STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

ALASKA STATE BOARD OF PHARMACY

MINUTES OF MEETING
September 15-16, 2011

*These **FINAL** minutes were prepared by the staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.*

By authority of AS 08.01.070(2) and in compliance with the provision of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held on September 15th and 16th, 2011 at the Atwood Building, 550 West 7th Ave., Suite 1270 Anchorage Alaska.

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:00 a.m. Those present constituting a quorum of the board, were:

Lori DeVito, R.Ph.
Anne Gruening, Public Member
Richard Holm, R. Ph.
C. J. Kim, R. Ph.
Dirk White, R. Ph.

Absent: Ted Mala, Public Member

Present from the Division of Corporations, Business and Professional Licensing were:

Brian Howes, Investigator & PDMP Program Manager
Susan Winton, Sr. Investigator
Quentin Warren, Chief Investigator
Mary Kay Vellucci, Licensing Examiner

Present from the Department of Law

Dan Branch, Assistant Attorney General – via telephone
Peter Putzier, Assistant Attorney General
John Parisi, Assistant Attorney General

Visitors present:

Denise Valentine, Board of Nursing
Nancy Davis, AkPhA

Ruth Carter, DEA
Steve Sanchez, DEA
Daina Huyen, Walgreens

Review of Agenda

The members reviewed the agenda. No changes were indicated.

Upon a motion duly made by M. DeVito, seconded by Mr. White, and approve unanimously, it was

Resolved to approve the agenda as presented.

Agenda Item 1 **Review of Minutes**

The members reviewed the minutes from the May, 2011 full board meeting and the August 26, 2011 teleconference. Several typographical errors were pointed out but there were no revisions to the content or intent of the minutes.

Upon a motion duly made by Mr. Kim, seconded by Ms. DeVito, and approve unanimously, it was

Resolved to approve the minutes from the May 2011 full board meeting as amended.

In reviewing the August teleconference minutes, it was clarified there will be two types of waivers for this program. The first is a waiver from reporting at all. This was allowable and implied by AS 17.30.200. The second is a waiver from reporting electronically. The latter licensees must report in a paper format, as the waiver addresses only the method of report. Mr. Howes created draft forms for these two purposes and they were included in the board packet additions. No changes were requested for the August, 2011 teleconference minutes.

Upon a motion duly made by Ms. DeVito, seconded by Ms. Gruening, and approve unanimously, it was

Resolved to approve the minutes from the August 26, 2011 teleconference.

Agenda Item 2 **Ethics Disclosure/Goals and Objectives**

The board read the goals and objectives and into the record:

1. The board will continue to educate licensees regarding the Pharmacy Practice Act and pharmacy regulations.

2. The board will continue to provide input and comment on any proposed legislation/regulations involving medications or pharmaceutical care.

3. The board will continue to promote effective patient counseling by licensees.

4. The board will continue to assess and evaluate the Multi-state Pharmacy Jurisprudence Examination (MPJE).

5. The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.

6. The board will continue to assess and evaluate the licensing of pharmacy technicians.

7. The board will continue its affiliation with NABP and send one board member to the District Seven NABP meeting and two members to the annual NABP meeting. The Division's budget currently allows only one out-of-state travel per fiscal year; this was generally used for attendance at the District Seven NABP meeting.

8. The board will continue to evaluate the impact of current regulations and the need for new regulations.

9. The board will continue to evaluate regulations regarding collaborative practice, and to establish procedures for reviewing/approving appropriate protocols for collaborative practice.

10. The board will assess and evaluate the growing public concern regarding abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs and development of a prescription drug monitoring program.

It was noted the goals needed to be cross referenced to the Annual Report and the recent point of view of the board. Ms. Vellucci offered to do this prior to the next board meeting.

There were no ethics violations to report.

Agenda Item 3 **Division Items**

Annual Report: Mr. Holm noted, and Mr. White agreed, the number of new licenses issued in FY2011 seemed significantly large. Ms. DeVito stated she thought her term ended in 2012, although *Identification of Board* states it expires on March 1, 2014. This was a typographical error and needs to be corrected to read "March 1, 2012."

It was noted John Cotter had been appointed to the board.

Upon a motion duly made by Mr. White, seconded by Mr. Kim, and approved unanimously, it was

RESOLVED to go into Executive Session in accordance with Alaska Statute 44.62.310 (c) (2) to discuss board business.

Board and staff to remain.
Off record at 9:25 a.m.
On record at 9:50 a.m.

Mr. Holm stated for the record Recommendation #3 in the Sunset Audit states "Board of Pharmacy and staff within the Office of the Governor should work together to increase the pool of qualified applicants available for board appointments."

Ms. DeVito exited at 9:52 a.m.

Mr. Kim stated he accepted a position as the State of Alaska pharmacist, effective October 17th. He offered to provide a job description to determine if there would be a conflict of interest between this position and continuing to serve on the board. Mr. Kim will forward the job description and an inquiry to Brandon Maitlen at Boards and Commissions with a cc to Chair Holm for a final ruling.

Ms. DeVito returned at 10:05 a.m.

Board of Pharmacy Expense Report: Ms. Vellucci informed the member Misty Frawley is the new Admin Officer II who replaced Kathy Mason. Ms. Frawley was standing by in case the members wanted to consult her regarding the Expense Report. Ms. Vellucci relayed to Director Habeger the board's May, 2011 request for the Division to acquire an alternative funding source/allocation for legal expenses accrued in FY11. He replied an alternative funding source was not available and license fees were the only source of revenue available to the Board of Pharmacy. At that time, data indicated the anticipated increase per license would be approximately $50.

The members requested increased authority in determining the final licensing and renewal fees. Ms. Vellucci stated this could be discussed now directly with Ms. Frawley. The members chose to have the pertinent section of the today's minutes forwarded to Ms. Frawley and Mr. Habeger for their review and invited them to participate at the next scheduled meeting.

Mr. White advocated for pharmacy technicians by stating generally, most live "paycheck to paycheck" and therefore increased licensing fees adversely impact them most.

Formal Request: Mr. Holm made the following formal request with the unanimous consent of all board members:

1. Allocate additional funds to the board of pharmacy in FY12 to cover legal debt accrued in FY11. Members agreed this debt was the direct result of doing the board's job and as such, should not be passed on to licensees. If this requires an appropriation or allocation from the legislature, then it is incumbent upon Senior Management at the Division to approach the legislature for this appropriation.
2. Enact a budget line item in FY 12 for *Contingency Expenses* to cover the costs of litigation or other unplanned expenditures. This would prevent the board from repeatedly accruing debt and stabilize licensing fees between biennial renewals. Ms. Vellucci commented this idea was presented during a staff meeting introducing Deputy Commissioner Curtis Thayer and Commissioner Susan Bell. Mr. Thayer agreed in principal with the idea at that time.
3. Mr. Holm stated he was certain this was needed for all boards, not just pharmacy.

Members commented that funds acquired from board business that was allocated to the State's General Funds ultimately created a debt that licensees had to pay. This, in principal, was unfair. Reassignment of professional boards' resources to the State

General Funds was problematic for all Professional Boards, not just the Board of Pharmacy, because the cost of doing board business was not sufficiently or fairly covered with the current budget format. Mr. White added the Board of Pharmacy was only asking for resources generated by the Board of Pharmacy. And, stabilizing licensing costs between even two biennial renewals by utilizing contingency funds would save the expenses incurred from multiple departments to enact fee changes.

Mr. Holm added the Pharmacy Board seriously considers cost as it conducts business, as exemplified by their recent goal to incorporate email as an acceptable first line of communication, thereby eliminating postage and printing costs, as well as decreasing the cost of labor to conduct board business.

Email Policy: The members reviewed the memo dated August 30, 2011 from Sara Chambers in response to their request from the May, 2011 board meeting.

The members unanimously agreed they want to continue to move in the direction of electronic methods of communication for all board business. They also agreed the consent statement in Ms. Chambers' memo should be incorporated verbatim into renewals and applications.

Agenda Item 5 Investigative Report

Susan Winton, Sr. Investigator and Quentin Warren, Chief Investigator joined the meeting.

Probationary Report: There are four probationary licenses with the Board of Pharmacy. Ms. Winton provided a summary of the status of these licenses and later distributed a written *Probation Report for the Alaska Board of Pharmacy* which was added to the record.

Upon a motion duly made by Mr. White, seconded by Ms. DeVito, and approved unanimously, it was

RESOLVED to go into Executive Session in accordance with Alaska Statute 44.62.310 (c) (2) to discuss licensing.

Board, investigators and staff to remain.
Off record at 10:15 a.m.
On record at 10:35 a.m.

Upon a motion duly made by Mr. White, seconded by Mr. Kim, and approved unanimously, it was

RESOLVED to extend the probation in case number 2600-04-004 until the February 16-17, 2012 Board of Pharmacy. meeting and have Investigations determine if violations occurred in the last probationary period.

The action above pertained to pharmacist Douglas Bartko.

Upon a motion duly made by Mr. White, seconded by Ms. DeVito, and approved unanimously, it was

RESOLVED to accept the voluntary license surrender in case number 2600-09-006.

This action above pertained to pharmacist Daniel Dennis English. The order was signed by the chair and given to Ms. Winton.

Investigator's Report: A written report created by Investigator Gary Keiser and routed to the members in the board packets. The content of the report was summarized by Ms. Winton. The practitioners in the two ongoing drug diversion cases are not practicing and have open criminal matters, all of which is public record.

Imposition of Civil Fine without Censure or Reprimand (hereafter referred to as Imposition of Civil Fine): Ms. Winton distributed sample copies of this disciplinary tool and the pertinent regulations and statutes which give the board authority to utilize this option in disciplinary matters. The following points regarding the Imposition of Civil Fine were made by Ms. Winton:

- This tool has been used successfully by the Medical Board.
- It provides a level of discipline between no-action or a warning letter and a Consent Agreement with terms, conditions or limitations on a license.
- It is a significantly less costly option to the board and the licensee because it does not involve litigation for either party, or further labor from the division or the board.
- It is typically applied to administrative violations.
- It is classified as disciplinary action.
- It is a public document.
- It cannot be used in a case related to patient care.
- It waives the right to an administrative hearing, appeal or reconsideration.
- It brings the matter at hand to a final resolution.
- It cannot be applied retroactively.

- It is not reported to the National Practitioner Data Bank (NPDB), primarily because it is not related to patient care.
- When a practitioner is reported to the NPDB, it may adversely affect patient care because insurers may then reject a practitioner. This disrupts continuity of care.
- Malpractice insurance (and therefore medical care costs) typically does not increase if a violation is not reported to the NPDB.

A discussion about the Imposition of Civil Fine occurred among the members. Ms. Winton stated she was not familiar with the statutes and regulations for the Prescription Drug Monitoring Program (PDMP) and therefore she could not speak to the relationship between this tool and the PDMP. In response to a question from Mr. White, it was clarified the Imposition of Civil Fine could be applied to a patient care violation; however, in that case it must be reported to the NPDB.

Upon a motion duly made by Ms. DeVito, seconded by Ms. Gruening, and approved unanimously, it was

RESOLVED to adopt the use of the Imposition of Civil Fine Without Censure or Reprimand for future violations not related to patient care.

Break: Off record at 11:00 a.m.
On record at 11:15 a.m.

Agenda Item 6 Regulation Projects

Dan Branch, Assistant Attorney General joined the meeting telephonically and Brian Howes, PDMP Program Coordinator, joined the meeting in person.

Prescription Drug Monitoring Program: Prior to the meeting, the members and Program Manager received:

- Information about the Advisory Committee Resolution.
- Draft of 12 AAC 52.895: Challenge Information in the Database.
- 8/26/11 Re-adopted PDMP regulations.
- Two year data purge requirement information.
- Draft forms for the two types of waivers adopted 8/26/11.

Mr. Howes stated 158 in state facilities and about 50% of the out of state facilities have registered. Other out of state facilities were waiting to see if they will get a waiver or were having some issues. In August, approximately 40,000 prescriptions were entered in the system. Mr. Holm asked if the system flags an individual person who was accessing an unusual number of prescribers, unit doses or prescriptions. Mr. Howes said no, because the parameters to flag had not yet been created. This led into discussions about the flagging data in the PDMP, thresholds for action and fines.

Mr. Howes stated the purpose of the flagging data and creating thresholds was to initiate notifications to that effect with the provider(s).

Dan Branch, Assistant Attorney General and Jun Maiquis, Regulation Specialist joined the meeting telephonically.

Mr. Branch stated AS 17.32.200(d) strictly limits release of information acquired from the PDMP data and the confidentiality protection is extremely strong. Information can only be obtained legally "when the pharmacist (or prescriber) initiates a profile request for a patient they are currently providing services to." Information must be acquired first hand in order to be legal. Mr. Branch clarified the statute does not allow any PDMP information to be distributed as a "head's up" notification to pharmacists, prescribers, law enforcement or any other entity. This includes all PDMP information acquired at the Department and the Division. He then talked about the legislative purposes of the PDMP and added "the legislature did not want to use this (PDMP) to give probable cause to police officers." He said if this is not what the board wanted, they could request a legislative change.

Mr. Holm said he understood why the legislature did the law in that way. The information was there for prescribers and dispensers if they chose to seek it.

Patient profile data was not yet being released because compliance with data submission was not yet at a level where a profile result could be considered accurate or valid. Mr. Howes thought this should be resolved by late October or early November.

Mr. White initiated a discussion about Social Security Numbers and/or Driver's License numbers being requested by Relay Health. He said this jammed his computer system and it was not a prescription requirement in Alaska. Mr. Howes said it was a requirement of the 4.1 ASAP Standards that were adopted. Mr. Branch added PDMP regulation 12 AAC 52.855 (c) (3), adopted 8/26/11, requires the patient to provide only name, date of birth, purpose of the request and the date range for the profile. Mr. Howes and the members agreed the Patient Identifiers in ASAP 4.1 will be made optional as opposed to being a required field. Mr. Howes said he would follow through with Relay Health.

Because ASAP is not interfaced with most pharmacy computer software systems, entering method of payment is also problematic. Mr. White's pharmacy point of sale (pos) entries are not compatible with the "cash or credit" ASAP data requirement. Mr. Holm commented if this is a problem for one facility, it is also a problem for others. Mr. White asked Mr. Branch to respond re AS 17.30.200 (b) (3) which requires the pharmacy to submit "method of payment" in their PDMP data submissions. Mr. Branch confirmed pharmacies are required to submit methods of payment to the board. Entering this information manually was unrealistic due to the time and labor involved. It was equally unrealistic for a pharmacy to change their software from a known, functional, familiar program to something new only to accommodate the PDMP pos requirement. Mr. Holm said most pharmacy software systems typically record that if a prescription sale was billed to Medicaid, Medicare or a private insurer, and the amount of the co-pay or total amount due for all pharmacy items. The software typically was not programmed to record whether a sale is cash or credit. Mr. Howes said he would research this question and report back to the board later in the day

Agenda Item 7 Public Comments

No public comments were offered at the meeting.

Lunch: Off the record at 12:05 p.m.
On the record at 1:07 p.m.

Agenda Item 8 **Licensing Native Health Care Facilities**

Mr. Putzier joined the meeting. He informed the members he is now working as an AG with the State Department of Transportation, regarding the Anchorage and Fairbanks airports.

Upon a motion duly made by Mr. White, seconded by Ms. DeVito, and approved unanimously, it was

RESOLVED to go into Executive Session in accordance with Alaska Statute 44.62.310 (c) (1) (4) to discuss board business.

Board, staff and AG to remain.
Off record at 1:10 p.m.
On record at 1:48 p.m.

Mr. Parsi, Special Attorney General assigned to this case upon Mr. Putzier's transfer, provided his contact information to the board members. He agreed to participate in the next board meeting at 1:00 on Thursday February 16, 2012. Chair Holm thanked Mr. Putzier for his work with the Board of Pharmacy.

Agenda Item 6 **Regulation Projects (cont'd)**

Prescription Drug Monitoring Program (cont)

Upon a motion duly made by Mr. Kim, seconded by Ms. DeVito, and approved unanimously, and considering the cost to the public, it was

RESOLVED to readopt the Article 9: Controlled Substance Prescription Database regulations based on the August 26, 2011 amended regulations.

The board reviewed the draft form titled Certification of No Dispensing of Controlled substances. It was created to certify a pharmacy does not dispense controlled substances, and would therefore, be exempt for reporting to the PDMP. The members agreed facilities must update the certification annually to verify they have not changed this practice and notify the board within thirty days if they begin dispensing controlled substances to an

Alaska resident. To confirm the legality of these requirements, Dan Branch, Assistant Attorney General, re-joined the meeting telephonically. He stated these requirements are within the authority of the board. They are addressed in 12 AAC 52.865 (e) of the regulations that were re-adopted earlier this date. He reiterated this form is technically a certification, not a waiver, because the facility is certifying they are not dispensing controlled substances. Conversely, when/if the certified information becomes untrue, the facility is required under AS 17.30.200 (b) and 12 AAC 52.865 (c) to report that to the board. Therefore, mandating licensees notify the board within thirty days if they begin dispensing controlled substance is legitimate and does not create a new requirement. According to Mr. Branch, it informs licensees what the requirements are. Mr. Howes stated he would add a separate bullet point under the certification statements to reflect this.

Ms. Vellucci asked the members to determine how the following statement in the draft certification form would be revised: "My pharmacy will resubmit this form every year with our pharmacy license renewal in order to…" She stated this would be inefficient for the division and mislead to licensees about who to contact for the PDMP. Mr. Holm pointed out renewals are biennial and this re-certification was intended to be done annually. It was decided the statement would be changed to "My pharmacy will resubmit this form at the end of each calendar in order to recertify the pharmacy does not deliver any schedule II, III IV or V controlled substances to end users who have an Alaska State address." The title of the document was changed to "Certification of No Controlled substances Dispensed."

The draft version of Request for Waiver from Electronic Reporting was reviewed by the board members for content and accuracy. The members agreed to the following:

- Title changed to Request for Paper Submissions of PDMP Data.
- Change the word "waiver" to "requests."
- Change the statute and regulation-citing statement to "Alaska Statute 17.30.200 (b) requires the reporting of all controlled substances dispensed or delivered in Alaska be done in a format established by the Board of Pharmacy. The format is

established in 12 AAC 52.865. Exceptions to the electronic method of controlled substance reporting are listed in 12 AAC 52.970. A facility meeting the exception criteria will submit PDMP data in paper. The purpose of this document is to identify how your facility meets this requirement.'

- Delete the first checkbox statement "that never dispenses controlled substance prescriptions."
- Delete the asterisk on the fourth checkbox.

The members agreed both forms must be notarized.

Mr. Howes then followed up on Mr. White's comments earlier this date regarding the "cash or credit" payment method for prescriptions required in ASAP. He said "it's there if you want to fill it in but it's not going to require you to input this data." The purpose is to identify if insurance is being billed electronically or if the prescription is being paid in cash. This information was derived from a consulting a colleague of Mr. Howes in Georgia.

Mr. Branch reminded the members there are drafts of regulations describing the method by which a person can contest information provided by the PDMP and the two year data purge. Both topics are mandated by statute. He asked the members to consider these drafts and informed them the regulations need to be public noticed. Mr. Holm stated the members would review this drafts in the evening and the items would be added to the agenda the next day.

Agenda Item 9 **DEA**

Ruth Carter and Steve Sanchez joined the meeting.
Ms. Carter informed the members

Emergency Drug Kits on Fishing Vessels: A Seattle pharmacy, which is not licensed in Alaska, is shipping emergency drug kits to Alaska fishing vessels. Her firsthand experience is primarily with vessels on Aleutian Islands. Most kits are being mailed to Dutch Harbor, which is not a DEA registrant. The DEA was informed kits were stolen from a seafood company. She wanted to know if the Alaska Board of Pharmacy has a regulation that permits shipping of drugs in this

manner. She added federal regulations mandate they must be shipped to a DEA-registered location. She was unaware of any exemption to out of state licensing for shipping controlled substances into Alaska. Mr. Holm replied a pharmacy must be shipping to an individual in Alaska under the authority of a prescription and be licensed as an out of state pharmacy by the board. She asked how this applied to emergency kits on fishing vessels, as the medications are given to the crew and administered by the crew. Typically they are mailed to the captain. Mr. Holm briefly described the licensing criteria for wholesalers and out of state pharmacies. Ms. Carter stated in order for a vessel to do this, the captain is supposed to appear in person to the pharmacy board and provide a written request on letterhead for the medications he is requesting. This is not occurring. The kits are being shipped to the Aleutians and it appears the captain is sending a crew member to pick up the drugs from a location that is not DEA registered. Ms. Carter stated she interprets this to be the location is acting like a pharmacy, without a pharmacy license, because the only way the vessel can acquire the drugs is from a pharmacy. She asked the members if they interpret it this way as well.

Mr. Holm asked about existing pharmacies in Dutch Harbor and it was stated one Alaska Native pharmacy exists there. The vessel crew claims that facility cannot provide them with what they need and therefore they do not consent to using it. Mr. White stated this type of transaction may be loosely based on Maritime Law and the Coast Guard may be able to assist.

Ms. Carter was informed that minimally, the pharmacy must be licensed in order to ship medications to Alaska. Further, the Board of Pharmacy does not have jurisdiction over the other prescribing boards. Beyond that, the course of action to be taken would be determined by the DEA headquarters.

Automatic Dispensing Systems (ADS): Mr. Sanchez stated when the DEA refers to *Automatic Dispensing Systems* they are primarily referring to ADS in Long Term Care Facilities that are serviced and controlled by "home" pharmacies, including the necessary documentation such as 222s and in invoice for CS III - Vs. When this

process is done according to regulations, the machine is licensed by the DEA and has its own unique DEA number in order to comply with their regulations requiring DEA registration for every location that dispenses Controlled substances. Mr. Sanchez agreed to forward a summary of this to the board members

Ms. Carter added the DEA also allows ADS in telepharmacies. Mr. Holm replied there are only two remote pharmacies licensed in Alaska: Alicia Roberts in Craig/Klawock and Safeway in Ketchikan. The former is the only one that is operational. The other Alaska telepharmacy ADS Ms. Carter referred to are likely to be property of Alaska Native health care facilities.

Mr. Sanchez then addressed four problematic areas related to Alaska Remote Pharmacy Regulations and facilities.

1) 12 AAC 52.425 (h) "*Under a telepharmacy system a prescription drug is considered as being dispensed by the central pharmacy and distributed by the remote pharmacy"* is contradictory to federal regulations because each separate location, meaning the remote pharmacy and the central pharmacy, must both be registered with DEA. The transfer is then done on 222s and invoices.

2) In practice, the Central Pharmacy in Sitka is repackaging, relabeling and sending medication to the Alicia Roberts Remote Pharmacy in Craig. It is routed from Sitka DEA number to the Remote Pharmacy DEA number. However, DEA regulations require a manufacturer's license to repackage, relabel and distributing controlled substances to another registrant. He used the wholesaler Cardinal as an example, stating they can only send you a stock bottle. They cannot repackage and relabel the medications because they are not licensed as a manufacturer. The Sitka/Alicia Roberts is further complicated by 12 AAC 52.425 (e), which states the remote pharmacy can only acquire its drugs from the central pharmacy. Technically, the central pharmacy can only distribute a stock bottle to the remote pharmacy. They cannot, for example, repackage or relabel medications to sixteen count or thirty count.

3) Documentation: The proper DEA documentation is not occurring between the Central and Remote Pharmacy.

4) Access: The staff at Alicia Roberts has also accessed controlled substances from the Pyxes machines inside the pharmacy after the pharmacy is closed. There is also a Pyxes machine outside of the pharmacy at the Alicia Roberts facility. Mr. Sanchez stated Pyxes machines that are outside of a pharmacy and grant access to Controlled substances when the pharmacy is closed are designed for tele-hospitals

Mr. Sanchez stated there are licensing, record keeping and regulatory issues with remote pharmacies in Alaska. He acknowledged the content of 12 AAC 52.425 (j), which states the central and remote pharmacies must be in compliance with all laws governing the practice of pharmacy, but added current Alaska remote pharmacy regulations are contradictory to federal law.

In response to a question from Mr. White, Mr. Sanchez explained DEA registration is done under two general classifications: pharmacy or hospital. They typically mirror the licensing classification of the state, but have no equivalent to a remote pharmacy. The Alicia Roberts Medical Center is registered with the DEA as a hospital clinic. This, according the DEA, allows them to have a pharmacy and fill medical orders among other things. He added most remote pharmacies in other states are DEA classified as a pharmacy. They comply with all requirements, do not repackage or relabel and "when the pharmacy is closed, it is closed."

Ms. Carter stated the Alicia Roberts Remote Pharmacy needs to change its DEA registration to become licensed as a pharmacy, not a hospital clinic, to operate as intended. The only way they should have been licensed as a hospital clinic with the DEA was if Alaska licensed them as a hospital clinic. She and Mr. Sanchez acknowledged the resolution of this circumstance belongs to the DEA.

In response to questions, Mr. Sanchez stated he has been on site twice at Alicia Roberts and informed them of their federal violations. Ms. Carter said the DEA is approving ADS at telepharmacies where technicians get the drugs from the ADS and give them to the patient. The village clinics need to be registered with the DEA. "They have drugs. They need to be registered with the DEA." This is what is occurring in other states at native and tribal locations and the DEA will allow this same in Alaska.

Ms. Vellucci said she understood that a pharmacy had to be licensed with the state in order to be licensed by the DEA. Ms. Carter said some facilities here are claiming federal exemption. A board member replied Alaska Native Health Care facilities have been required to be state licensed since an AG opinion was issued to this effect in 1992. Ms. Carter was provided with a copy of the 92 opinion. She stated when Alaska decides to enforce it, the DEA will require a state license for their registration. She was informed the 92 opinion is valid now and used as criteria by investigations. It is undergoing an additional layer or scrutiny at the AG's office. The final opinion in response to the review is tentatively scheduled to be announced at the February 2012 Board of Pharmacy meeting. Ms. Carter stated Indian Health Service is not exempt from federal DEA requirements.

Mr. Holm said Community Health Aides would need to become licensed as Pharmacy Technicians. The pharmacy technician licensing requirements were summarized, noting licensure does not require academic or experiential certification.

Ms. Carter clarified the DEA does not register Pyxes machines in hospitals, only the ones in Long Term Care facilities that are being operated by pharmacies. Pyxes machines are covered by the hospital DEA registration, as long as they are located at the same location as the hospital.

Mr. Sanchez said the DEA did a site visit to an Alaska clinic that has an InstyMed machine in a public, common area. Patients independently access medications from the machine which contains controlled substances. The practitioner and InstyMeds are both registered, separately, with the DEA as required. However,

the DEA requires the dispenser of controlled substances to initial DEA documents. A violation exists because there is no dispenser in this scenario, given the machine dispenses the medication. Also, an ADS does not meet the federal definition of "dispenser." A Washington clinic opted not to have controlled substances in its ADS and arranged for authorized staff members to enter the code in the machine and hand dispense the medication to the patient. If this clinic were to have controlled substances, the DEA would accept that arrangement. Interestingly, he noted, the InstyMeds advertising promotes the "convenience" of a patient being able to access medications independently.

Mr. Holm described the efforts between the Board of Pharmacy and the Medical Board regarding ADS and the related request for a definition of "physician dispensing." Ms. Vellucci stated she attempted to schedule time for Medical Board and Pharmacy Board members to meet on this subject in May 2010 because their board meetings were scheduled the same days in Anchorage. Unfortunately, there was not time in their agenda. Ms. Carter stating she was planning to contact Ms. Stovern at the Medical Board to begin working through this subject.

Ms. Gruening asked how InstyMeds gets their inventory. Mr. Sanchez replied RedPharm Drug, a licensed distributor, sends stock bottles to a different company that repackages and relabels the drugs. That company then sends the drugs to the DEA-registered entity with the InstyMed machine. In other words, that company sells it to the practitioners.

Ms. Carter stated the insurance billing for medications dispensed from a physician's office is commonly done incorrectly. The practitioner purchases the stock bottle from wholesaler. Medication is dispensed from the clinic in an ADS. Typically the clinic bills the patient's insurance as if the medication was dispensed from a pharmacy, not based on the fact it was dispensed in a physician's office. There are fine distinctions based on the presence or absence of a complete, legitimate prescription. Mr. White commented if a legitimate prescription is written and the practitioner bills an insurer, the practitioner is practicing pharmacy and in violation of Board of Pharmacy regulations. Mr. Holm added

this also presents a financial gain ethical issue among practitioners using ADS because they are monetarily compensated for the medications they prescribe. Ms. Carter agreed. She stated the cleanest way for a practitioner to prescribe medications is to write a prescription, copy it for the record then give it to the patient to be filled at a pharmacy. Mr. Sanchez stated insurance auditors are starting to catch on to this and Mrs. Carter said she is referring this to HHS (Health and Human Services).

Medical Marijuana: Mr. Holm recounted the history of the board's goals and efforts regarding the creation of statutes and regulations for the safe dispensing of medical marijuana in Alaska. Ms. Carter said a pharmacy would have to be federally registered to carry medical marijuana. It is a schedule I and the DEA only issues registrations for schedules II through V. A petition to move it to schedule II was denied in June 2011. Even if Alaska did issue licenses for medical marijuana, the DEA would not allow them to carry it.

There was discussion about medical marijuana laws in other states. Ms. Vellucci offered to route to Ms. Carter and Mr. Sanchez the detailed summary of the project that was originally created for the AkPhA Board of Directors.

Ms. Carter stated the issue of whether or not a pharmacist can or cannot add a DEA number was discussed among a group of DEA supervisors on September 9th. The conclusion was if the state law allows the DEA number to be added to a prescription, the pharmacist may add it.

Agenda Item 11 AkPhA Report

Nancy Davis joined the meeting. She stated AkPhA would have any necessary back up data for CE Audits that may not be viewable on the CPE Monitoring Program. She and Ms. Vellucci agreed to talk further about this. She provided the members with information about 2012 scholarships and continuing education courses. The next National Take Back Day is scheduled October 29th and collection sites can be found on the DEA website at www.dea.gov. The dates for the 2012 Annual Convention are

February 17-19 at the downtown Marriott. There was discussion about the job shadowing regulations as it pertains to a pharmacist career preparation request initiative Ms. Davis received from the Anchorage School System. Mr. White suggested a mock lab may be a solution for the program design. She will forward the request to Ms. Vellucci for review.

Break: Off record at 4:05 p.m.
On record at 4:19 p.m.

Agenda Item 12 License Applications

The board reviewed the pharmacist license application for Ashley Hall. The application was tabled in July 2011 to review her pharmacist work experience and determine if it meets the definition of "pharmacy practice." Ms. Hall was available telephonically if needed.

Upon a motion duly made by Ms. DeVito, seconded by Mr. Kim and approved unanimously, it was

> **Resolved to approve the pharmacist license application for Ashley Hall.**

The board members then reviewed other pending applications.

Upon a motion duly made by Mr. White, seconded by Ms. Gruening, and approved unanimously, it was

> **Resolved to approve the pharmacist license application for Katherine Anderson.**

Upon a motion duly made by Mr. White, seconded by Ms. Gruening, and approved unanimously, it was

> **Resolved to approve the pharmacy technician license application for Geralbert Barros.**

Upon a motion duly made by Ms. DeVito White, seconded by Ms. Gruening, and approved unanimously, it was

Resolved to approve the pharmacist license application for Alicia Wells.

The board members then reviewed and approved routine license applications and collaborative plan applications.

Upon a motion duly made by Mr. White, seconded by Ms. DeVito, and approved unanimously, it was

Resolved to approve the Fred Meyer Collaborative Practice applications as read into the record.

Agenda Item 13 Technician CE Audits

The board reviewed Continuing Education audits for pharmacy technicians.

Upon a motion duly made by Mr. White, seconded by Mr. Kim, and approved unanimously, it was

Resolved to approve the continuing education audits as read into the record.

The board recess at 5:05 p.m.

Friday September 16, 2011

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:04 a.m. Those present constituting a quorum of the board, were:

Anne Gruening, Public Member
Richard Holm, R. Ph.
C. J. Kim, R. Ph.
Ted Mala, Public Member
Dirk White, R. Ph.

Absent: Lori DeVito, R.Ph.

Present from the Division of Corporations, Business and Professional Licensing were:

Mary Kay Vellucci, Licensing Examiner

Review of Agenda

Mr. Kim stated the board needed to finish the discussion about adding DEA numbers to allowed changes to CS II prescriptions. Mr. Holm added this topic to New Business. Pending items for the PDMP were the Resolution for Advisory Committee, review of draft regulations regarding the two year data purge and procedures to contest information provided in a patient profile. Time permitting, the members would revisit the topic of ADS.

Upon a motion duly made by Mr. White, seconded by Mr. Kim, and approved unanimously, it was

Resolved to approve the agenda as amended.

Agenda Item 11 New Business

Intern Questionnaire: Mr. Kim and Mr. White recently participated in creating new questions for the MPJE. The workshop provided training related to psychometrics. They advised no true/false questions. There was discussion about the purpose and integrity of the questionnaire. Options discussed regarding the management of the questionnaire were:

- Notify the preceptor (aka sponsor) of the intern's incorrect answers on the questionnaire, and ask the preceptor review that content with the intern during the rotation.
- Create multiple questionnaires.
- Place the questionnaire at a secure location on the Board of Pharmacy website. This would be more efficient for all involved and better maintain its integrity. Ms. Vellucci agreed to consult IT at the division about this prior to the next board meeting.

The members commented initiatives such as these convey the board's involvement and commitment to the professional development of interns and preceptors.

Mr. Holm stated interns come to their rotations with a packet of information about their clinical rotations including comments from previous preceptors. Interns are supposed to show the packet to their preceptors at the beginning of their rotations, although frequently they do not offer this unless they are asked.

The members agreed to create ten questions for the intern questionnaire prior to the next board meeting, keeping in mind the

purpose is to teach interns how to read the Alaska regulations and locate information. Public members were asked to create questions from the perspective of a consumer, highlighting the aspects of the regulations that are meaningful to them and represent the consumer/patient perspective. Ms. Vellucci will provide the members with notes about regulations that changed since the questionnaire was last reviewed. The members were asked to submit the new questions to Ms. Vellucci three-four weeks prior to the next board meeting so they could be routed in the board packets.

Mr. Holm provided further information about the testing requirements for intern and pharmacist license applicants for the benefit of the new members.

Intern Application Regulations: The board members reviewed *12 AAC 52.120 Review of Pharmacist Intern License Application* in response to apparent misunderstandings among licensees and preceptors about the necessity for an intern to have an assigned preceptor at each and every location where the intern works, regardless of whether s/he is interning for wages or as an educational requirement. Mr. Holm described a situation that occurred in Fairbanks last year to illustrate this point. He said the misunderstanding was due, in part, to the fact that the intern licenses are issued for two years and at the time of initial licensure they have a sponsor. The board's intention, and the intention of the existing regulations, is for all interns to have a preceptor at all times. The board agreed to amend the regulation to reflect that.

The board then discussed the language in the regulation addressing the educational requirement for an intern license:

12 AAC 52.120 (a) A pharmacist intern license will be issued to an applicant who (3) has (A) completed the third year of a five-year or six-year pharmacy curriculum in a college of pharmacy accredited by the ACPE.

Discussion occurred about accelerated, accredited curriculums which are not congruent with the "five or six year pharmacy curriculum" statement in this regulation. Other variations in pharmacy curriculums at Albany and Philadelphia colleges were noted by Mr. White. Members acknowledged that, theoretically, the completion of the first year of an accelerated curriculum may represent more pharmacy education than completion of the first year of a five or six year curriculum. Ms. Vellucci stated this language frequently creates delays in the intern licensing process because the wording in the Verification of Education form must mirror the regulations. Schools that do not describe themselves as

five or six year programs leave this item blank, resulting in an incomplete application. The board discussed several options for changing this regulation and the implications of each proposed change.

Upon a motion duly made by Mr. White, seconded by Mr. Kim and approved unanimously, it was

> **Resolved to amend 12 AAC 52.120 by adding "(e) An intern must always have a current Alaska licensed pharmacist as a sponsor for each intern work assignment." And amend 12 AAC 52.120 (a) (3) (A) to state "completed the first year of a professional pharmacy curriculum in a college of pharmacy accredited by the ACPE."**

Collaborative Practice Plans: Ms. Vellucci pointed out 12 AAC 52.240 Pharmacist Collaborative Practice Authority (g) requires any change in a Collaborative Plan to be approved by the board prior to implementing the change. This also applies when the only the principal pharmacist changes, due primarily to staffing changes. However, a change in the Pharmacist in Charge requires board notification within ten days.

A lack of continuity of care and interruption in services occurs while a new Collaborative Practice Application is being drafted and routed for board approval due to only a change in principal pharmacist. A recent example of this was further complicated by the fact that the existing, approved Collaborative Practice Application was not at the facility for the new principal pharmacist to review. Instead, it was on file in the out of state corporate office.

Ms. Vellucci informed the board there was not a regulation that would prohibit the board from imposing a fee for Collaborative Practice Applications. The members agreed this was reasonable. They were informed the Licensing Supervisor suggested twenty five dollars per application. Mr. Kim asked about the difference between a new Collaborative Practice Application and a renewal. Ms. Vellucci said there was essentially no difference in the amount of work between them and explained the reasons why this is so. The current fees for a Change in the Pharmacist in Charge were then discussed.

Upon a motion duly made by Mr. White, seconded by Mr. Kim and approved unanimously, it was

> **Resolved to amend 12 AAC 52.240 Pharmacist Collaborative Practice Authority by adding "a signed copy of the approved**

Collaborative Practice Application and protocols must remain at the location at all times." Also add "The board must be notified within ten days of a change in the Principal Pharmacist." Also add "A change in Principal Pharmacist only will not require the submission of a new Collaborative Practice Application or board approval prior to implementation." Also add "the fee for a Collaborative Practice Application or Renewal is $50" and "the fee for a change of principal pharmacist in a Collaborative Practice Plan is $25."

Upon a motion duly made by Mr. White, seconded by Mr. Kim and approved unanimously, it was

Resolved to amend 12 AAC 52.200 by adding "the fee for a change of pharmacist in charge is $25."

Agenda Item 5 Regulations (continued)

Pharmacist Allowed Changes to Schedule II Prescriptions: Mr. Holm described recent regulations, effective September 17, 2011, which lists the changes a pharmacist can make to schedule II prescriptions. It was brought to the attention of the board the list does not include adding the prescriber's DEA number. Ms. Carter statements from September 15th were repeated, specifically, this issue was discussed among a group of DEA supervisors on September 9th. The conclusion was if the state law allows the DEA number to be added to a prescription, the pharmacist may add it.

Upon a motion duly made by Mr. White, seconded by Ms. DeVito, and approved unanimously, it was

RESOLVED to add "DEA Number" as 12 AAC 52.460 (c) (7)

Automatic Dispensing Systems: Further discussion tabled until next board meeting.

Break: Off record at 10:30 a.m.
On record at 10:43 a.m.

Agenda Item 12 Correspondence

NABP

- *2011 MPJE State-Specific Review*: Previously discussed.

- *Iowa Drug Repository Program*: The chair asked for this information to be routed to the Department of Law to determine if the Board of Pharmacy would have statutory authority to implement a project such as this.

General, no discussion

- *Report of Theft or Loss of Controlled Substance*: SEARHC, Juneau.
- *Reverse Distributors Inquiries:* Provided to board members to illustrate new trends in correspondence being received at the division. The Alaska board currently has no regulations addressing this.
- *Nuclear Pharmacies Inquiries*: As above.

General, Reply Requested:

- *Samuel Simmonds Memorial Hospital* requested an exception to the 3 day medication supply rule for suspension-formulated antibiotics. The board would not grant this exception, but suggested the situation can be resolved by entering into an agreement with a Fairbanks pharmacy to provide Remote Pharmacy Services. Mr. Holm stated he was willing to discuss this directly with the person who inquired. Members said other factors that may enter into this were the configuration of their outpatient pharmacy services, the hours of the pharmacy and the utilization of their Pyxes machine.
- *Deb Hansen, Providence Alaska Medical Center:* Requested an exception to allow the use of expired medications during a shortage. The board members would not go on the record as authorizing the use of expired medication.
- *Peer Recovery Network:* Mr. White suggested this be referred to the state association.
- *Fairview Health Services re Medication Therapy Management Services*: The board members confirmed a pharmacist must be Alaska-licensed to perform this service. The scope of services from the Alaska-licensed pharmacist must be evaluated to determine if they are actually Shared Pharmacy Services. Mr. White and Mr. Holm said if the pharmacy is being reimbursed for the service, they should be licensed as a Shared Pharmacy assuming they meet the other regulation critiera.
- *Inquiry re Investigational Drugs:* The board of pharmacy has no regulations restricting the use of investigational drugs. The facility in question is licensed by the board as an out of state pharmacy.

After all correspondence was reviewed, the members had a general discussion about their range of statutory in relation to other states. The board cited risks to public health and safety which exist

because they do not have adequate purview over all medications in the state, regardless of their location. For this reason, they asked for the following question to be referred to the Department of Law:

"What would it take for the Board of Pharmacy to have control over all medications in the state, regardless of their locations?"

Agenda Item 18 Office Business

Election of Officers: The members agreed Board of Pharmacy officers will remain the same in the coming year.

Upon a motion duly made by Mr. White, seconded by Mr. Mala, and approved unanimously, it was

Resolved to retain the same Board of Pharmacy Officers during the next year.

*Fourth Board Meeting***:** Mr. Holm said statutorily a fourth board meeting is allowed. The funding for this was requested in the Annual Report. The members agreed a fourth board meeting is necessary to conduct PDMP board business. They do not have adequate time to deliberate matters before them during a meeting, as illustrated by the number of topics that are tabled due to time constraints. The need for a fourth meeting is also justified by the number of teleconferences with more than one agenda item that occurred in the past calendar year. They agreed the spring meeting would be held in Juneau so board members would have the opportunity to meet with legislators.

Upon a motion duly made by Mr. White, seconded by Mr. Mala, and approved unanimously, it was

RESOLVED to seek final approval to fund four Board of Pharmacy meetings per year.

Board Meeting Schedule: The following tentative schedule was agreed upon by the board members:

- November 17-18, 2011: Anchorage
- February 16-17, 2012: Anchorage
- April 19-20, 2012: Juneau
- August 23-24, 2012: Anchorage
- November 15-16, 2012: Anchorage

State Convention: Mr. White initiated a discussion about acquiring funding approval for the licensing examiner to participate in the Alaska Pharmacist Association Annual Convention in Anchorage on February 17-19. He stated it is beneficial to her because it educates her about multiple aspects of the practice of pharmacy. It is helpful to licensees and colleagues because she answers questions and provides them with information.

Upon a motion duly made by Mr. White, seconded by Mr. Kim, and approved unanimously, it was

RESOLVED to request funding for the licensing examiner to attend the 2012 Alaska Pharmacists Association Annual Convention in Anchorage after the February, 2012 board meeting in Anchorage.

Wall Certificates and Travel Authorizations were signed.

Agenda Item 13 Pharmacist Continuing Education Audits

The board members reviewed approximately 150 pharmacist continuing education audits.

Upon a motion duly made by Mr. White, seconded by Mr. Mala, and approved unanimously, it was

RESOLVED to approve the pharmacist continuing education audits as read into the record.

The meeting was adjourned at 1:15 p.m.

Respectfully Submitted:

_____
Mary Kay Vellucci,
Licensing Examiner

Approved:

Dick Holm, Chair
Alaska Board of Pharmacy

Date: _____