MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
August 30, 2017

Conference Call
Board Office - Boise, Idaho

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

Chairman Nicki Chopski, PharmD, attended the meeting telephonically and called the meeting to order at 9:00 a.m. Also attending telephonically were Board member Rich de Blaquiere, PharmD, and several members of the public. In the Board office were Ed Sperry, Public Member, Holly Henggeler, PharmD, Kris Jonas, PharmD, Alex J. Adams, PharmD, MPH, Executive Director, Andy Snook, Deputy Attorney General, Meredith Oliver, the Board's intern from the University of Mississippi, Dalila Del Real, the Board's Intern from Idaho State University, and Ellen Mitchell, Program Information Coordinator.

Public members who identified themselves on the conference call include:

- Susie Pouliot and Molly Steckel, Idaho Medical Association (IMA)
- Lee Flinn, Idaho Primary Care Association (IPCA)
- Laura Churns, Albertsons
- Tim Frost, Pacific University
- Michael Klepser, Ferris State University
- Krystalyn Weaver, National Alliance of State Pharmacy Associations
- Heidi Hart, Andrew Baron, Jeff Larson, Michael Triolo, Terry Reilly Health Services
- Ed Rickerts, Quarles & Brady
- Mark Johnston, CVS

The Board took up the matter of the August 1-2, 2017 minutes. Dr. Jonas noted some minor corrections. Dr. Henggeler motioned to approve the minutes with the discussed corrections. Mr. Sperry seconded, and the motion carried unanimously.

The Board took up the matter of negotiated rulemaking. Dr. Chopski indicated since the bulk of the comments received were related to Chapter 4 Rules Governing Pharmacist Prescriptive Authority, those comments would be addressed first. She indicated we would address Chapters 1-3 and Chapter 5 if there was time today and if not they would be addressed at the October meeting. No comments were received regarding Chapter 6. Dr. Chopski called for Board and public comment regarding Chapter 6. Hearing none the Board directed Dr. Adams to publish Chapter 6 in the Administrative Bulletin in October as drafted.

Chapter 4 – Rules Governing Pharmacist Prescriptive Authority

Dr. Chopski asked Dr. Adams to present the comments received regarding Chapter 4; the Board had tasked Board staff with researching several comments raised by medical groups at the August 1-2, 2017, negotiated rulemaking meeting, and Board staff conducted research and prepared summaries. Dr. Adams noted that he had sent 753 pages of research, clinical guidelines, and trade articles for the Board to review for this call.

The following is a summary of the feedback and comments received and the Board's actions.

Dr. Chopski asked Dr. Adams to review comments received on 020.06 Notification. Dr. Adams noted the prior concern from the IMA:

> "Nothing in this rule outlines how a pharmacist will identify the patient's primary care provider. If it is a question on a patient questionnaire, will pharmacists be required to inquire further if the patient leaves that question blank?"

Dr. Adams suggested the following amendment to rule 020.06 to address the IMA's concern:

> "The pharmacist must inquire about the identity of the patient's primary care provider and, if one is identified by the patient, provide notification within five (5) business days following the prescribing of a drug.

Following a brief discussion the Board granted unanimous consent to move forward with Dr. Adams' suggested language.

Dr. Adams noted a second part of IMA's concern:

> "Should the pharmacist be required to review previous prescriptions for the patient to assess whether there appears to be a consistent physician of record? Presumably a pharmacist would not prescribe medications to a diabetic patient without knowing if that patient is under the active care of a physician?"

Dr. Adams noted that there are some items on the list where it may be more important to notify the prescriber of record rather than the patient's primary care provider. For example, if the prescriber of a valid infusion order is not the patient's primary care provider, it may make more sense to notify the individual who ordered the infusion order itself. To address this issue raised by IMA, Dr. Adams suggested the following amendment to rule 020.06:

> "In the instance in which the pharmacist is prescribing to close a gap in care or to supplement a valid prescription drug order, the pharmacist must alternatively notify the provider of record."

Following a brief discussion the Board granted unanimous consent to move forward with Dr. Adams' suggested language.

Dr. Adams noted that the IPCA expressed concern related to the notification provision that there may be unintended consequences in that patients may seek treatment from pharmacists instead of establishing themselves with a primary care provider. IPCA indicated that they do not have any studies validating this concern. Mr. Sperry was confident as more people seek treatment, pharmacists will refer as appropriate. Dr. Adams indicated it would be a great opportunity for primary care providers to partner with pharmacies and provide a list of providers in the area that were accepting new patients. The Board believes that this concern is best addressed between providers in the community, rather than addressing it in law.

Dr. Adams next moved to rule 020.07 Documentation. He listed IPCA's concern:

> "The proposed rules for documentation would apply to a pharmacist prescribing drugs for various conditions ranging from motion sickness to a statin drug. This is a contrast to requirements applied to physicians. The Idaho Board of Medicine requires a physician to maintain adequate patient records, or legible records that contain at a minimum, subjective information, an evaluation and report of objective findings, assessment, or diagnosis, and the plan of care."

Dr. Adams indicated he reviewed the Board of Medicine rules. He suggested the following amendment to rule 020.07 to address the IPCA concern:

> "The pharmacist must maintain documentation adequate to justify the care provided, including, but not limited to the information collected as part of the patient assessment, the prescription record, any notification provided as required under this section, and the follow-up care plan."

Following a brief discussion the Board granted unanimous consent to move forward with Dr. Adams' suggested language.

Dr. Adams next addressed IMA's comment on rule 020.07:

> "Requiring documentation be made available to the patient or the patient's provider only "upon request," splinters the medical home model of care. Documentation will be kept in silos where the patient's other providers will not have knowledge of, or access to, records regarding a patient's treatment or medication history. Patients don't always know what is important clinical information to convey to their primary care physicians who then cannot provide optimal care to their patients if only an incomplete medical record is accessible."

The Board indicated that the "upon request" language had been carried over from House Bill 4, but that all information retained by the pharmacy can be requested by the patient or their providers, as allowable under HIPAA. The Board noted there may be confusion between the mandatory notification requirement, which will automatically go to the provider, and the requirement to maintain documentation, which can be requested at any subsequent time. Following a detailed discussion regarding some confusion created by the requirement to provide documentation 'upon request' the Board granted unanimous consent to strike that portion of the rule and move forward, while reaffirming that any record should be provided to the patient or provider as allowable under HIPAA.

The IPCA asked the Board to encourage voluntary participation in the Idaho Health Data Exchange (IHDE). Dr. Adams reminded the Board that IHDE had presented to them a few years ago and the Board was very supportive of their program. Dr. Adams has a call scheduled with IHDE later in the week to determine what the other medical boards are doing. Dr. Chopski asked Dr. Adams to determine if there are fees associated with participation. The Board re-affirmed their support of voluntary participation among pharmacies and pharmacists. Dr. Adams indicated that neither the Board of Medicine, nor the Board of Nursing require participation in the IHDE, and that the comment did not request this either. He indicated he will assess how these other boards have encouraged voluntarily participation so that the Board of Pharmacy could match or exceed their efforts. Dr. Adams noted that he understands from IHDE's senior marketing coordinator that IHDE has presented to the Board of Nursing, but not the Board of Medicine.

Dr. Adams indicated there were no comments received regarding rule 022 Pharmacist Prescribing of Devices.

Dr. Adams next presented comments for rule 023 Pharmacist Prescribing Based on CLIA-Waived Test. The Idaho Society of Health-System Pharmacists noted that the CLIA Waived tests occasionally have false negatives, and asked the Board to consider removing the requirement of the tests and allow diagnosis on symptoms alone. The Board noted that all of the research for flu and strep is anchored around CLIA-waived tests and all tests have false negatives. Following a brief discussion the Board chose to maintain the CLIA-waived test requirement as currently drafted. The Board noted that studies have shown this to improve antimicrobial stewardship, a key part of mitigating widespread antibiotic resistance.

Dr. Adams noted the Board had asked staff to research the concern previously raised by IMA with respect to rule 23.01 Influenza:

> "Prescribing antivirals to pediatric patients can be difficult because children are more susceptible to the neuropsychiatric effects that have been seen in antivirals for influenza, i.e., psychosis. Primary care physicians and pediatricians use clinical judgment based on the medical history and overall health of the child when deciding whether to administer antivirals. Pharmacists would not have access to the medical history of the child and would be less able to use appropriate clinical judgment."

Dr. Adams provided multiple studies for the Board to review. In brief, he indicated the pediatric age for Tamiflu appeared to be lowered from 1 year to 2 weeks in 2012. The reports of neuropsychiatric events were mostly from Japan and a decade old. The package insert reiterates no connection has been established between these events and Tamiflu. Further, the package insert indicated: "Estimates of neuropsychiatric event frequency cannot be made but they appear to be uncommon based on usage data." While the package insert does not provide an estimate, Dr. Adams shared one estimate he found:

- 8 events per million prescriptions in adults in the U.S.
- 19 events per million prescriptions in children in the U.S.

Dr. Adams also contacted an infectious disease professor to assess the Board's findings. The professor indicated the incidents are rare and that that experts agree the benefits of treatment far outweigh the risk. Given the totality of evidence, Dr. Adams asked the Board if it should remove flu from the list or limit treatment to adults based on the data. After lengthy discussion, the Board is in support of leaving it on the list given the clear benefits relative to the risks. Dr. Adams asked the audience to submit additional information and/or studies that the Board should review prior to the October meeting.

Dr. Adams next took up IMA's comment on rule 023.02 Group A Streptococcus:

> "Regarding pediatric patients, fifteen percent of children are colonized (strep carriers) and will test positive even when strep is not the cause of their illness or even when they are not sick. Clinical decision making around this issue is frequently not straightforward and would be difficult to do at the pharmacy level."

The Board had tasked staff with researching this concern, and Dr. Adams had provided research for the Board to review in advance of the call. In brief, he indicated IDSA guidelines suggest no treatment for asymptomatic patients; the Board rule specifically indicates treatment for "symptomatic" patients. If a symptomatic carrier presents, it is prudent to treat them according to feedback Dr. Adams had received from two infectious disease professors. Dr. Adams again called on the audience for additional information and/or studies that the

Board hasn't seen. He reiterated the draft rules are based on a preponderance of the evidence gathered and encouraged stakeholders to come forward if they have additional information. The Board directed Dr. Adams to leave medications indicated for Group A Streptococcus on the list and will review any additional information submitted by external stakeholders at the October meeting.

Dr. Adams indicated that the IDSA guidelines specifically refer to the condition as "Group A Streptococcal Pharyngitis" and he recommended amending the rule to mirror this language. Following further discussion the Board granted unanimous consent to update the title to Group A Streptococcal Pharyngitis.

Dr. Adams next took up IMA's comment relative to rule 024.01 Pharmacist Prescribing for Clinical Gaps in Care. One part of their comment noted:

> "There are many reasons it is clinically inappropriate for a pharmacist to prescribe a statin for a diabetic patient. Assuming there is a gap in care could be an inappropriate or even dangerous assumption. Diabetic patients are complicated patients who are usually on multiple medications."

Dr. Adams noted that this measure stems from the ACC/AHA guidelines, and that the Medicare program had adopted this measure as a national goal for improvement. To assess the extent of the gap, and if there were legitimate reasons for exclusion, as had been indicated by IMA, the Board solicited input from the statin use in patients with diabetes (SUPD) measure developer, the Pharmacy Quality Alliance (PQA). Per PQA:

- "The SUPD measure is endorsed by the National Quality Forum (NQF #2717) and evaluates the percentage of patients ages 40-75 years who were dispensed a medication for diabetes that received a statin medication (a higher rate is better)."
- "The American College of Cardiology/American Heart Association (ACC/AHA) guidelines recommend the use moderate- to high-intensity statin therapy for primary prevention for persons aged 40 to 75 years with diabetes (class 1 recommendation). The American Diabetes Association also recommends the use of statin therapy for patients with diabetes between the ages of 40-75."
- "Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality for patients with diabetes in addition to being the largest contributor to costs of diabetes care. Patients with diabetes aged 40 to 75 years are at a markedly increased lifetime risk for the development of ASCVD, experience greater morbidity, and are at a decreased likelihood of survival following the onset of ASCVD.[1] Data from meta-analyses including over 18,000 patients with diabetes from 14 randomized trials of statin therapy, showed a 9% proportional reduction in all-cause mortality and 13% reduction in vascular mortality for each mmol/L (39 mg/dL) reduction in LDL cholesterol."
- "This SUPD measure is endorsed by NQF (#2712). It is currently on the Medicare Part D display page for 2018 (using 2016 data), and the Centers for Medicare and Medicaid (CMS) plans to add it to the Part D 2019 Star Ratings (using 2017 data)."
- "Patients with diabetes frequently do not receive interventions or meet target goals to reduce cardiovascular risk. Approximately 33% to 49% of patients with diabetes do not meet their target goals for A1C, blood pressure, and LDL cholesterol levels. In an analysis of US national registry data from 204 cardiology practices from May 2008 through October 2013, 38% of patients ages 40 to 75 years with diabetes and no cardiovascular disease had not been prescribed statins. The analysis also showed wide variation in statin use across cardiology practices included in the study."
- "The 2017 Medicare Part D Display Measures (using 2015 data) are publicly available: Among 528 Part D contracts, the reported rate for the Statin Use in Persons with Diabetes measure (DMD17) ranged from 59% to 89% (mean, 75%; standard deviation, 4.1%)."

Dr. Adams noted he was unable to find comments from medical groups expressing concerns over legitimate gaps when CMS solicited public comments on inclusion of the measure as part of the Star Ratings program. The Board reviewed the studies showing the gap, and compared the rate of legitimate exclusions (e.g., pregnancy) and found that these legitimate reasons account for a tiny fraction of the reported gap. During discussion, Dr. Henggeler noted the overwhelming evidence shown in the studies and the notification of the provider within five days, she is comfortable with leaving this rule as written. She noted that

medication carries benefits and risks. Following extensive discussion the Board directed Dr. Adams to leave the rule as written.

Dr. Adams noted that there were other elements to IMA's concerns with rule 024.01:

> "A patient may not be on statins because of elevated liver function tests. The pharmacist would not know this."
>
> "The standard of care is that when a new statin is started, the patient should have appropriate labs checked no later than 3 months after starting the statin. A pharmacist is not in a position to perform, obtain, or interpret these labs."

Dr. Adams noted that these concerns may stem from confusion over current pharmacy law. Dr. Adams noted that nearly every state allows pharmacists to order and interpret lab tests. Nearly 10,800 pharmacies held CLIA certificates of waiver (COW) in a 2015 study. Idaho has allowed pharmacies to obtain a COW for years, and Idaho was reported as having one of the highest rates nationally of pharmacies performing CLIA-waived testing.

In addition, IMA commented:

> "Patients are prescribed diabetic medications (metformin likely being the most common) for a variety of non-diabetes-related conditions. The pharmacist is not in a position to differentiate between patients who are or who are not diabetics in these situations or to assess the need for statins."

Dr. Adams stated that pharmacists differentiate between diagnoses every day as part of the counseling requirement. The Board indicated requiring prescribers to note the diagnosis as part of the prescription drug order would be alleviate this concern if it is one. The Board has discussed this several times, most recently at its April 2017 meeting, and invited all parties to work with the Board toward having the diagnosis added as a requirement on valid prescription drug order as it would have many benefits to public health. Ohio recently required it for controlled substances to provide pharmacists one more tool to combat opioid overprescribing. The Board granted unanimous consent to leave statins for diabetes patients on the list and again asked stakeholders to submit additional evidence related to the studies the Board has reviewed for the October meeting.

The Board next took up comments related to rule 024.02 Short-Acting Beta Agonists (SABA). IMA commented:

> "Managing asthma, a potentially lethal condition, can be difficult. Part of asthma management from a primary care physician standpoint is knowing how frequently a patient is refilling albuterol, getting them back into the office if refills are happening too frequently, and explaining that additional refills will not be authorized until the patient is seen. It is critical to know why the patient is using more asthma medication than prescribed. Having refills at the pharmacy level could interfere with patients returning to their physician for crucial follow-up care and improvement of controlled medication management."

Dr. de Blaquiere noted that he believes the notification requirement satisfies this concern. The pharmacist is required to notify the patient's provider of record within five (5) days, and thus the provider will remain abreast of frequency, while ensuring the patient continues to receive the medication that is needed. Following discussion the Board granted unanimous consent to amend the rule to narrow the prescribing authority to only patients with asthma, and only to patients who had a previous prescription for a SABA. Thus, the pharmacist could not start a SABA for a patient who had never been on one, but could continue one if the patient ran out. The Board amended the language as follows:

> "Short-Acting Beta Agonists. Short-acting beta agonists (SABA) for patients with asthma who have had a prior prescription for a SABA, and who have a current prescription for a long-term asthma control medication."

The Board next took up rule 025 Pharmacist Prescribing of Travel Drugs. The Board had tasked Board staff with researching the extent to which this is covered in the current pharmacy curriculum. The Board had discussed in length comments submitted by medical groups regarding the pharmacist education requirements, and the Board felt this may be one area to specify a requirement. Dr. Adams indicated the Accreditation Council for Pharmacy

Education (ACPE) specifically listed travel immunizations in its standards and guideline documents, but did not speak specifically to “travel medicine.” Dr. Chopski asked if Dr. Adams reviewed the curricular standards for nursing and medicine. Dr. Adams indicated he did not, but noted that one of the studies he sent the Board suggests that travel medicine is not core to their curriculum either. Following extensive discussion the Board granted unanimous consent to amend the rule to add a pharmacist education requirement. The Board did not want to establish a specific number of hours for the program, and did not want to limit it to ACPE programs as some national and international groups on travel medicine also offer programming that may be useful. The amendment follows:

> “A pharmacist who successfully completes an accredited CPE or CME course on travel medicine may prescribe any non-controlled drug recommended for individuals traveling outside the United States that are specifically listed in the federal CDC Health Information for International Travel (e.g., Yellow Book). The pharmacist may only prescribe drugs that are indicated for the patient’s intended destination for travel.”

The Board next took up rule 026 Pharmacist Prescribing to Supplement an Infusion Order. The comment that had been previously submitted to the Board had an “etc.” at the end of each bulleted list. Dr. Adams cut this from the draft rule as he believes it is at odds with House Bill 191, which requires the listing of drugs, drug categories, or devices. Dr. Adams received feedback from a participant at the Twin Falls listening session that this list may be missing Emla cream. Rather than listing a specific brand product, Dr. Adams suggested that if the Board wanted to act on this requirement that they should consider broadening it to “local anesthetics for IV port access.” Following discussion, the Board granted unanimous consent to add it to the rule.

In addition, the Board had received a comment from John Sullivan on rule 026 that noted the heparin units as currently drafted use an unapproved abbreviation. The Board granted unanimous consent to spell out “units per milliliter” in connection with the heparin flush prescribing.

The Board discussed comments received regarding rule 027 with respect to a pharmacist prescribing a SABA in an emergency. He indicated he believes the concern was rooted in confusion that a pharmacist would simply give a SABA to a patient in respiratory distress without consideration to the underlying cause, and that the patient would not seek further care. Dr Adams noted the rule, as drafted, would only be exercised in an emergency situation while an ambulance is on its way. To assess if there could be any harms from a patient using a dose of SABA while an ambulance is on its way, Dr. Adams contacted a professor in the pulmonary field. The professor indicated that even if the patient had congestive heart failure, pneumonia, or a heart attack, a low dose beta agonist albuterol “would not worsen anything.” Dr. Adams also referenced an article to that effect, which he had shared with the Board from the Journal of Emergency Medicine. Based on the evidence and discussion, the Board chose to leave the rule as drafted. The Board invited additional evidence or feedback from stakeholders prior to the October meeting.

The Board had received several comments requesting additional products be added to the rules for pharmacists to prescribe. The Board indicated it did not want to consider new products at this late juncture, with the exception of medications of Lyme disease prophylaxis, since this had been submitted in advance, research was shared with the Board in advance of the call, and IMA had also been provided a good faith heads up in advance of the call. Following a discussion of Lyme disease prophylaxis the Board granted unanimous consent to add rule 028 as follows:

> “Pharmacist Prescribing for Lyme Disease Prophylaxis After a Recognized Tick Bite: A pharmacist may prescribe antimicrobial prophylaxis for the prevention of Lyme disease in accordance with clinical guidelines.”

The Board invited specific feedback on this addition for the October meeting.

Dr. Adams presented a comment received from IPCA on rule 200:

> “Who sets the statewide pharmacy prescribing protocols? What happens if an individual collaborative agreement does not comply or is significantly different from the statewide protocol? A physician assistant or registered nurse is required to enter into an agreement with a physician for supervision. These agreements should have similar supervising requirements.”

Dr. Adams noted that this language is not new, and that it is existing law that has been moved into this chapter as part of the reorganization of the law book into different chapters. Dr. Adams detailed the history of the rule, having first been included in a docket related to emergency preparedness for catastrophic events. Since it was existing law, the Board granted unanimous consent to keep it as is, but invited additional feedback from stakeholders for the October meeting.

The Board circled back to rule 020.01 Education. The Board discussed the education provision at length at the first negotiated rulemaking session based on comments received from the public. Dr. Adams noted that no additional specific concerns were submitted in writing for the follow-up meeting, though he had heard one verbal comment from the Board of Medicine meeting. Specifically it was noted that some of the studies the Board is using stem from other countries, and it was suggested that pharmacy education in the countries may be "more clinical." He contacted ACPE as they accredit all U.S. Doctor of Pharmacy (PharmD) programs and consult internationally. ACPE indicated the United States requires the entry-level doctorate degree versus a bachelor's or master's degree in the reference countries. ACPE further shared that the U.S. PharmD programs have more experiential and inter-professional requirements than international programs.

The Board took up rule 20.03 related to patient assessments. ISHP submitted a comment noting that clinical guidelines are not always available for each condition on the list. Dr. Adams noted that he has used the guidelines on the website provided by the Agency for Healthcare Research and Quality to identify relevant guidelines, and confirmed that that is indeed the case for several conditions (e.g., lice and cold sores). The Board granted unanimous consent to amend this section to emphasize clinical guidelines, when available, and the use of evidence-based research as a fallback when clinical guidelines are not available. The amendment follows:

> "03. Patient Assessment. The pharmacist must obtain adequate information about the patient's health status to make appropriate decisions based on clinical guidelines or evidence-based research findings and mitigate potential contraindications and interactions, among other potential adverse health outcomes.
>
> a. At a minimum, for each drug or drug category the pharmacist intends to prescribe, the pharmacist must maintain a patient assessment protocol based on current clinical guidelines, when available, or evidence-based research findings that specifies the following:
>
> i. Patient inclusion and exclusion criteria; and
> ii. Explicit medical referral criteria.
>
> b. The pharmacist must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings. The pharmacist's patient assessment protocol, and any related forms, must be made available to the Board upon request."

Dr. Adams inquired about the Board's desire to list specific clinical guidelines, rather than just defining "clinical guidelines" in Chapter 1. Dr. Chopski is hesitant to list guidelines by organization or association. She indicated there are sometimes two different sets of guidelines for some conditions, diabetes as an example. Dr. Chopski asked Dr. Adams if the Board of Medicine or Board of Nursing lists specific guidelines, and he indicated he is not aware of them doing so based on his review of their laws. The Board chose not to list specific sets of clinical guidelines in the rules at this time but invited additional feedback based on the experience of other health professions.

Dr. Adams noted that medical organizations have submitted comments to the Board about listing specific medical referral criteria in rules. The Board reiterated these are best addressed in the protocol as it would otherwise necessitate constant rule updates. Washington State presented to the Board on their protocols at a previous meeting for conditions such as urinary tract infections (UTIs). The Board encouraged any stakeholders with concerns over referral criteria to submit protocols based on clinical guidelines, and noted that this would be a great opportunity for collaboration. Dr. Adams shared an anecdote he heard from Canada in which the physician who had expressed the most concerns ended up drafting a protocol that the Board shared as guidance, and that the same physician now

speaks favorably on the topic and has received grant funding to evaluate the patient care gains that have been achieved from pharmacist prescribing.

The Board concluded Chapter 4 by reviewing rule 021. Dr. Adams noted that no concerns were submitted for lice, cold sores, or motion sickness, and Dr. Henggeler indicated the medical groups even expressed support for their inclusion. Groups have, however, submitted concerns for both nausea and UTIs. The Board tasked staff with researching these concerns, and multiple studies and clinical guidelines were circulated in advance of the meeting.

Dr. Adams reviewed IMA's concerns over UTIs. For one, IMA noted:

> "Prescribing for an uncomplicated urinary tract infection almost always will require a new diagnosis. This means that in almost all cases a pharmacist may not prescribe for a UTI without performing a CLIA waived test. At the very minimum, this rule ought to require a pharmacist to perform that test."

Dr. Adams noted that similar concerns were raised by a member of the Board of Medicine, who suggested a urine culture is part of the standard treatment guidelines. Dr. Adams shared his research on the most up-to-date ACOG guidelines revealed the following:

> **"**When is a urine culture necessary?
>
> "The initial treatment of a symptomatic lower UTI with pyuria or bacteriuria does ***not*** require a urine culture." (emphasis added)

Dr. Adams reiterated the Board's previous discussion about the diagnosis and treatment of UTIs via phone call, which do not involve a urine culture. The Board had been provided five (5) studies on diagnosis and management via phone call, and several lay articles on this as well. The Board decided not to require a urine culture as a result of the clinical guidelines and the common practice of treating via phone call, but invited additional evidence on this for the October meeting.

The IMA additionally submitted comments relative to UTIs as follows:

> "It can be very dangerous for a pharmacist to assume a diagnosis of "Uncomplicated Urinary Tract Infection" simply because a patient has had one or more UTIs in the past. Clinical examples presenting as pain with urination and/or frequency of urination include (but are in no way limited to):
> - STI's – herpes, chlamydia, gonorrhea, syphilis, etc.
> - Rheumatologic issues: Reiter's syndrome
> - Yeast infections (which may be the presenting symptom of new diagnosis of diabetes)
> - Uncontrolled diabetes
> - Bladder cancer
> - Pyelonephritis
> - Kidney stones
> - Constipation
> - Endometrial/Uterine cancer
> - Endometriosis"

The Board reiterated its position that the differential diagnosis via phone call has proven successful, and that the required protocol requires inclusion, exclusion, and referral criteria that would distinguish between these. Stakeholders who have concerns are encouraged to collaborate on a protocol or send additional research for consideration at the October meeting.

The Board also reviewed the research Dr. Adams sent around related to nausea. The Board found that nausea prescribing is common in Canada, and that only two provinces narrowed this authority, and did so to pregnancy-related nausea. The Board is not aware of any issues that have arisen in Canada. Dr. Adams asked the Board if it wished to narrow the nausea prescribing to continuing previous nausea medications that the patient has been prescribed. After discussion, the Board granted unanimous consent to keep the rule as drafted, but invited additional evidence to be submitted for the October meeting.

Dr. Chopski called for additional comment regarding Chapter 4, Dr. Baron from Terry Reilly expressed his concern regarding nausea, though he expressed support for pharmacist prescribing generally. Dr. Chopski asked Dr. Baron to meet with Board staff prior to the October meeting and consider drafting a protocol to address his concerns.

No other verbal comments were provided on the call.

Chapter 1 – General Provisions

Dr. Adams shared that no comments were received for Chapter 1, but that staff had one suggestion of adding "reverse distributor" to the list of outlets that are licensed as limited service outlets. Dr. Adams explained that this is not a change in policy, because the Board currently licenses reverse distributors as such, and it is merely attempting to make the list complete. Following a brief discussion the Board granted unanimous consent to add reverse distributor as a limited service outlet.

Chapter 2 – Rules Governing Licensure and Registration

Dr. Adams noted he has heard of a draft policy that a pharmacist intends to bring to the National Association of Boards of Pharmacy that would standardize the CPE timeline to coincide with the calendar year. Dr. Adams noted that Board compliance staff is supportive of this change. Following discussion the Board granted unanimous consent to amend rule 33 as follows:

> "Pharmacist License Renewal: CPE Requirements:
> Each pharmacist applicant for license renewal must complete fifteen (15) CPE hours each calendar year between January 1 and December 31."

Dr. Chopski noted that she would like to look at this provision again at the October meeting.

The Idaho Veterinary Medical Association (IVMA) submitted the following written comments prior to the meeting:

- Expressed support of the elimination of Veterinary Drug Technician and Veterinary Drug Outlet registrations.
- Suggested moving current Board of Pharmacy regulatory authority for veterinarians to the Board of Veterinary Medicine.
- Suggested separating human and veterinary prescriber drug outlets

Dr. Adams believes separation will make it easier to coordinate with the Board of Veterinary Medicine in regulation of these facilities. Following discussion the Board granted consent to separate the two. Dr. de Blaquiere expressed concerns over getting rid of oversight of veterinary offices that dispense for outpatient use, and Dr. Adams will invite IVMA to the October meeting for further discussion.

Chapter 3 – Rules Governing Pharmacy Practice

Dr. Adams shared the following additional comments submitted prior to the meeting:

- Rule 201.04, regarding an unsafe work environment due to understaffing and who is ultimately responsible? The Board chose not to address this comment at this time.
- Rule 302, request to add a phone number as a requirement of the prescription order. The Board attempted to address this matter in prior years and will not take it up again at this time.
- Rule 303, which allows a pharmacist to fill a prescription one time in 12 months. Dan Houdeshell who lost his son due to a lack of a refill is very supportive of this rule and shared information on other states that have recently adopted "Kevin's Law."

Jeffrey K. Larsen, Director of Business Management at Terry Reilly Health Services submitted the following written comment prior to the meeting:

- 314.02 Destruction or Return of Drugs or Devices: Restrictions Institutional Facility
  - Suggested adding 'federally qualified heath centers' and defining the same.

Following a brief discussion the Board approved the change as follows:

> "Did Not Reach Patient. Non-controlled drugs that have been maintained in the custody and control of the institutional facility or dispensing pharmacy may be returned if product integrity can be assured. Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no

more than a twenty-four (24) hour supply for a drug order, or up to a seventy-two (72) hour supply for a drug order if warranted for good patient care."

Dr. Adams presented rule 400.02 that was tabled from the last meeting. He and Fred Collings agreed to strike the rule as long as staff still received the DEA Form 106. Rule 400.02 was found to be above and beyond federal requirements. The Board granted unanimous consent to strike the requirement in 400(02) related to inventory after discovery of theft or loss.

Edward D. Rickert, Attorney for MedAvail Technologies, which is a manufacturer of automated dispensing systems (ADS), submitted the following written comments prior to the meeting:

- 204.07 Drug Outlets That Dispense Drugs to Patients Without an Onsite Pharmacist or Prescriber
  - Suggested adding an additional exemption clarifying the ADS is an extension of the drug outlet that operates it and doesn't require separate licensing
- Suggested adding a rule to address record storage for self-service ADS
- Suggested revising the definition of 'reconstitution' to allow drug products that need to be reconstituted to be dispensed from ADS with premeasured water so patients may reconstitute the product at home.

Following a brief discussion Mr. Rickert and Dr. Adams will work together to draft language to present to the Board at the next meeting. The Board further expressed its belief that the reconstitution rule as drafted already covers the scenarios Mr. Rickert raised, and that no change was needed at this time as it is already permitted.

Chairman Chopski called for further public comment. Hearing none, Dr. Henggeler motioned to adjourn, Mr. Sperry seconded, and the motion carried unanimously. Meeting adjourned at 11:10 a.m.