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
May 20-21, 2010

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 May 20-21, 2010 at the Atwood Building, 550 West 7th Ave., Suite 602.

Agenda Item 1 **Call to Order/Roll Call**

The meeting was called to order by Dick Holm, Chair at 9:03 a.m. Those present constituting a quorum of the board, were:

Anne Gruening, Public Member
Leah Handley, Public Member
Richard Holm, R. Ph.
Mary Mundell, R.Ph.
Dirk White, R. Ph.
C. J. Kim, R. Ph.

Absent:

Steven Johnson, R.Ph.

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

Peter Putzier, Assistant Senior AG
Mary Kay Vellucci, Licensing Examiner
Brian Howes, Chief Investigator

Visitors present:

Ron Miller, RPh, Safeway
Nancy Davis, AkPha

Agenda Item 2 **Review of Agenda**

The board reviewed the agenda. Items number four and ten were switched to accommodate Kathy Mason's schedule. Mr. White requested his role as the Alaska Delegate to the NABP Annual Meeting be added to the agenda. Mr. Holm reviewed this briefly with the group and they unanimously consented. Mr. Holm and Ms. Vellucci signed Mr. White's travel grant application for the NABP Annual Meeting.

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

RESOLVED to approve the agenda as amended.

Agenda Item 3 **Review of Minutes**

The board reviewed the minutes from the February 18-19, 2010 meeting. Two typing errors were pointed out by Ms. Handley and no other corrections were made

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

RESOLVED to approve the minutes of the September 24-25, 2009 Pharmacy Board Meeting as amended.

The board reviewed the minutes from the teleconference on April 2, 2010. No changes were made.

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

RESOLVED to approve the minutes of the April 2, 2010 teleconference.

Mr. White said he wanted to add the Reinstatement of Expired Pharmacist Licenses to the agenda for the September meeting.

Agenda Item 4 **Ethics Disclosure/Goals and Objectives**

There were no ethics violations to report.

Mr. Holm asked Ms. Gruening if she had an opportunity to watch the Ethics Video. Ms. Vellucci agreed to resend the link to the Department of Law to Ms. Gruening so she can watch it prior to the next board meeting.

Mr. Holm agreed with the unanimous opinion of the board, noted in the February 2010 meeting, that Ms. Handley's possible future work as a Certified Nurse's Aide did not conflict with her role as a Public Member to the Board of Pharmacy. Ms. Handley stated she would go to Boards and Commissions to further this effort. Mr. Holm stated it may be possible to acquire a waiver for Ms. Handley to continue to fill this role with her current certification.

The board noted the goals and objectives and made no changes.

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.

Agenda Item 4 **<u>Medical Marijuana</u>**

The board discussed the similarities and differences among the fourteen medical marijuana programs which enacted laws to legalize medical marijuana, as outlined by ProCon.org. Mr. White provided general pharmacology education regarding medical marijuana and its derivatives in response to a comment from Ms. Handley.

Mr. Holm stated

"*Alaska law permits use of marijuana for certain medical needs. Legal users are issued an identification card which is required to be carried and present when using or possessing. This also applied to the caregiver of the patient. Although it is legal for medical use, there is no provision for obtaining the drug legally and no provision existing to ensure safe, clean reliable sources. Federally, the DEA, last year, announced they will no longer be enforcing medical marijuana issues. That being the case, it would appear a logical and necessary step for the State of Alaska to set up a means of handling and regulating this legal use to ensure safety, purity of product, standardization of potency and a reliably available legal source. Revenues could be realized to offset any costs for this service through licensure and also taxation of product."*

Availability would be realized through licensed, approved growers within Alaska. Growers would be required to be licensed by the Board of Pharmacy, obtain a manufacturer's license, obtain wholesale drug license, provide security as set forth by state and federal law and provide record keeping including quantities and weights as set forth by state and federal law. These obligations applied from beginning to end, "from seed to the finished product." Growers would need to work with and cooperate with the DEA, maintain Quality Assurance including lab testing of all lots, be at least partially owned by a licensed pharmacist and be overseen operationally by the same. The number of facilities to be licensed would be determined by region to minimize shipping distances. Medical marijuana would be treated as a Class III controlled substance or possibly Class IV, like marinol. He stated a prescription would be required and five refills in a six month period seemed to be reasonable parameter. The growing facility would be expected to develop a commercial product including properly labeled packaging according to FDA regulations and product distribution to retail outlets. Retails outlets would be licensed pharmacies only. The motivation to move this project forward, he said, was to avoid problematic situations, such as those in California. He noted "California's SB 420 also grants implied legal protection to the state's medicinal marijuana dispensaries and that's where they're running into problems… other states don't have that."

Mr. White said Maine started a state licensing task force in January of 09 and it would be beneficial to know its outcomes so Alaska would not need to "reinvent the wheel."

Mr. Holm said if the board wanted to pursue this we would need to convince the state legislators it was necessary and take the Montana position i.e. keep the entire process entirely within the State of Alaska "from grower to end user, from seed to consumption." Mr. White added under the constitution it was a state's right issue. He asked if this would be done by statute or by state regulation. Mr. Holm stated the board would be writing regulations for the statutes that exist unless the AGO determined the board would need to address the grower, specifically to allow that by law, or other issues.

Ms. Vellucci asked if the intention was to accept other state's registry. The answer was "no" because the intent was to keep the entire process within the state of Alaska. Mr. Holm added it would be helpful to have an AG opinion about accepting out of state registries to determine if that would put the board at federal risk. Ms. Mundell stated the prescriber needed to have a long, face to face, established relationship with the patient to prescribe medical marijuana, as with other prescriptions. The prescriber would need to thoroughly identify the diseases, conditions and history of the patient which indicated medical marijuana was an appropriate treatment.

Ms. Mundell stated physician training in the appropriate use of medical marijuana was warranted. This may be statutory in nature because the Board of Pharmacy cannot direct the Medical Board. Mr. Holm commented requiring this initially would slow the process, although it could be done separately through the Medical Board. Mr. White likened this recommendation to the additional prescriber registry required for a suboxone prescription.

Mr. Holm asked the board if there was consensus among them to pursue this project, as outlined in the discussion. The unanimous consensus of the board was to get the medical marijuana regulations in place first and then lobby the medical board on the point made by

Ms. Mundell. All members agreed to pursue this regulation project. The next step was to provide the board meeting minutes to the Regulations Specialist, the goal being creation of draft regulations prior to the September board meeting and then review by the Department of Law.

A number of board members agreed the current possession limit for medical marijuana was too low. Mr. White stated several medical marijuana patients (who grew their own marijuana according to law) told him the low plant number limit, combined with the time it took to grow from seed to maturity, made it necessary for them to purchase marijuana from the street.

Agenda Item 5 **Legislative Update**

Mr. White informed the board the Sunset Bill passed, extending the Board of Pharmacy until 2018.

The board reviewed the list of legislative bills in the board packets and noted all expired.

Ms. Mundell stated she re-read the information regarding the Pharmacist's Right of Conscience from the February board meeting. She noted it banned discrimination against a pharmacist who practiced according to the proposed legislation. However, a pharmacist or pharmacy owner that did not agree could not discriminate against a pharmacist who did. She made the point the legislation needed to be non-discriminatory across the board.

The board discussed the PBM Bill and encouraged its re-introduction in the next legislative session. The board also fully supported the state association's continued lobbying efforts toward that end.

Agenda Item 6 **Regulations**

Job Shadowing: The board was extremely pleased with the quantity and quality of public comments received on this topic and encouraged continued interaction from those practicing in the profession. Each comment was reviewed and a list of edits to the proposed regulation was created. Edits to the regulations would be entered prior to the May 21st board meeting and the topic would be revisited.

Break: Off the record at 10:16 p.m.
On the record at 10:36 p.m.

Temporary Pharmacist Licensing: The board reviewed the memo dated May 6, 2010 from Ms. Vellucci which described why the current regulation was obsolete and the consequences of its existence in the statutes and regulations. The board then reviewed the pharmacist licensing requirements individually to determine if any requirement could be modified to issue a temporary license. The timeliness of receipt of licensing items had greatly improved since the regulation was originally created over ten years ago, largely due to significant improvements in technology and communications. The board concluded there was no specific licensing requirement which consistently created a delay and all required items needed to be on file before a license could be issued.

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

RESOLVED to repeal 12 AAC 52.100, Temporary Pharmacist License in its entirety and repeal its correlating references in 12 AAC 52.010 Classification of Licensure (a) (2) and 12 AAC 52.090 Examination Requirements and Registration (2) (b)

Agenda Item 7 **New Business**

Federal Changes to CS II Prescriptions: The board discussed the DEA's Interim Final Rule for electronically prescribed controlled substances and the article addressing changes to Schedule II prescriptions written by Mr. Johnson in the April, 2010 edition of the Alaska State Board of Pharmacy Newsletter. Obstacles to implement the DEA Final Rule were cited. It was noted the board has no purview over the DEA rules. The Alaska Board of Pharmacy regulations on controlled substances were also reviewed. The board agreed they could provide clarification on changes which can be made to Schedule II prescriptions and listed them as follows:

"A pharmacist can modify or add the following information to Schedule II prescriptions after oral consultation with the prescribing practitioner (not his agent):

- Date of issue – may be added but not changed
- Patient's address
- Drug strength
- Drug dosage form
- Drug quantity – may be modified in conjunction with change in strength only, but not to exceed the original total dosage prescribed
- Directions for use

A pharmacist may never change the name of the drug (except to generic), name of the patient or the signature of the practitioner."

The board requested this information be routed to the Regulations Specialist to incorporate into a draft revision of the controlled substances section of the Statues and Regulations. Ms. Mundell and Mr. Holm then explained how clarifying changes to Schedule II prescriptions would also circumvent potential reimbursement problems with PBMs and insurance carriers.

The board agreed the DEA needed to clarify their rules for electronic prescribing. Until that time, the board could only clarify changes to CIIs in an attempt to assist pharmacy practitioners in Alaska.

Mr. White added e-prescribing technology typically routed a prescription to a default pharmacy, which is often not the pharmacy chosen by the patient. He described the subsequent adverse consequences for the patient as well as the preferred pharmacies and stated the DEA should correct this element as they work through the e-prescribing procedures.

Agenda Item 9 **MPJE Item Writing**

The board reviewed the NABP's Alaska 2010 MPJE Item-Writing Assignment and the MPJE IWW Booklet from March 2010. They stated for the record they were satisfied with the Alaska MPJE as it was and would submit new questions when the regulations in Alaska change.

Ms. Handley exited at 11:20.

They noted Alaska regulations had less volume than other states. They suggested the NABP be informed of this after the draft minutes are approved.

Ms. Handley returned at 11:25.

Agenda Item 8 **Licensing Federal Facilities**

Mr. Holm introduced Mr. Putzier and informed the board his purpose was to acquire background information from the board pertaining to the pending opinion from the Department of Law regarding licensing of federal facilities by the Alaska Board of Pharmacy.

Mr. Putzier stated his efforts focused on background research due to the complexity of the issue and the extensive history. He researched the relevant state regulations and national legislation. He interviewed representatives from other agencies and facilities to determine how their roles interfaced with the larger question at hand.

Upon a motion duly made by Ms. Mundell, seconded by Ms. Handley, and approved unanimously, it was

> **RESOLVED to go into executive session in accordance with AS 44.62.310 (4), to discuss matters involving consideration of government records that by law are not subject to public disclosure.**

Board staff to remain during executive session.

Off the record at 11:44 a.m.
On the record at 12:19 p.m.

Lunch: Off record at 12:20 p.m.
On record at 1:35 p.m.

Agenda Item 10 **Expense Report**

The board reviewed the Expenditure and Revenue Report as of May 7, 2010 and 12 AAC 02.310 Board of Pharmacy Fees. The board expressed concern over limiting the allowed surplus of funds because it did not permit saving for anticipated litigation or other unplanned expenses.

Agenda Item 11 **Correspondence**

The board discussed the items in the correspondence section of the board packets.

NABP March 18, 2010 NABP Role in NPDB Reporting: No action required.
March 7, 2010 District 7 Meeting Location: No action required.

Other March 19 & 22, 2010 CVS Correspondence Re Shipping Errors: No action required
February 5, 2010 Walgreen Report of Theft/Loss: No action required.
February 5, 2010 Soldotna Professional Pharmacy Report of Theft/Loss: No action required.
February 8, 2010 Soldotna Professional Pharmacy Report of Theft/Loss: No action required.

May 1, 2010 InstyMeds Pamphlet/Pharmaceutical Vending Machines*:* Mr. Miller stated he had multiple phone calls from patients requesting refills and transfers of prescriptions that were originally dispensed from pharmaceutical vending machines. Other pharmacists stated they have received similar requests. Mr. White stated *Envisions* website advertised a facility with a vending machine as having a pharmacy. Mr. Miller described questionable representation from Medco along these same lines. Regulations clearly state a facility or provider cannot legally represent themselves as having a pharmacy or pharmacist based solely on the presence of a pharmaceutical vending machine. Several other violations based on pharmaceutical vending machines were identified from locations in the Anchorage, Mat-Su region. Mr. Kim showed the board a confidential antibiotic prescription. On it, the sig read "one for ten days." The physician did not write quantity to be dispensed as ten. He wrote it as thirty because the vending machine only contained this antibiotic in thirty-unit increments. Therefore, the patient received three times the amount of medication prescribed to accommodate vending machine parameters. Finally, it was noted by several board members that the Securities and Exchange Commission stated a physician cannot "refer to him/herself for financial gain." The use of pharmaceutical vending machines in a physician's office was an infraction of this SEC regulation. Several board members noted controlled substances were contained in some vending machines. Mr. Howes, Chief Investigator, who was present during this entire discussion, asked if the DEA was aware of this. Ms. Vellucci informed the board she scanned a copy of the *InstyMeds* pamphlet to the director of the Medical Board and the reply essentially stated the medical board historically had no negative reaction to them. Ms. Mundell stated this reaction was likely to be based on the concept of "physician dispensing." Mr. White cited 08.80.410 "*Use of the Term 'Pharmacist' Prohibited: A person may not assume or use the title 'pharmacist,' or any variation of the title, or hold out to be a pharmacist, without being licensed"* and Section 08.80.420. "*Certain Advertising Prohibited: (a) A person may not use or exhibit the title 'pharmacist,' 'assistant pharmacist,' or 'druggist,' or the descriptive term 'pharmacy,' 'drug store,' 'drug sundries,' or other similar title or term containing the word 'drug,' in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.*"

It was decided a letter from the Board of Pharmacy would be written to the Medical, Nursing and Dental Boards with copies to Dan Brown at the Department of Law, Terry Marquardt at

the DEA and the Investigative Staff. The letter was to outline the statutory instances of illegalities resulting from the use of pharmaceutical vending machines and inquire about numerous questionable practices related to their employ. Clinics and facilities with these devices would be identified by the Investigative Staff and informed they are to cease and desist from continued statutory violations. Ms. Vellucci will construct the letter for review, edits and approval by the board.

Agenda Item 12: **Prescription Drug Monitoring Program**

Mr. Howes reported the RFP was done and the contract went out for signature to RelayHealth McKesson NDC Health Corporation. He projected there should be sufficient funds to operate for four years. All pharmacies would be required to submit data on a monthly basis. The goal was to begin implementation in January 2011 with testing of systems in July 2010. RelayHealth had been doing this in other states and therefore the technical implementation should have minimal flaws. Draft regulations with corrections to Article 9: Controlled Substance Prescription Database were distributed by Mr. Howes. The Division and the contractor would construct the application referenced in 12 AAC 52.855 (1) which would be accessed as an online document. Mr. White asked about the content of the application. Mr. Howes stated the application was primarily directed toward verification of identity, licensing and registrations to confirm the applicant was eligible to participate in the program. The board would review the distributed corrections to Article 9: Controlled Substance Prescription Database and the PDMP conversation would continue on May 21.

Agenda Item 11: **AkPhA Report**

Ms. Davis asked Mr. Howes how Investigations handles requests for an Alaska pharmacist who needed addiction recovery services. Mr. Howes stated this is typically handled on a case by case basis. Mr. Howes added the State Medical Association has their own program. The testing was expensive and the cost was the burden of the (potential) licensee in the case of a person with an MOA who was self reporting or a person who was under disciplinary action. According to Mr. Howes, standard recovery services, such as those for a lay person, were typically not as effective for medical professionals. A better success rate is achieved through recovery programs designed for medical providers.

Ms. Davis distributed a report containing Continuing Pharmacy Education, Legislative Issues, Bylaws Revision and Pharmacy Education Committee update. Statements of credits from AkPhA were mailed in the end of May.

Next year's AkPhA convention will be February 18-20th at the Downtown Marriott. It was likely they will provide the CPR and Medication Management again next year.

SB38 proposed regulation for PBMs did not make it through this session. AkPhA will be getting new sponsors for the next session and re-introducing that legislation. Kathy Munoz may sponsor the bill on the House side. HB235/SB174 for loan forgiveness included pharmacy, dentistry and optometry. This bill provided a support fee, which was basically an Alaska funded loan, for a WICHE-accredited school. This bill is not dead. It is now with the Department of Education. Ms. Davis then related this as a starting point for loan forgiveness and stated with Health Care Reform it was projected the need for pharmacists would increase by 14%. In SB139 died this session. The Alaska Primary Care Association

collaborated with others to construct a loan repayment program. It was a high ticket item and would be reintroduced. It benefited pharmacists licensed in other states who would come to Alaska due to our immediate need for pharmacists.

Brian Schilling is the chair of the Pharmacy Education Committee. Pre Pharmacology classes are now in place at UAA, UAS and UAF. Funding is being sought for an advisor for the Pharmacy Education Program. AkPhA would approach the legislature for this purpose.

The AkPhA modified their bylaws to include a voting Pharmacy Technician to the board of directors and for the past president to also be a voting member.

Introducing AkPhA in the Board of Pharmacy mailings addressed to new licensees was discussed. Ms. Davis and Ms. Vellucci would correspond to that end prior to the next board meeting. Ms. Davis also offered to include news from the Board of Pharmacy on the AkPhA website. She is working with Gateway to establish a web management system that would allow for online payment of fees and convention expenses.

Agenda Item 14 **Public Comment**

Mr. Miller stated the two topics of interest to him, medical marijuana and pharmaceutical dispensing machines, had already been discussed. The board provided him with a synopsis of the previous dialogue.

Break: Off record at 3:10 pm
On record at 3:25 pm

Agenda Item 15 **Licensing Applications**

Ms. Vellucci distributed the License Application List and other files to the members.

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

> **RESOLVED to go into executive session in accordance with AS 46.62.310 (c)(2), to discuss applications and licenses with "yes" answers.**

Board and staff to remain
Off record at 3:27 pm
On record at 3:55 pm

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

> **RESOLVED to deny the pharmacy technician application for Laura Brown under 12AAC 52.140 (2) "certifies that the applicant has not been convicted of a felony or other crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently."**

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

RESOLVED to approve the license applications as read into the record for Interns Jessica Tilbury and Sarah Peitz and out of state pharmacy Snyder Center of Pain Pharmacology.

The board also reviewed and approved three collaborative practice applications and twelve pharmacist applications.

The board recessed until 9:00 a.m. on Friday.
Off the record at 4:23 p.m.

Friday, May 21, 2010

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:10 a.m. Those present constituting a quorum of the board, were:

Anne Greuning, Public Member
Leah Handley, Public Member
Richard Holm, R. Ph., Chair
C. J. Kim, R. Ph.
Mary Mundell, R.Ph.
Dirk White, R. Ph., Vice Chair

Absent:

Steven Johnson, R.Ph.

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

Mary Kay Vellucci, Licensing Examiner
Peter Putzier, Assistant Senior AG
Brian Howes, Chief Investigator
JoAnna Williamson, Investigator

Agenda Item 16 **Review of Agenda**

No changes were made to the agenda.

Agenda Item 18 **CE Audit**

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

RESOLVED to approve the Continuing Education documentation as presented in Case No. 2500-10-005.

This information pertained to pharmacist John Deutsch in response to the random audit of his 2008-2010 license renewal.

Agenda Item 17 **Investigative Report**

Jo Anna Williamson, Board Investigator joined the meeting. Ms. Williamson reviewed the Investigator's Board Report and provided updates on open complaints, open investigations and closed cases. A discussion then ensued about the new investigator hired partially to work "yes" answers on renewals. The revised DOL policy for "yes" answers on renewals was discussed. The board also summarized the previous day's discussion regarding pharmaceutical vending machines for Ms. Williamson's benefit.

Agenda Item 19 **Regulations**

Job Shadowing, continued: Edits to the text for 12 AAC 52.250 were read into the record. The board noted the edits were based entirely on public comments and therefore the hope was the regulation would not need to be public noticed a second time.

12 AAC 52 is amended by adding a new section to read:

12 AAC 52.250 Job Shadowing in Pharmacy. (a) A pharmacist in charge or preceptor
of a pharmacy may allow a student to job shadow in the pharmacy only as specified in this section.

(b)Before a student begins a job shadowing program under this section, the pharmacist in charge or preceptor must obtain a record of the name of pharmacy, name of the student and name of the pharmacist in charge or preceptor in Section A of the Job Shadowing Documentation form. The form must be signed by the pharmacist in charge or preceptor, student and parent or guardian if less than eighteen years old.

HIPPA education, compliance and documentation is the obligation of the pharmacist in charge or preceptor.

(c) A pharmacist in charge or preceptor may not allow

(1) a student in a job shadowing program to

(A) receive any remuneration or other compensation;

(B) perform job shadowing for more than (50) hours;

(C) perform any functions reserved for licensed, certified or registered pharmacy personnel.

(2) a ratio of job shadowing student to pharmacist in charge or preceptor other than one to one.

(d) After completion of the job shadowing program by a student, the pharmacist in charge or preceptor must complete Section B of the Job Shadowing Documentation form which includes the date and time in hours student was present and job shadowing in the pharmacy, any patient counseling observations, problems that may have occurred during job shadowing. The Job Shadowing Documentation form must be kept in the pharmacy record for at least two years after the job shadowing program has been completed.

(e) In this section,
(1) "job shadowing" means <no changes>
(2) "student" means a student who is at least at a high school equivalency level.

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

RESOLVED to approve as so read 12 AAC 52.250 Job Shadowing in Pharmacy.

Break: Off the record at 10:00 a.m.
On the record at 10:17 a.m.

Dan Branch and Jun Maquis joined the meeting via teleconference.

Shared Pharmacy: The board reviewed Steve Weaver's edits for the Shared Pharmacy regulations, dated April 13, 2010 and the text of the seven page regulations. The board emphasized throughout the discussion the intention of the regulations is to keep Shared Pharmacy Services within the state. During the meeting two edits were made to page one of the regulations. In 12 AAC 52.443 (a) "in this state" is to be kept in the regulation. The board also deleted In 12 AAC 52.443 (b) (1) (B) "is registered as an out of state pharmacy under AS 08.80.157." These regulations also contained an addition to 12 AAC 52.460 (a) allowing a faxed prescription to be filled if it is signed by the prescribing practitioner's authorized agent.

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

RESOLVED to accept as revised and edited the amendments to 12 AAC 52.

Remote Pharmacy: The board discussed Mr. Branch's memo of April 20, 2010 describing approaches used by other states. South Dakota required the remote pharmacy applicant to demonstrate there was a need for it. The Iowa regulations provided standards to demonstrate need and put the burden of proof on the applicant.

Ms. Mundell pointed out the board had now come "full circle" in attempts to move this regulation forward. She described how the board, in conjunction with AkPhA members, had formerly created draft remote pharmacy regulations based on a similar model from the NABP. This attempt was ultimately thwarted because attempted definitions for "community" and "limited access" were found to be unacceptable.

Mr. Branch replied this new model may negate the need for those definitions because the board would make case by case determinations of need based on the criteria set forth. Mr. Holm stated this model would require re-evaluating the need for each remote pharmacy during the renewals to determine if the criteria continue to be met.

The board reviewed the draft regulations created in May 09 which referenced the Ten Mile Rule. They were public noticed at the end of August 09. They discussed the possible outcomes of adopting this version and chose that path.

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

RESOLVED to adopt 12 AAC 52.423 Approval for operation of a remote pharmacy, version 5/28/09, without changes.

Note: These same regulations were adopted in September 09. The board wanted them resubmitted to the Department of Law to get their feedback at this point in time.

Prescription Drug Monitoring Program (continued). Mr. Howes joined the meeting. The board had the opportunity to review the 5/18/10 draft regulations provided yesterday by Mr. Howes.

The first question presented was related to waivers. Mr. Howes explained the intention of the waiver was to allow for resolution of technical problems, such as those that may occur in very remote areas. Mr. White stated this sounded like a *temporary* waiver. He also asked for definitions of "low" and "financial hardship." There was discussion about who would pay for technology upgrades if needed to operate the PDMP. Mr. Holm asked how much of the actual data and internal operations of the PDMP were going to be overseen by the board, for example, the approval for various required forms, the data collected and proposed policies.

Dirk White out at 10:35.

Mr. Holm also asked Mr. Howes to define "the agent" referred to in the draft regulations. Mr. Howes explained he would fill that role. The waivers, threshold for action would fall within the investigative umbrella.

Dirk White in at 10:40.

Ms. Mundell explained the ER providers were looking forward to having PDMP information because of frequent patient requests for pain medications. A discussion then ensued about the application and enrollment processes.

Concerns were expressed by board members regarding the parameters for confidentiality of information, issues of privacy, cost and ongoing funding beyond the next four years. Additionally, the board chair stated the program needed to have an established sunset date so its processes and benefits could be re-evaluated. Also, the Board of Pharmacy's goals needed to be more clearly identified prior to activation of the program so implementation, evaluation and reevaluation could be done according to the Board of Pharmacy's objectives. A period of internal audit by the board of pharmacy needed to be established in regulation and provisions for the program impact specifically on the misuse of narcotics needed to be measured. Mr. Howe stated "a type of Advisory Committee" was established in the statute and suggested the board of pharmacy appoint a representative to this committee. He would then approach the Nursing, Medical, Dental and Veterinary Boards to acquire their representatives which would then comprise the Advisory Committee. Ms. Mundell suggested the Advisory Committee be delegated to with the goal setting, internal audit functions and the other concepts previously noted.

Mr. Holm initiated a discussion about oversight of the PDMP. He stated the oversight of the PDMP was intended to be a direct function of the Board of Pharmacy, not Investigations. He did not want the Board of Pharmacy to be used "in name only." Others agreed.

Mr. White stated he did not want the Board of Pharmacy to incur the costs of the program. Mr. Howes stated the user fee was estimated to be $20 per year and the Board itself was not to be charged. A discussion about HIPPA laws and liability occurred. Mr. Howes stated from his research accusations of HIPPA violations were rare among existing PDMPs. This was contradicted by Mr. Holm's mention of the PDMP violations in Virginia. Mr. Howes stated the information provided to him via the PDMP would be no different than what he could acquire at the present time, only the format of the information would vary. He also anticipated the Division of Legislative Audit would approach him when the program was implemented.

Mr. Holm and Mr. White asked how controlled substances dispensed from the offices of dentists, veterinarians, physicians, PAs and ANPs would be accounted for in the PDMP, as well as compounded controlled substances, given that some compounded controlled substance may not have an NDC number. Mr. Howes stated the paper reporting version would be submitted in those cases.

Mr. Howes stated he would make the changes discussed today, including but not limited to sunset clause, advisory committee and internal audit. The board requested to see the revised regulations as soon as they were available and have a teleconference to review them. Mr. Holm stated the board would need to have the meeting minutes, the 5/18/10 draft revisions and the newly proposed regulations prior to a teleconference in order to make informed decisions.

Agenda Item 20 **Office Business**

The board signed the TA forms and wall certificates.
The board adjourned at 10:45 a.m.

Respectfully Submitted:

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Mary Kay Vellucci, Licensing Examiner

Approved:

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Dick Holm, Chair
Alaska Board of Pharmacy

Date:_____