February 7, 2019	August 15, 2019
April 11-12, 2019	August 29, 2019
June 13, 2019	October 23-24, 2019
July 11, 2019	

Dr. de Blaquiere motioned to start tomorrow's meeting at 9:00 a.m. Dr. Jonas seconded, and the motion carried unanimously.

Dr. Jonas motioned to adjourn, Dr. Henggeler seconded, and the motion carried unanimously. Meeting adjourned at 3:28 p.m.

October 25, 2018

Chairman Nicole Chopski, PharmD, called the meeting to order at 9:00 a.m. In addition to Dr. Chopski, those in attendance included Vice Chairman, Holly Henggeler, PharmD; Rich de Blaquiere, PharmD; Kristina Jonas, PharmD; Ed Sperry; Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Fred Collings, Chief Investigator; Andy Snook, DAG; Jaime Thompson, Wendy Shiell, and Amy Hickerson, CPhT, Compliance Officers; Misty Lawrence, Management Assistant; Ellen Mitchell, Program Information Coordinator and several members of the public.

Dr. Chopski took a moment to recognize Dr. Jonas and Mr. Fraser's birthdays.

Rule Docket No. 27-0101-1801 – Chapter 1, General Provisions

Following a brief discussion, no changes were made to the docket. Dr. Jonas motioned to approve the docket as written, Mr. Sperry seconded, and the motion carried unanimously.

Rule Docket No. 27-0102-1802 – Chapter 2, Rules Governing Licensure and Registration

Following a brief discussion, no changes were made to the docket. Mr. Sperry motioned to approve the docket as written, Dr. Henggeler seconded, and the motion carried unanimously.

Rule Docket No. 27-0103-1802 – Chapter 3, Rules Governing Pharmacy Practice

Following a brief discussion Dr. Henggeler motioned to approve carving out psychotropic drugs per the feedback from medical stakeholders as follows:

05. Prescriber-Authorized Substitution.
e. Prescriber-authorized substitution does not apply to biological products, ~~or~~ narrow therapeutic index drugs, or psychotropic drugs.

Dr. de Blaquiere seconded, and the motion carried unanimously.

Rule Docket No. 27-0104-1802 – Chapter 4, Rules Governing Pharmacist Prescriptive Authority

Dr. Adams noted he sent the proposed changes to various stakeholders, including the medical association to review. Dr. Henggeler motioned to approve the change as follows:

026. PHARMACIST PRESCRIBING TO SUPPLEMENT AN INFUSION ORDER.
06. ~~Emergency Kit Drugs~~ Additional Supplemental Drugs. Methylprednisolone, hydrocortisone, diphenhydramine, epinephrine, and normal saline.

Dr. de Blaquiere seconded, and the motion carried unanimously.

Rule Docket No. 27-0105-1801 – Chapter 5, Rules Governing Drug Compounding
Following a brief discussion Dr. Jonas motioned to approve the following addition to the docket:

> **101. STERILE PRODUCT PREPARATION 05.d.** An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet, or a comparable compounding area when authorized by USP 797.

Dr. Henggeler seconded, and the motion carried unanimously.

Rule Docket No. 27-0106-1801 – Chapter 6, Rules Governing DME, Manufacturing, and Distribution {Repeal}

Dr. Henggeler motion to accept the repeal of Chapter 6, Dr. de Blaquiere seconded, and the motion carried unanimously.

The Board took up the Legislative Proposal regarding the Controlled Substance Act. Following a brief discussion Dr. Henggeler motioned to accept 37-2713 Schedule V, Dr. de Blaquiere seconded, and the motion carried unanimously.

The Board reviewed the changes that were discussed yesterday and presented for comment. Dr. Henggeler expressed her concern over the multi-state licensure in regards to the Board's discipline authority and the potential financial impact to the agency. Following a spirited discussion Dr. de Blaquiere motioned to accept the changes as presented, including updated language regarding agents of prescribers, which conforms to recent federal law changes while addressing Mr. Johnston's concerns. Mr. Sperry seconded, and the motion carried, with Dr. Henggeler opposed.

Dr. Adams presented an update on Just Culture. He will work with Mr. Fraser to set benchmarks for the April meeting. Dr. de Blaquiere wants to pursue safety in pharmacy and delve into medication errors. Approaching errors from a punitive angle isn't as helpful as looking at processes and why the error occurred. Dr. Adams will invite ISMP to the April meeting and some others that are using root cause analysis, Corrective Action Plans, and the assessments from OSHU.

Dr. Adams presented an update of the Strategic Plan for 2019.

Hearing no further business, Dr. Jonas motioned to adjourn, Dr. de Blaquiere seconded, and the motion carried unanimously. Meeting adjourned at 11:20 a.m.