**MINUTES OF THE**
**IDAHO STATE BOARD OF PHARMACY**
**August 1-2, 2017**

**Idaho State Capital**
**Boise, Idaho**

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

Chairman Nicki Chopski, PharmD, called the meeting to order at 8:00 a.m. In attendance were Board members Kris Jonas, PharmD, Ed Sperry, Public Member, and Holly Henggeler, PharmD. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director, Lisa Culley, CPhT, and Jaime Thompson, Compliance Officers, Andy Snook, Deputy Attorney General, Misty Lawrence, Management Assistant, Ellen Mitchell, Program Information Coordinator, Meredith Oliver, the Board's intern from the University of Mississippi, and several members of the public.

Dr. Jonas indicated that the draft minutes of the July 12th meeting referenced the listening sessions conducted in various parts of the state, but did not mention the two sessions held in Boise. Dr. Jonas motioned to approve the July 12, 2017 minutes with the discussed corrections. Dr. Henggeler 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

Dr. Jonas motioned to approve the Consent Agenda. Mr. Sperry seconded, and the motion carried unanimously.

Dr. Chopski introduced the Negotiated Rulemaking Session. She commended all those who submitted written comments and those in attendance. Dr. Chopski believes all participants have the same goal of improving the health and welfare of all Idahoans, though she noted there may be some differences of opinion in how to achieve that goal. Dr. Chopski noted that each comment will receive proper consideration. The Board has been working on the drafts since January 2017, and has taken an evidence-based approach and has looked to the literature as well as other jurisdictions as a starting point. Dr. Chopski asked Dr. Adams to give an overview of the rulemaking process for those that have not attended any of the public sessions that have led up to today's public comment period.

Dr. Adams shared that the Board's approach to this rulemaking has been to organize the rule book into chapters by subject, and to focus specifically on the practice of pharmacy versus the business of pharmacy, and to create room for new models of care and new technology as it becomes available. There have been no substantive changes proposed to the rules regarding compounding, DME, distribution, or manufacturing. Similarly, the Board has preserved the intent of all rules related to controlled substances.

The Board conducted two public strategic planning meetings, with the first one in January 2017 focused on Licensing and Registration reform and the second held in March 2017 focused on Permissionless Innovation. During the April, June, and July 2017 Board meetings, the Board reviewed early drafts of the rules along with evidence and data to support the suggested changes. The Board incorporated public feedback at each of the open meetings. Dr. Adams also conducted five public listening sessions around the state during the month of July, presented at various conferences, and engaged in personal meetings with multiple stakeholder groups.

This meeting begins the first of two negotiated rulemaking sessions, with an additional negotiated rulemaking conference call scheduled for August 30, 2017, as published in the

August edition of the Idaho Administrative Bulletin. The August 30th conference call will be an opportunity for the public to comment on changes made during this initial negotiated rulemaking meeting. The Board's intent in hosting the meeting via conference call is to allow stakeholders across the state an opportunity to participate. Following the August 30 meeting, the Board intends to publish its Proposed Rules in the Administrative Bulletin on October 4, 2017, followed by a Proposed Rulemaking Hearing on October 25, 2017. Lastly, the Board intends to publish its Pending Rules in the December edition of the Administrative Bulletin.

Dr. de Blaquiere arrived at 8:30 a.m.

Dr. Chopski opened the public comment period with Chapter 4, Rules Governing Pharmacist Prescriptive Authority. The meeting minutes will briefly summarize core elements raised by those commenting; written comments that were submitted will be archived in full as part of the rulemaking docket.

Dr. Adams indicated that he saw two primary questions regarding legislative intent. First, several written comments noted that some of the drugs listed by the Board are for conditions that require a diagnosis, such as lice or cold sores, and the commenters felt that House Bill 191 specifically excluded drugs that require a diagnosis. Dr. Adams shared a note from the Legislative Services Office (LSO) regarding the use of the word "or" in I.C. § 54-1704(5)(e)(iii), as enacted by House Bill (HB) 191 (2017):

> "Or" is a disjunctive particle used to express an alternative or to give a choice of one among two <u>or more</u> things. *Frasier v. Frasier*, 87 Idaho 510, 514, 394 P.2d 294, 296-297 (1964). It's therefore unnecessary to list "or" after each item in the list; the use of the word once indicates that the list presents alternatives. This is discussed on page 30 of LSO's Concise Drafting Manual. If (i), (ii), and (iii) were intended to be read as requirements instead of alternatives, the word "and" would have been included following (ii).

The Legislative Services Office indicated that the initial draft of HB 191 included "or" after each item in (e)(i) through (iv) and that they advised that this was unnecessary.

Dr. Adams noted that HB 191 thus gave the Board discretion when a diagnosis is needed if the condition is minor, or if the condition requires a CLIA-waived test in order to diagnose, or if the drug is to be used in an emergency.

Dr. Adams noted that he had received comments regarding the rules not listing actual drugs or drug classes, instead focusing on conditions. Dr. Adams noted the language from HB 191: "Drugs, **<u>drug categories</u>** or devices." (emphasis added) Dr. Adams noted that the term 'drug category' was added to enable the Board to draft rules that are broader than individual drugs. Drugs are categorized in many ways, according to both national and international health organizations. For example, drugs can be categorized according to their chemical structure, their mechanism of action, or by the diseases/conditions they are intended to treat. Dr. Adams noted precedent in legislation both in Idaho and elsewhere to organize by condition, as this may be more transparent and understandable (e.g., "FDA-approved drugs **indicated** for lice" as opposed to "scabicides.")

No follow-up comments regarding legislative intent were offered by commenters at the meeting.

The Idaho Medical Association (IMA) submitted written comments prior to the meeting. Ken McClure and Molly Steckel attended at the meeting. Ms. Steckel highlighted a few of the specific concerns of the IMA, reiterating her board is not strictly opposing the draft language, but would like to work with the Board of Pharmacy to create alternative verbiage. The IMA's main concerns as highlighted by Ms. Steckel include:

- <u>Nausea</u> – Although a common ailment it can be the sign of a more serious disease state.
- <u>Uncomplicated UTI</u> – This will require a new diagnosis, meaning in most cases a pharmacist may not prescribe for this condition. The pharmacist should be required to perform a CLIA waived test.

- Influenza (specifically in pediatric patients) – Children can be more susceptible to neuropsychiatric effects that have been seen when prescribing antivirals for children.
- Group A Strep - Roughly 15% of children are carriers and test positive but don't need treatment.
- Diabetes – There isn't necessarily a gap in care if a patient is not prescribed statins by their primary care provider.
- Short Acting Beta Agonists – Rescue inhalers can be used too often and part of asthma management from a primary care standpoint is knowing how often a patient is filling their albuterol.
- Travel Drugs – Have the potential to contribute or compound mental health issues. Blanket authority shouldn't be granted.

Dr. Adams noted the IMA's concern over fragmented care as it is also a concern of the Board's. The Board's desire is for patient treatment to be patient centered, team based, and coordinated among all health care providers, and has added the notification requirement to facilitate communication between a prescribing pharmacist and primary care provider. Dr. Adams asked Mr. McClure if his association had any recommendations or suggestions aside from the required notification included in the draft rules, and asked specifically what retail clinics are doing to address this concern. Mr. McClure didn't have any specific suggestions and indicated the concern is based on the notification coming after the patient has received the prescription, believing the communication between the pharmacist and physician should come prior to the patient ingesting the medication. He believes the breakdown is in the retail setting, though the process would work well in an institutional setting.

Jenny Arnold, PharmD, Washington State Pharmacy Association (WSPA) attended the meeting to express her organization's support of the Board's draft rules. Dr. Arnold coordinated the development of the curriculum for the Clinical Community Pharmacist Tools, which is a collection of Accreditation Council for Pharmacy Education (ACPE) approved continuing education modules that are currently in use in Washington State. Washington pharmacists are currently prescribing for many of the conditions that are proposed in the Board's rules. The program starts with the fundamentals of pharmacist care including patient assessment. She indicated that pharmacists are using protocols to identify whether a patient's symptoms fit within clinical guidelines, or if alarm symptoms are present that may trigger a referral. As an example, if a patient's symptoms are consistent with the uncomplicated urinary tract infection (UTI) protocol, the pharmacist must determine whether they can treat the patient for the illness or if referral symptoms are present. The Clinical Community Pharmacist Tools provides 13 modules covering different disease states. Dr. Arnold stated pharmacists are treating patients with minor illnesses every day as patients seek over-the-counter (OTC) pain medications, nausea medication, and a multitude of other OTC medications. These rules give patients that can't access primary care due to work barriers or other barriers a safety net and an option other than the emergency room or urgent care clinics for access to medical care.

Dr. Adams inquired if Dr. Arnold had suggestions for the draft language regarding education. Dr. Arnold noted she was pleased to see that there isn't an hour limit on education as it allows pharmacy schools to integrate the training into their curriculums. She feels an hour requirement can exclude some high quality programs. Dr. Arnold noted that approximately 5% of Washington pharmacies are Clinical Community Pharmacies. These pharmacies triage, assess, and prescribe for patients with minor ailments, while referring patients with certain symptoms. Most of these pharmacies are currently treating uncomplicated UTIs, and a sample treatment protocol had been submitted and reviewed by the Board.

Tim Frost, PharmD, attended the meeting to commend the Board for taking an evidence-based approach to pharmacist prescribing. Dr. Frost submitted a study regarding pharmacist prescribing of statin medications that was conducted in community pharmacies. He stated that the study showed that pharmacists can identify care gaps, provide patient assessment, and monitoring of the progress of these patients. Dr. Frost asked that the rule be extended to all patients and not just those with diabetes. Dr. Frost indicated that another study noted that patients were 3.3 times more likely to achieve their cholesterol goals when a pharmacist prescribed their medication over other prescribers.

Lorri Walmsley, Senior Manager, Pharmacy Affairs, Walgreen's expressed her support for the Board's conservative approach to pharmacist prescribing. She appreciates the education requirement is broad, allowing corporations to adopt appropriate risk mitigation strategies;

she noted that Walgreen's ensured all their pharmacists were trained prior to allowing prescribing of Naloxone even though there was no requirement in Idaho law to do so.

Pam Eaton, Executive Director, Idaho State Pharmacy Association, and Idaho Retail Pharmacy Council, submitted prior written comment. Her comment was related to desire for pharmacist prescribing of prophylactic flu treatment for those living in the immediate household to a patient that has tested positive using a CLIA waived test. She reiterated that as a community, pharmacists are conservative and often slow to adapt. She provided examples of slow uptake, which she indicated meant that these prescribing rules are unlikely to open the floodgates to inappropriate prescribing. She noted that pharmacists are generally conservative as it related to expanded duties and will ensure they are well trained prior to taking on prescribing to patients.

Mark Johnston, RPh, CVS Regulatory Affairs and NABP Executive Committee, shared a Centers for Medicare & Medicaid Services (CMS) informational bulletin dated January 17, 2017 that states in part:

> "CMCS recognizes that states continue to look for innovative tools to address pressing public health issues, such as the opioid epidemic or preventing influenza infections. State flexibilities in expanding the ability of pharmacists to prescribe, modify, or monitor drug therapy for certain medications may be effective at helping to address such issues by improving access to care. CMCS encourages states to consider using these methods to promote access particularly to those drugs that can help address priority public health issues."

Mr. Johnston reiterated the federal government recognizes the gap in health care and is asking states to do exactly what Idaho is doing with pharmacist prescribing. He also asked that all OTC medications be recognized in patient prescribing as diabetic test strips are included. He noted that it is a long standing practice for pharmacists to prescribe OTCs, though many payers do not pay for them as payment is at the discretion of the payer. He also asked the Board not to over-regulate the education requirement to provide these services. He believes excessive education requirements may defeat the legislature's goal of increasing access to safe and effective care by expanding pharmacist prescribing. He also asked the Board to consider adding a rule that pharmacists may prescribe certain drugs and devices to supplement an infusion prescription. He provided examples where this may be of use, and specifically suggested saline, heparin, infusion pumps, and some acute infusion reaction medications.

Dr. Adams inquired as to the maximum heparin dose of 100 units per milliliter proposed by Mr. Johnston. It was explained that this is the common dose for a heparin flush; heparin for other therapeutic uses has a dose range much higher than the maximum proposed.

Dennis McAllister, RPh, indicated the ACPE standards for colleges have been in place for 20 years. He agrees most pharmacists will work where they are comfortable and where they have knowledge and jurisdiction. Mr. McAllister commended the Board for formalizing what has been happening in rural pharmacies for many years.

Paul Cady, Dean, Idaho State University College of Pharmacy (ISU) commended the Board on the draft rules. ISU has been preparing students for services such as those outlined in the Board's draft rules for many years and he has been waiting for the time to come for pharmacists to be allowed to do what they have been trained to do. ACPE requirements include patient assessment and the College has prepared their students to care for complicated patients, and he believes the training is more than adequate. All professions must adapt to changes in their fields as things change. He supports the concept of reporting prescriptions to the primary care provider as it is what should be done in a team-based approach. He shared an experience where he had been to an urgent care and received new medication, but when he had returned to his primary care provider they were unaware that he had received them. There is no requirement for urgent care clinics to notify primary care providers of treatment or prescriptions even though the clinic collects the information. He looks forward to other categories of medications being added to pharmacist's prescriptive authority in the future.

Linda Garrelts MacLean, RPh, Vice Dean, Washington State University expressed her support of the Board's draft rules. She worked on a research project in Washington related to pharmacist prescribing for roughly 25 illnesses, many of which overlap with the conditions included in the Board's draft rules. Ms. Garrelts MacLean's indicated her project was quite successful. Pharmacists at several companies, including Fred Meyer, Bartell Drug, Costco,

etc. participated in the research. She noted strong, positive patient feedback and noted that results are going to be published soon. She noted that there have been zero reported adverse events due to therapy.

Laura Churns, PharmD, Albertsons, Director of Legislative & Regulatory Affairs, expressed her company's support of Chapter 4 and the increased access to patient care. She asked the Board to consider expanding the authority of this chapter to include hormonal contraceptives, prenatal vitamins, yeast infection medications, and propecia.

Following a brief break, Dr. Chopski asked Dr. Adams to share the remaining written public comment submitted to the Board.

The Idaho Academy of Family Physicians submitted written comment prior to the meeting, their comments included:

- Education – Education standards regarding the list of medical conditions are not defined by the rule. Standards should be set to achieve, monitor, and maintain competency on listed conditions along with a regular review of the standards.
- Patient-Prescriber Relationship – Concerns related to a pharmacist achieving a patient prescriber relationship.
- Collaboration – No clear restrictions on which patients are appropriate for consultation or referral. Due to the lack of restrictions the patient-centered medical home model of care would be fractured.
- Follow-Up Care Plan – A clear course of action should be developed for follow-up with all patients.
- Notification – The term 'if applicable' is obscure and should be replaced with a clear process.
- Documentation – The term 'upon request' leaves notification of the patient and their provider on the patient, this should be changed to mandatory and be the responsibility of the pharmacist.

The Idaho Primary Care Association submitted written comment prior to the meeting as summarized below:

- 020.01 Education – Concerns regarding how competence is determined, achieved, and maintained.
- 020.03 Patient Assessment – Concerns regarding lack of access to patient's health records.
- 020.06 Documentation – Questioned how the data will be transmitted.
- 021.05 UTI – Concerns regarding determination of 'uncomplicated' and process of diagnosis.
- 022.01-05 Question regarding provision of devices and if they would only be supplied to patients with an existing asthma diagnosis.
- 024.01-02 Clinical Gaps – Concerns regarding the primary care provider should be managing gaps as they have access to current lab results and a comprehensive medical history of their patients.

Michael E. Klepser, PharmD, Professor, Ferris State University College of Pharmacy encouraged the Board to expand clinical access for prophylactic agents for family members and close contacts as warranted for influenza.

Allison Dering-Anderson, PharmD, Clinical Associate Professor, University of Nebraska College of Pharmacy shared lessons learned in recent studies:

- Exacting thresholds are not helpful, thresholds for referral are much easier to work with and actually result in better care;
- Prophylaxis therapy for household members of an influenza positive patient should be written into protocols with guidance on who should be offered prophylaxis and who should be referred;
- Vaccination recommendations should be a part of collaborative agreements (when used) and protocols to assure that they are not missed.

Deanna Tran, PharmD, BCACP, Assistant Professor, Co-Director, Pharmacy Practice Laboratories, University of Maryland School of Pharmacy, submitted research she had conducted on pharmacist-prescribed travel drugs.

Hannah Renner, PharmD, Community Pharmacy Research Fellow, University of Pittsburgh School of Pharmacy, submitted research indicating only 63% of U.S. adults with diabetes aged 40 and over take a prescription cholesterol-lowering medication, though the American College of Cardiology/American Heart Association guideline indicates patients with diabetes aged 40-75 should be treated with moderate to high intensity statin medications. She noted her research on pharmacist intervention to increase statin prescribing rates in this guideline-recommended population.

Heather Hammerstedt, MD, and Chuck Washington, MD, emergency room physicians submitted separate but nearly identical comments highlighting the following:

- Sect 020.01 Education: there are no specific recommendations for education to be achieved before prescribing for the conditions outlined.
- Sect 020.03 Patient Assessment: how will the pharmacist diagnose the conditions in 021-025?
- Symptoms of nonemergency and emergency illness overlap 90% of the time. It is easy without the appropriate training to miss a more serious condition.
- Sect 021.04 Nausea: how will pharmacists diagnose a condition based on nausea?
- Sect 021.05 Uncomplicated UTI: How will pharmacists determine?
- There is no provision in the proposed rules to put any limits on the age of the patient that a pharmacist can prescribe for
- There is no provision in the proposed rules to prohibit a pharmacist prescribing for certain high risk patients/conditions: pregnancy, etc.

No comments were received regarding the Collaborative Pharmacy Practice and Statewide Protocol rule, which has been organized into this section from the existing rules.

Mr. Sperry stated he believes the Board has taken great care in drafting these rules and appreciates the public comments from various stakeholders. Mr. Sperry asked Mr. McClure and Ms. Steckel about efforts to educate physicians regarding the prescribing of opioids. Ms. Steckel indicated the information obtained from the American Medical Association has indicated there is no correlation between education and prescribing habits. Some providers are more educated than others in regards to this type of prescribing based on their specialties. They are also talking with the Office of Drug Policy on this topic.

Dr. Chopski asked Dr. Adams to open public comment on Chapter 1. The Board is adding draft language regarding Standard of Care based on the March 2017 presentation by Anne Lawler, Executive Director of the Idaho Board of Medicine. Dr. Adams summarized public comment submitted by Pam Eaton on behalf of her organizations, related to Unprofessional Conduct which included:

- Excessive provision of controlled substances – There is no definition of ‘clearly excessive.’
- Prescriber incentives – Concerned about how this impacts company goals regarding flu shots administered, etc.
- Standard of Care – Concerned the definition is too broad and vague.

Dr. Adams summarized the public comment received regarding Chapter 2:

- From a listening session – feedback that the Board should consider a two-year license vs. an annual renewal.
- Dr. Adams also noted there are two instances in which the word “nonresident” may be added to clarify the registration requirement.
- No comments were received regarding any of the fee modifications.

Dr. Adams summarized the public comment received regarding Chapter 3:

- From a listening session – One pharmacist asked if professional judgement could be overridden by corporate policy.
- Bill Silvius – the current language prevents the change in package size for controlled substances, and he provided an example of where this would be useful and in the best interest of patient care for a controlled substance.

Pam Eaton submitted the following comments on behalf of the Retail Pharmacy Council:

- Prescription Drug Order Validity: Tampering – Requests clarifying language that would constitute tampering.

- Prescription Drug Order Validity – Requests language to clarify earliest fill dates for patients receiving multiple prescriptions.
- Recordkeeping Inventory after Theft – Suggests changing from 48 hours to 72 hours as 48 hours is insufficient time to complete an inventory.
- Reporting Requirements: Employment Changes – Recommends striking the rule as the PIC may not be aware of the new place of employment and the burden should be on the licensee.

No comments were received regarding Chapters 5 or 6, either in writing or verbally at the meeting.

John Sullivan, PharmD, Idaho State Hospital Association, expressed the support of his organization for the Board's draft rules.

Dr. Chopski called for miscellaneous comments, not related to any existing rulemaking.

Dr. Adams shared public comment submitted by Kelly Krawtz, PharmD, BCPS on behalf of St. Luke's internal medicine physicians requesting guaifenesin with codeine be a schedule 4 medication so it is reported to the PMP.

Dr. Adams shared a written comment from Charles Clark, RPh, from Salmon, expressing his concerns related to the Board's direction and to telepharmacy.

Ms. Garrelts MacLean shared an update on the Pharmacy Technician Immunization Program waiver, for which WSU created a technician immunization training program. They are about to publish the results and the article will be shared with the Board. She indicated the program was a great success in building confidence in the technicians that participated. WSU has continued to improve their training program, and have increased from a 2 hour program to a 4 hour program based on feedback from pharmacists and technicians. They will launch a 'train the trainer' program in the future.

Dr. Cady expressed his position to have the OTC Schedule 5 medications be prescribed by pharmacists so they are reported to the PMP, which he believes will create a better picture of all controlled substances received by patients.

Cassandra Carper, PharmD, from Walmart expressed concern that some pharmacists may not be comfortable telling their employers they are uncomfortable with the ratio.

Dr. Chopski thanked all for participating in the negotiated rulemaking session. The Board members will deliberate on all the feedback received, and take up the rules the following day to consider changes based on the feedback.

The Board next took up the matter of Consent Agenda: Stipulations, which contained one item related to Marley Drug. Marley Drug representatives did not attend the meeting, nor did their legal counsel. Marley Drug is located in Winston-Salem, North Carolina. During a review of their dispensing records by the North Carolina Board of Pharmacy, it was discovered that Marley Drug was shipping prescription medication to Idaho residents without proper licensure between May 2015 and December 2016. By signing the Stipulation and Order Marley Drug agrees to pay fine in the amount of $7,600. Dr. Henggeler motioned to approve the stipulation, Dr. Jonas seconded, and the motion carried unanimously.

Dr. Chopski asked Dr. Adams to frame the conversation regarding Corrective Action Plans (CAP). Dr. Adams referenced the presentation by Anne Lawler, Executive Director of the Board of Medicine in March 2017. Staff has reviewed the current Delegated Authority (DA) list and identified those that are minor and could be resolved using CAP and not reported as discipline to HPDB. If a registrant or licensee chooses not to accept the conditions of CAP, or if the individual does not complete the CAP in the stated time, the Board retains the option of pursuing an Administrative Complaint or a Stipulation and Consent Order. Following a brief discussion, Dr. Jonas motioned to accept the CAP policy as written. Mr. Sperry seconded, and the motion carried unanimously.

Misty Lawrence presented the Board's financial report:

- At fiscal year close expenditures were up 18.3% over last year and receipts were up 11%. For comparison, in FY 16 Expenditures were down -4.5% and Receipts up 6%
- Highlights of changes in Revenue.

    - Fines increased by 75% - or $31,800 over last year. FY15-$20,700; FY16-$42,300 104% increase and FY17 $74,100.
    - Miscellaneous Revenue Increased by 15% or $1,600 over last year. This is revenue from overpayments, refund processing fees, and return check fees. We refunded $7,400 of the $12,100 collected.
    - Other licensing fees decreased by 14%, or $13,200. This includes significant decreases in late fees. Reinstatement, and prior year fees as well as an increase in background checks, $3,200 or 100 BGC's.
    - Registration fees were up 10%, or $135,100, and licensing fees were up 8%, or $26,800.
- Fiscal year 2017 ended with 96.7% of the budget expended.
    - Personnel Cost was 99.4% expended –$73.46 was reverted. After early distribution of Change in Employee Compensation and allowable bonuses we were able to move the remaining amount to Capital Outlay (CO).
    - Operating Expenditure (OE) was 91.2% expended. A total of $60,872.47 was reverted.
    - Original OE appropriation was 99.9% expended with only $872.47 reverted
    - $60,000 was as a supplemental to cover the Health & Welfare contract. Unfortunately, none of these funds were expended before the end of the fiscal year.
- CO - $250,000 originally appropriated for the licensing system has been carried over to FY18. CO was 100% expended. Staff was able to secure the visual portion of the new board room setup and purchase adjustable legs to modify the remaining desks in the office.
- Beginning of the fiscal year cash balance was $2,411,780. Ending cash balance was $2,610,200. Showing an increase of $198,420 over last year.

**Renewal Period Update:**

12,550 renewal notices sent out.

- Of those 11,426 or 91.04% renewed, 98.87 renewed on-time; 1.13% renewed late
- 35 or .28% - have not provided all required information
- 559 or 4.45% - are currently not renewed
- 530 or 4.22% - notified staff they are not renewing

Pharmacists that currently hold CS registrations were required to register with the PMP, all but 9 are accounted for.

**Year End Licensing Info:**

New applications - Approved: 3387, increase of 102 or 3% over LY

Total license/registration issued in FY17 22048, increase of 888 or 4%

Current Active Licenses: 20,739

- In-State Pharmacies: 383
    - Retail: 289
    - Hospital: 58
    - Limited: 36
- Prescriber Drug Outlets: 285
- Mail Service: 626
- Nonresident Central Drug Outlet: 41
- Outsourcing Facility: 33
- Nursing Home: 58
- DME: 420
- Veterinary Drug Outlet: 9
- Manufacture: 457
- Wholesaler: 505
- Distributor: 310
- OTC Wholesaler: 213
- Narcotic Treatment Center: 3
- Non-Pharmacy Retail Outlet: 1227
- Pharmacists total: 3253
    - Licensed 2666
    - Registered, nonresident 587
    - Controlled Substance Registrations: 1779
- Student Pharmacist: 393
    - In-school: 366
    - Graduates: 27
- Pharmacy Technicians: 2545
    - Certified: 1686
    - Training: 565
    - Grandfathered: 294
- Veterinary Drug Technician: 25
- Practitioner Controlled Substance: 8156

The Board took up the waiver request from Archway Apothecary. Matthew Hardey, Secretary/Treasurer, attended the meeting telephonically. Mr. Hardy is requesting a waiver from the 'sixth day' of operation requirement of rule 730. His pharmacy only provides nicotinamide adenine dinucleotide (NAD), which is a sterile solution only available to physicians as a nutritional supplement for the treatment of drug addiction. Following discussion Mr. Sperry motioned to approve the waiver request contingent of the pharmacy providing only NAD to physicians, and the waiver expires on July 1, 2018. Dr. Jonas seconded, and the motion carried with Dr. Henggeler opposed.

Nicole Fitzgerald, interim Director of the Office of Drug Policy (ODP), provided an update on the Millennium Fund Grant Prescription Drug Take Back program. The request was to purchase prescription drop boxes and to provide funds for marketing to grantees. The goal is to increase the ability of patients to dispose of unused and unwanted medications through convenient disposal locations. In May, ODP selected 11 pharmacy organizations, serving 21 locations. Some pharmacies have used marketing funds for television and radio ads to bring awareness to the program. ODP will be funding additional drop boxes. Funding is available until June 2018, and interested pharmacies were encouraged to contact either ODP or the Board for additional information.

Dr. Jonas motioned to amend today's agenda and address the brief summary of agency legislation and the executive session today instead of tomorrow, as the Board's business has completed early. Dr. Henggeler seconded, and the motion carried unanimously.

Dr. Chopski asked Dr. Adams to lead the discussion of 2018 agency legislation. Dr. Adams distributed the draft language for 54-1733 Transmission of a Written Drug Order. He indicated if this legislation passed in 2018, the Board would need to promulgate rules surrounding the change, and it would only become operational if the Board adopted rules.

Mark Johnston, presented information regarding PhotoRx, which has been approved in Arizona as a pilot program. The mobile application is still in development, and isn't available yet. Following the presentation the Board granted unanimous consent to move forward with draft language for future legislation.

Dr. Adams shared there is some non-substantive cleanup of the Controlled Substance Act (CSA) that is being proposed for the annual CSA bill. This was work left behind by the Board's previous executive director, and the time seemed right for the Board to move forward with it. Dr. Adams will share the language with external stakeholders and the Board can take it back up at the October meeting.

Dr. Henggeler motioned to enter executive session as allowed by Idaho Code 74-206. (1)(a) - (b) as they relate to items related to employees. Mr. Sperry seconded, roll call vote resulted with all in favor. The Board entered executive session at 2:11 p.m. Dr. Henggeler motioned to leave executive session. Dr. de Blaquiere seconded, and the motion carried unanimously. Executive session ended at 2:51 p.m.

Mr. Sperry motioned to adjourn, Dr. de Blaquiere seconded, and the motion carried unanimously. Meeting adjourned at 2:55 p.m.

**August 2, 2017**

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

Chairman Nicki Chopski, PharmD, called the meeting to order at 8:00 a.m. In attendance were Board members Rich de Blaquiere, PharmD, Kris Jonas, PharmD, Ed Sperry, Public Member, and Holly Henggeler, PharmD. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Lisa Culley, CPhT, and Jaime Thompson, Compliance Officers, Andy Snook, Deputy Attorney General, Misty Lawrence, Management Assistant, Ellen Mitchell, Program Information Coordinator, Meredith Oliver, the Board's intern from the University of Mississippi, and several members of the public.

Dr. Chopski gave an overview of the day and shared that there were a few items moved to yesterday's agenda given extra time available. She assured those in attendance if they were there for one of the moved items, she would give them an opportunity to speak to the item. She asked Dr. Adams to remind the Board of public comments as they discussed any

changes to the final drafts. Dr. Adams reviewed the public comments that had been submitted both in writing and verbally. The Board deliberated on each comment, and a summary of the Board's action is noted below.

**Chapter 1** – **Rules of Procedure.**

Discussion of Chapter 1 resulted in the following:

- Change the title of Chapter 1 from "Rules of Procedure" to "General Provisions" to better capture that Chapter 1 establishes general provisions and serves as a parent chapter for the five following chapters.
- 22.08 Excessive Provision of Controlled Substances – no change.
- 22.11 Prescriber Incentives – no change.
- 22.16 Standard of Care – no change.
- 22.17 Unnecessary Service or Procedure – no change.

**Chapter 2 – Rules Governing Licensing and Registration.**

- 007 Official Board Journal – strike 'and copies may be obtained from the Board office' as all newsletters are online. This change will be made for all chapters.
- 030 Added 'Nonresident' for clarity; the Board is trying to highlight the distinction between pharmacist licensure vs. registration. Registration is a pathway that only certain nonresident pharmacists may pursue.
- 035 Added 'Nonresident' for clarity.
- Regarding comments to provide a two year license, the Board made no change.

**Chapter 3** – **Rules Governing Pharmacy Practice.**

Dr. Adams reminded the Board they had received one comment regarding the pharmacist to support personnel ratio. Following a brief discussion the Board determined they did not want to re-address the ratio at this time. Following discussion the Board made the following determinations related to Chapter 3:

- 100.02 Prescriber Delegation – add 'or pharmacist intern.'
- 300.03 Tampering – no change.
- 300.06 Expiration – no change.
- 400 Inventory After Loss – no change at this time, though staff will connect with the DEA to better understand how the Board's current rule differs from the federal Controlled Substances Act. Board staff will address this on the August 30th conference call.
- 402.02 Employment Changes – strike the duplicative reporting requirements in terms of change of employment, which currently requires both the PIC and the individual to report in 10 days. The Board felt reporting by the PIC is still important in the instance an individual was terminated for controlled substances related causes. To address termination for adulteration, rule 402.05 was amended to require reporting of adulteration or misappropriation of a controlled substance in accordance with Section 37-117A of Idaho Code.
- 402.04 Individual Information Changes – add 'in employment or changes' for clarity to the individual reporting requirements.

**Chapter 4** – **Rules Governing Pharmacist Prescriptive Authority**

- 020 – Added 'all nonprescription drugs and devices' to coincide with existing practices; the Board wanted to avoid having to otherwise list OTC drugs individually.
- 020.01 Education – There were general comments about the education requirements related to medications pharmacists may be prescribing. The verbiage regarding prescribing was adapted from the Nurse Practitioner Act. The Board discussed previous Idaho legislation, and examples from other jurisdictions. Dr. Jonas noted that there are differences between new graduates and seasoned practitioners, and that there is a professional responsibility for all health professionals to keep up to date in accordance with their practice. Following considerable discussion Dr. Jonas motioned to leave the verbiage of 020.01 as written. Dr. de Blaquiere seconded, and the motion carried with Dr. Henggeler opposed.

- 020.02 Patient-Prescriber Relationship – no change; the confusion from the comments seemed to stem from a misreading of the statute, which Dr. Adams clarified by reading a statement from the Legislative Services Office (LSO). The Board heard no further comments or concerns related to legislative intent after the LSO analysis was read.
- 020.03 Patient Assessment – added:

> 'At a minimum, the pharmacist must maintain a patient assessment protocol based on current clinical guidelines that specifies the following:
>
> a. Patient inclusion and exclusion criteria; and
> b. Explicit medical referral criteria.
>
> The pharmacist must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines. The pharmacists' patient assessment protocol, and any related forms, must be made available to the Board upon request.'

The Board noted that this added language is intended to address the concerns raised by medical groups. By requiring pharmacists to maintain a treatment protocol linked to a clinical guideline that sets guideposts for the Board's expected standard of care. The Board noted that several comments asked about setting age limits or carving out high-risk populations in the rules; the Board noted that there are *de facto* age limits and limitations on high-risk populations because of the link to clinical guidelines. As an example, Dr. Adams noted that the national guidelines related to statin use in patients with diabetes is targeted to patients between the ages of 40 and 75. If, however, the Board limited in rule the statin use in patients with diabetes to patients in this age range, the Board would have to update the rule every time the clinical guidelines changed. It would be a constant process and even with temporary rules, there would be lags between when clinical guidelines change and when a temporary rule becomes effective. Thus the Board deferred to prevailing clinical guidelines, as other health professions have, and requires updating when necessary. By requiring a protocol linked to clinical guidelines, the Board is setting the bar higher than other health professions currently require. Making the protocols available to the Board upon request creates an accountability mechanism as the compliance officers may request the protocol for audit at any point in time.

- 020.05 Follow-up Care Plan – no change, as this language is adapted from House Bill 4, which the legislature approved unanimously.
- 020.06 Notification – changed "if applicable" to "if identified by the patient," which clarifies that the pharmacist is expected to notify the patient's primary care provider, however some patients may not have a primary care provider, and thus if none is listed, no notification is able to be given. Dr. Adams noted that in his testimony to the Senate, he indicated a one-size-fits-all approach may not be possible, and asked if the Board wanted to consider requiring notification for only a subset of the drugs or drug categories in which notification made the most clinical sense. He noted it may not be important for certain conditions (e.g., lice or cold sores). Dr. Chopski commented she believes the notification after prescribing requirement is critical and wants notification for all pharmacist prescriptions. The Board discussed notification as an additional accountability mechanism built into the rules. If a pharmacist deviates from clinical guidelines, the provider who receives the notification can file a complaint with the Board. This accountability mechanism goes above and beyond other health professions currently.
- 020.07 Documentation – add 'any notification provided' which requires pharmacists to document the notification provided under 020.06. This reflects the importance the Board ascribes to the notification requirement.
- 021.04 Nausea – Dr. Adams will conduct additional research for the August 30 meeting pursuant to concerns raised. The Board wants to learn more from the jurisdictions on how they have addressed the stated concerns, and if the concerns have materialized.
- 021.05 Uncomplicated UTI – Dr. Adams will conduct additional research for the August 30th meeting. In particular, the Board will learn more about current practices regarding the management of UTIs via phone call.
- 023 Pharmacist Prescribing Based on CLIA Waived Test – Dr. Adams will conduct more research for the August 30th meeting based on comments regarding neuropsychiatric effects in pediatric patients; add 'When a person has tested positive for influenza, a pharmacist may additionally prescribe an antiviral medication to an

individual who has been exposed to the infectious person and for whom clinical guidelines recommend chemoprophylaxis.'

- Streptococcus - Dr. Adams will conduct more research for the August 30th meeting based on the comments submitted regarding strep carriers.
- 024 Clinical Gaps (statins) - Dr. Adams will conduct more research for the August 30th meeting to try to gauge the extent to which the national gap, reported to be near 40%, could be attributable to legitimate exclusions, such as pregnancy in diabetic patients aged 40 to 75.
- 025 Travel Drugs – add 'non-controlled drugs' to coincide with the language in House Bill 191. Dr. Henggeler expressed her desire to have an education requirement around travel drugs. Following a brief discussion, the Board directed Dr. Adams to conduct additional research for the August 30th meeting to assess the extent to which this is included in the pharmacy curriculum.
- Add section 026 Supplements to an Infusion Order, with a limitation on the heparin dose to 100 units per milliliter.
- Add section 027 Emergency Situations, which limits the prescribing of these drugs to an emergency, limits the quantity to 'the minimum quantity necessary', and requires the pharmacist to contact emergency medical services as soon as possible. This adapts language that was used in the opioid antagonist and epinephrine auto-injector prescribing that has been previously approved by the legislature.

Mr. Sperry reminded the audience of his experience serving on the Utah Medical Board. He reiterated the Board has taken an evidence-based approach to drafting the rules and are within the scope of the legislative intent. Mr. Sperry took issue with the comments regarding education as he believes physicians haven't taken the initiative to educate around the opioid issue. He stated he has always had exceptional care from pharmacists. When his physician was unable to gain success in lowering his blood pressure his physician referred him to the pharmacist, who was able to get his blood pressure down.

Dr. Chopski thanked all participants, and welcomed any organizations to meet with Board staff in the time-period between rulemaking sessions to provide more feedback or assist with research on the outstanding topics.

Dr. Adams provided a recap of the items that were moved from today's agenda to yesterday. There were no public comments for these items.

Christopher Erb attended the meeting to update the Board on his progress toward obtaining an Idaho Pharmacist License. Mr. Erb has been working at MedSync Pharmacy with Josh Gerke, PharmD. He stated he has enjoyed the practice setting and is happy to be back in the pharmacy. He is 50 months into his PRN contract and has been successful in the program. Mr. Erb shared that he had received a charge of disturbing the peace for a recent interaction; the case is working its way through the court system. He is about three months from sitting for the NAPLEX. Dr. Adams cited the possible change in the rules that could affect Mr. Erb's time frame. The Board thanked him for his update and thanked him for attending the meeting.

Dr. Chopski called for further public comment. Hearing none, Dr. Henggeler motioned to adjourn, Dr. de Blaquiere seconded, and the motion carried unanimously. Meeting adjourned at 11:40 a.m.