

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

February 18-19, 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 February 18, 2010 at the Atwood Building, 550 West 7th Ave., Suite 1270 and February 19, 2010 at the Anchorage Downtown Marriott, 820 W. 7th Avenue, Juneau Ballroom.

Agenda Item 1 Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:07 a.m. Those present constituting a quorum of the board, were:

Leah Handley, Public Member
Richard Holm, R. Ph.
Steven Johnson, R.Ph.
Mary Mundell, R.Ph.
Dirk White, R. Ph.
C. J. Kim, R. Ph. Entered at 9:10 am

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

Sher Zinn, Records and Licensing Supervisor
Jo Anna Williamson, Investigator
Jun Maiquis, Regulations Specialist
Dan Branch, Attorney General's Office
Mary Kay Vellucci, Licensing Examiner

Visitors present:

Lis Houchen, NACDS
Chuck Kopp, Office of Senator Fred Dyson

Agenda Item 2 Review of Agenda

The board reviewed the agenda. Chuck Kopp of Senator Fred Dyson's office was added to the agenda on February 18th from 10:45 am to 11:00 am. His subject matter was noted as current legislation regarding pharmacists' right of conscience. No other changes were made.

On a motion duly made by Mr. White, seconded by Ms. Handley 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 September 24-25, 2009, meeting. Mr. White inquired about including the pharmacy name on the job shadowing form. Clarification was given and no changes were indicated.

On a motion duly made by Mr. White, seconded by Mr. Johnson, and approved unanimously, it was

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

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

There were no ethics violations to report.

Ms. Handley informed the board she completed the Certified Nurse's Aide (CNA) course since the last meeting. She was now licensed as a CNA but was not employed for wages. She asked the board to clarify whether this presented a conflict of interest for her continued participation in the board. Ms. Handley understood no conflict existed as long as she derived no financial gain from her CNA license. Ms. Handley added she wanted to continue to be a board member. Ms. Handley and Mr. White said the Sunset Review addressed conflicts of interest. Mr. White noted the Sunset Review also inquired about the lack of a full board panel. Mr. Holm commented the board had been functioning with a vacancy for four years. Mr. Holm informed Ms. Handley to check directly with Boards and Commissions for direction about her circumstances before taking any action.

The board as a whole believed neither Ms. Handley's CNA certification nor any future employment as a CNA presented a conflict of interest with the Board of Pharmacy.

Mr. Johnson was made aware he needs to watch the ethics video prior to the next board meeting. Ms. Zinn informed the board this video can be viewed on the internet from the website at the Department of Law. Mr. Johnson was asked to inform Ms. Vellucci when this is completed so it can be documented.

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 5 **Expense Report**

Ms. Mundell noticed there was a \$200,000 roll forward in the last meeting, but the current roll forward was \$51,000. Ms. Zinn explained this was because the figures on the current financial overview were based on a projection.

Mr. White asked if the board was required to refrain from acquiring excess funds for a "rainy day" or unanticipated expenses, such as litigation. Ms. Zinn replied the licensing fees were adjusted biannually based on deficits or surplus dollars and the objective was to keep the balance sheet relatively level. Because of the two year renewal periods, the budgets will be notably greater in alternate years. She reviewed the history of licensing fees and noted although fees were raised in the last two renewal periods, they remained at \$180 for pharmacists for eighteen years prior to that. Mr. White stated, and Ms. Mundell agreed, they would like to see a "rainy day fund" due to potential new litigation in addition to the likelihood of litigation soon forthcoming.

Recommended licensing fees for the July 1, 2010–June 30, 2012 renewal were discussed. Ms. Zinn clarified licensing fees are reviewed by the board and the board can make recommendations. They also needed to be public noticed for thirty days as part of the regulation process.

It was mentioned each application and renewal has a \$50 application fee (aka "administrative fee") in addition to the licensing fee. Mr. White stated the application fee should be addressed at some point because this represented the majority of the labor from

the division. Ms. Zinn replied changing the application fee would require a regulation project because this fee was set in the Centralized Statutes.

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

RESOLVED to recommend the following Pharmacy licensing fees as of July 1, 2010 for the next renewal period:

Pharmacists:	\$200, decreased from \$300
Instate Pharmacies:	\$200, decreased from \$300
Drug Room:	\$200, decreased from \$300
Remote Pharmacy:	\$200, decreased from \$300
Technician:	\$ 50, decreased from \$100
Interns:	\$ 25, no change
Temporary License:	\$ 50, no change
Emergency Permit:	\$ 90, no change
Wholesale facilities:	\$400, no change
Out of State Pharmacies:	\$600, no change

Agenda Item 6

Regulations

Dan Branch, Assistant Attorney General, joined the meeting to discuss regulation projects. Jun Maiquis, regulation specialist, also joined the meeting via telephone.

The board considered the December 9, 2009 memo from Dan Branch regarding Proposed Regulations Concerning Shared Pharmacy Services and Drug Order Information, as well as the draft amendment to 12 AAC 52, Article 4 pertaining to Shared Pharmacies. The group discussion included consideration of the intention of the regulation, the pharmacy customer's perspective, step by step implementation of the regulation, the pharmacy's workflow impact, licensing requirements and definitions.

Subsequent to this discussion, Mr. Branch offered to redraft the amendment and return to the meeting later that day with a revised version accounting for the information provided in the day's dialogue. This was agreed upon and the topic was tabled until later that afternoon.

A memo dated February 16, 2010 regarding Proposed Regulations Concerning Operation of Remote Pharmacies 12 AAC 52.423 was distributed by Mr. Branch. The board reviewed this in its entirety with emphasis on the issues of geography and the Ten Mile Rule. The topic was also tabled until later that afternoon so the board members would have an opportunity to thoroughly review the memo he provided.

Mr. Maiquis explained the last pharmacy board meeting produced a request to open a regulation project pertaining to job shadowing in pharmacies. He created a draft of 12 AAC 52.250 and it was distributed to the group. Mr. Maiquis reminded the board they had several options at this juncture. The board could approve the draft to go out for public notice if it was acceptable as is. The board would then take action at the next board

meeting to adopt it. If the draft presented was not acceptable, it could be redrafted, tabled until another meeting, or no action could be taken.

Mr. Maiquis pointed out the public notice advertising options for regulations as well as the legal minimum requirements. The board chose to public comment the motion below to all pharmacy licensees, in addition to the minimum requirements.

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

RESOLVED to send out for public comment the proposed regulation, 12 AAC 52.250 Job Shadowing in Pharmacy, without revision.

Mr. Maiquis disconnected from the meeting.

Mr. Kim began a discussion of the requirements for reinstatement of pharmacist licenses. He pointed out there was no requirement for proof of good standing from the state(s) where the applicant had a current license, if the license was lapsed for two to five years. The requirements for reinstating lapsed pharmacist licenses were summarized by Ms. Vellucci. Ms. Zinn clarified changing the requirement would entail a regulation project. The current reinstatement regulations were reviewed. A group discussion occurred and identified some possible regulatory changes to add proof of good standing in the respective state(s) for this reinstatement application category. It was decided to table the topic until more time is available to discuss it at a later date.

Chuck Kopp from Senator Fred Dyson's office then took the floor and spoke regarding SB 197: Pharmacist's Right of Conscience as it related to emergency contraceptives. The objectives of the bill were to give pharmacists the same right of conscience as physicians had under Title 18 in addition to protecting pharmacists from litigation, disciplinary action and/or employment discrimination. If enacted, the pharmacist would "step out of the way" to exercise the right, "but would not step in the way" of filling the prescription. Mr. Kopp stated the bill was crafted directly to Title 8 and also protected a pharmacy which employed a pharmacist who exercised the content of this bill.

The proposed legislation added a section speaking to "pharmacist's right to refuse to refer, recommend or dispense emergency contraceptives" if the pharmacist had a personal, moral or religious objection. Ms. Mundell raised the question of how the proposed regulation would be implemented in remote areas with only one pharmacist in the community and a patient who presented a valid prescription for an emergency contraceptive. Mr. Kopp replied typically pharmacies made it known from the outset that emergency contraceptives were not available at their facility by notifying community members, prescribers and relevant others. They may also post a written notice to that effect. The patient would not come to that pharmacy if that was the only prescription to be filled, according to Mr. Kopp. He also indicated the intention of the bill was not to regulate the specific methods individual pharmacies utilized to implement the proposed bill.

Ms. Houchen from the National Association of Chain Drug Stores asked Mr. Kopp why the bill was limited only to oral contraceptives and why the bill included specific language about the right to refuse to refer or recommend. She added she did not question the regulation

addressed to the right refuse to dispense, but felt patient safety can be jeopardized by regulating the option of refusing to refer or recommend.

Mr. Kopp replied pharmacists in Alaska came to Senator Dyson's office and specifically requested assistance pertaining to emergency contraception. He indicated the language in the proposed bill did not prevent a referral from being made, nor did it instruct a pharmacist not to refer. When asked, Ms. Houchen stated Washington required pharmacists to "refer or recommend in a timely manner" any prescriptions not dispensed for that reason.

Mr. Kopp said he was open to further crafting of the amendment. Mr. Holm remarked he wanted to see the proposed legislation broadened to include the pharmacist right to refuse to fill any prescription because there were many legitimate reasons to do so.

Break: Off the record at 11:30 a.m.
On the record at 11:40 a.m.

Agenda Item 7

Continuing Education Audit

Karen Wilke, division paralegal, joined the meeting telephonically at 11:40 a.m.

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

RESOLVED to go into executive session in accordance with AS 44.62.310 (2), to discuss investigative and licensing matters.

Board staff to remain during executive session.

Off the record at 11:45 a.m.
On the record at 12:13 p.m.

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

RESOLVED to approve the late civil fine payment for case number 2606-09-001, contingent upon confirming the death of her father.

This case referred to pharmacy technician Annette Carelock, license #1656.

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

RESOLVED to accept the Default Revocation of Pharmacy Technician License for Case #2606-09-010 per AS 08.80.261 (1) and AS 08.01.075.

This case referred to pharmacy technician Anthea Wallin, license #2213. Mr. Holm subsequently signed the order.

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

RESOLVED to reinstate the pharmacist license for Case # 2606-09-005, pending the paralegal's correction to the name on page 2, paragraph 2 of the Decision and Order to Reinstate Pharmacist License.

This motion referred to license #1249 for Katherine Azmeh-Scanlan. Mr. Holm then signed the pertinent Continuing Education Review Form in the case.

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

RESOLVED to approve the Consent Agreement, Decision and Order for case # 2600-09-004 pending revisions to indicate the pharmacist was lacking four hours of continuing education and the fine should therefore be decreased to \$400.

For the record, the board noted the consent agreement was for Ronald Woitel, pharmacist license # 1000

Lunch: Off the record at 12:18 p.m.
On the record at 1:08 p.m.

Agenda Item 9 Investigative Report

Jo Anna Williamson, Board Investigator and Brian Howes, Chief Investigator joined the meeting. Ms. Williamson reviewed the Investigator's Board Report and provided updates on open complaints, open investigations and closed cases. Ms. Williamson said she had a matter to discuss in executive session.

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

RESOLVED to go into executive session in accordance with AS 44.62.310 (c)(2), to discuss investigative and licensing matters.

Board staff to remain during executive session.

Off the record at 1:15 p.m.
On the record at 1:44 p.m.

Ms. Mundell commented the number of open investigations was brought up during the Sunset Review. The number of closed investigative cases reported by Ms. Williamson indicated progress and improvement in that regard.

The board discussed Case # 2600-10-002 then determined no violation occurred and no further action was warranted. The conclusion pertained to the Pharmacist in Charge as well as the Pharmacist.

Mr. White asked Mr. Howes to compare the investigative review processes between the Medical Board and the Board of Pharmacy. Mr. Howes replied the Medical Board had a fairly set schedule for investigative case review, which was done by two members. Medical board files contained significantly more documents than pharmacy, he said. Investigators also called medical board members as needed to determine a course of action and some cases were determined without medical board member input at all. Mr. Howes told the board a goal in investigations was to have one standard of practice that applied to all professions. Mr. Holm and Mr. White offered to be available to the investigative staff as needed because they saw the value of it and it was found to be a good working arrangement with the Medical Board.

Agenda Item 10

PDMP Update

Brian Howes distributed documents titled *Alaska Prescription Drug Monitoring Program and ASPECT Timeline* for the project. In terms of funding, he reported there was approximately \$399k available at this point. He projected it would get the program implemented and running for one and one-half to two years. In 2011, Mr. Howes plans to apply for the second half of the grant, another \$400k, which could be used for an enhancement. The grant effective dates were September 1, 2009 through August 31, 2011. Because the implementation start date for the PDMP was delayed, Brian plans to do a grant adjustment to change the ending effective date from August 31, 2011 to February 1, 2012, thereby adding six months to the life of the initial grant.

Mr. Howes said the PDMP project was currently with the procurement manager in Juneau to establish the vendor. They want the contract to include a hosted system, meaning someone else hosted all of the data. This would eliminate hardware and software issues. The vendor would also be responsible for creating and maintaining the data uplink, addressing training needs and providing technical assistance.

He explained data uploads will be required every two weeks, although some pharmacies utilizing PDMPs in the lower 48 found it to be more efficient to upload during their daily back-up process. The final program would be likely to have accessibility by web or fax. Informational brochure samples were distributed to the board by Mr. Howes. The final brochures will be appropriately distributed by the investigative staff and made readily available. The public, prescribers and practitioners will be educated about the program and its processes. Some of the vendor contract terms will cover required training and access to a staffed 800# for inquiries.

The goal was to have a contract signed by the end of April and begin the operational work May 1st. Mr. Holm referred to the original timeline plan, specifically to have the initial training and orientation occur February, 2010 in conjunction with the annual AkPhA

convention because the convention provided the largest in person audience of pharmacy licensees. Ms. Mundell concurred.

Mr. Holm raised the question about measures being taken to avoid problems like those which occurred in Virginia. Mr. Howes responded by saying the issue was being closely examined, not only by internal IT staff, but also by the PDMP vendors collectively. He added private for-profit vendors were highly motivated to address and eliminate security issues for their own economic survival. Conversely, he said, state vendors may not have had that same motivation to the same degree. Virginia also hosted its own data and Alaska's PDMP would not be constructed that way. Mr. Howes made it clear his intention was not to cast aspersions on state or publicly managed PDMPs, such as those in Virginia, but he felt obligated to fully answer the question at hand, i.e., how will Alaska avoid security problems such as those which occurred in Virginia?

Mr. White asked if participation in the PDMP would be mandatory for every pharmacy and Mr. Howes answered in the affirmative. Mr. White then asked if a per-pharmacy cost analysis had been done to calculate the financial impact and additional operating expense for individual pharmacies to implement and maintain the PDMP. Mr. Howes replied the time involved would be equivalent to performing a standard data backup and therefore the speed capabilities of a pharmacy's existing computer system would be a factor in determining the time and expense involved. He indicated the data could be downloaded to a thumb drive or disk and then mailed to the vendor.

Mr. White referred to numerous, regularly occurring state and federal pharmacy mandates, all of which were un-funded. He cited multiple five to ten minute mandated tasks to demonstrate the sum of the work was actually quite significant. Mr. White did an oral, sequential timeline of the required steps to perform a routine PDMP task to further illustrate his point. The labor and overhead expenses incurred by an independent pharmacy to comply with the PDMP and other government mandates was then obvious. He compared the scenario to employing a pharmacy staff member to work four or five hours per week only for the government, vs. working for the actual pharmacy, and yet being mandated to pay their wages and benefits. He further followed this line of thought to illustrate how circumstances such as this contribute to the spiraling cost of health care. He concluded by saying compensation to pharmacies would be an incentive to comply with mandates, adding chain pharmacies can absorb these expenses much easier than independent pharmacies.

Ms. Handley pointed out an anticipated outcome of the PDMP was projected to be the cost savings created by fraud reduction. Mr. White responded by agreeing in theory, but further explained those savings would not be realized by independent pharmacies.

Ms. Houchen was asked by Ms. Mundell about other states employing PDMPs. Ms. Houchen informed the group in Wyoming the gathered data went to a Board of Pharmacy staff person on a weekly basis, who then compiled and analyzed the data to determine the frequency of controlled substances dispensed to an individual person. She reminded the group the data was only controlled substances. In Wyoming the data collection was done using existing documents and therefore avoided duplication of information.

Mr. White asked Mr. Howes who would receive the data, compile it and analyze it for the Alaska PDMP, and who would be charged for that person's time. For example, would

licensing fees increase? Mr. Howes stated from program's inception it was established that pharmacists and pharmacies would not absorb the cost of the program. The vendor will host the data, maintain the database and backup the data.

As the PDMP project progressed, thresholds for action need to be defined. Also, a pharmacist would be able to retrieve prescriptive data for a specific person and, if applicable, notify the prescribers about the information on the PDMP.

Mr. Johnson asked what happened to a provider found to be over-prescribing via the PDMP. Mr. White expanded on that by asking what happens to the patient. Mr. Howes replied "it gives a person some indicators to look at... it's not the be-all and end-all of the process." Options existed. For example, one state had an Intervention Officer who located the over-prescriber or patient and presented him/her with their options, typically consisting of treatment or filing charges.

Mr. White restated he agreed the PDMP in principle. Still, he wanted to know how independent pharmacies would be compensated from the savings realized as a result of the decrease in fraud due to the PDMP. Ms. Mundell replied Medicaid, for example, could compensate independent pharmacies by increasing their reimbursement rate. Mr. Howes added he tried to decrease the cost of the program by accessing as much grant money as possible. Mr. White repeated his request to Mr. Howes to create a financial incentive for independent pharmacies mandated to participate in the PDMP.

Break-Off the record at 2:20 p.m.
On the record at 2:26 p.m.

Agenda Item 11

Legislative Audit

Ms. Zinn confirmed the board had an opportunity to read the December 4, 2009 Legislative Audit for the Board of Pharmacy, then proceeded with her presentation.

Recommendation #1, Collaborative Practice Agreements: Per request of the Division's Operations Manager, recommendation number one was reviewed in depth. Ms. Zinn explained the auditors reviewed five Collaborative Practice Agreements. One did not conform to the regulations because the agreement stated it was in effect for one year, but it was approved by the board for two years. In response to that finding, Ms. Zinn revised the former Collaborative Practice Checklist and created the version which was included in the board packets. This version was more thorough and summarized all the regulatory requirements. It was used as a screening tool by the licensing examiner according to Ms. Zinn and was also included in the Collaborative Practice documents routed to the board for final approval. If the requirements were not met, the licensing examiner sent a letter to the pharmacist outlining the pending items. Mr. Holm noted this would prevent an incomplete agreement from being approved and prevent lapse of coverage in a Collaborative Practice Agreement. The analogy made was that Collaborative Practice Agreements were done in a manner very much like issuing other pharmacy licenses. The board acknowledged a problem existed with the review of Collaborative Practice Agreements and agreed the appropriate solution was to approve the revised Collaborative Practice Agreement Checklist created by Ms. Zinn.

Recommendations #2, Administrative support: Ms. Zinn explained this finding was primarily internal to the division's administrative processes and staff. She added this finding applied to nearly all boards which were audited.

Recommendations #3, Full Representation on the Board: Ms. Zinn stated she reviewed several other boards' Legislative Audits and found this recommendation to be included on several of them. Historically, Boards and Commissions had not been receiving applications to fill board vacancies. Mr. White said some potential applicants were unable to meet the absence of conflict of interest criteria.

Ms. Zinn initiated a discussion about the pending legal opinion from the Department of Law as mentioned on pages 15 and 16 of the Legislative Audit. This section spoke specifically to the absence of the legal opinion from the Department of Law regarding pharmacies of Native health organizations and their possible obligation to abide by the Board of Pharmacy Statutes and Regulations. A brief historical synopsis was provided by several members indicating the board had repeatedly sought clarification and decision from the Department of Law on this question and payment was issued by the Board of Pharmacy but the opinion remained unanswered to this day.

Ms. Zinn informed the board there was a new commissioner, new director and new attorney general since their last written inquiry about the status of the opinion. Because of this, she said, now was a good time for the board to write a memo requesting an update on the status of this legal opinion. Ms. Zinn suggested a memo be written to the Director of CBPL to request the status of the opinion and identify the attorney who was assigned to the project because the former attorney assigned to this case was no longer in that position. An exact accounting of the amount billed by the Department of Law and paid by the Board of Pharmacy for this opinion was requested by Mr. White and told it could be provided by the AG's Office upon written request in the memo. Because it had been almost seven years since the opinion was originally sought, Mr. White stated the Department of Law should include accrued interest on any reimbursement they provided for not rendering the opinion. Ms. Mundell clarified the preference was to have the Department of Law actually render a decision on the subject, and reimbursement would be sought only if they were unwilling or unable to do so.

Ms. Mundell then referred the board to two sections of legislative audit written materials. First, the letter she wrote to Pat Davidson, Legislative Auditor in December, 2009, which stated in part "the BOP wishes to work closely with the Attorney General's Office to determine licensure requirements by pharmacies run by Native health organizations." Second, page 16 of the Legislative Audit which gave an alleged report of the board's action in response to the absence of the legal opinion. In particular, she did not agree with the statement "Other than requesting status updates from DCCED and Department of Law, BOP has not taken further action." Ms. Mundell declared this was not true. The board had met with AGs several times and "have gotten nothing." Mr. White added AkPhA had a meeting with the new AG and Department of Law during the change to the Palin Administration and was told action would be taken right away on the issue. There was no subsequent communication from the Department of Law to the state association.

Ms. Mundell made the point if a person received a prescription for a controlled substance from a Native facility and then had the prescription filled at a retail pharmacy, the prescriber from the Native facility was required to have a federal DEA number. This was done in order

to protect the patient through the certification process verifying the prescriber had met the standards which rendered him/her competent to prescribe controlled substances. Mr. White commented the protections provided by the Board of Pharmacy were intended to apply to all Alaska residents, regardless of heritage, and provided public safety from pharmaceutical misadventures. It was mentioned Native health organizations always had non-Native beneficiaries and their current trend appeared to be expanding in that area. This was cited as another factor supporting the licensing of pharmacies in Native health organizations, according to Ms. Mundell. Mr. White and Ms. Handley agreed. According to Ms. Mundell, these examples illustrated the point that Board of Pharmacy purview over pharmacies of Native health care organizations would provide a safety net for Alaska residents who utilized these pharmacies and hopefully dispel the notion the board was financially motivated in this regard, as a few had suggested.

Ultimately it was decided the memo would be written by Ms. Vellucci, then go through Ms. Zinn and the proper channels to the director. It would briefly highlight the history of the issue at hand, request a date by which the opinion will be rendered, identify the attorney assigned to the case and request fees and interest to be reimbursed if it would not be completed, or show significant progress toward completion, within six months.

Agenda Item 12

License Application Review

Ms. Vellucci distributed the License Application List and files to the members. The files were reviewed by the members and subsequently

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.

Pharmacists: Caleb Bishop Finley, pending passing MPJE score and Anita Berk, pending passing MPJE and current NABP Application for license transfer

Intern: Garret Garber

Retail Pharmacy: Alaska Island Community Services Pharmacy, Wrangell, pending self-inspection

Out of State Pharmacy: Easy Scripts, Inc., Chicago, IL

Agenda Item 6

Regulations, cont'd.

Mr. Branch returned to the meeting at 3:05.

Jun Maiquis, regulation specialist, joined the meeting via telephone.

Mr. Branch distributed a revised version of Chapter 52

- 12 AAC 52.443, Approval for shared pharmacy services by pharmacy
- 12 AAC 52.444, Approval for shared pharmacy services by pharmacist
- 12 AAC 52.445, Shared pharmacy services
- 12 AAC 52.460 Prescription drug order information
- 12 AAC 52.995 Definitions

The board reviewed and approved the language changes proposed by the Department of Law. The board also noted that, although no public comments were received, special attention was paid to the cost to private persons of the regulatory action being taken.

Mr. Branch clarified the language changes would not require public notice because the essential structure and content had already been advertised. The revisions drafted by Mr. Branch were reviewed by the board and approved.

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

RESOLVED to adopt the regulation changes to 12 AAC 52.443, 12 AAC 52.444, 12 AAC 52.445, 12 AAC 52.460 and 12 AAC 52.995, as amended.

Mr. Branch distributed *Implementation of Telepharmacy in Rural Hospitals: Potential for Improving Medication Safety and Community Health Centers in Alaska by Census Area*. The former was intended to represent telepharmacy services as a safe and feasible option when direct contact with a pharmacist, the "Gold Standard," was not financially possible.

Mr. Branch recommended that additional similar research such as this be located, reviewed and added to the record in order to substantiate the validity of the service in the event of future litigation. Mr. White and Ms. Mundell acknowledged the Gold Standard was direct, in-person contact with the pharmacist, and the rest of the group concurred.

Ms. Mundell asked how it could be interpreted there was insufficient justification for the efficacy of Remote Pharmacy Services, given the extreme number of times this had been reviewed and discussed in detail at board meetings with written records to verify it.

Ms. Mundell also reported she read Bureau of Indian Affairs documents, similar to a Federal Policy and Procedure manual, which addressed similar geographical issues in the practice of medicine. They itemized an extensive list of medical providers (physician, practitioner, dentist, ophthalmologist, pharmacist, etc) and provided step by step instruction to the reader about the correct response if the service in question was not available for those who are non-eligible. Specifically, it said the lack of a provider in a thirty mile radius then justified the implementation of telemedicine. It included text indicating the introduction of a provider into that community negated the need for telemedicine.

Mr. Branch knew of this as the Thirty-Mile-Non-Beneficiary-Rule. His interpretation of its significance was primarily to define the distance a non-eligible beneficiary would have to travel to receive in-person medical services. He did not interpret the premise of the rule to be pro-telemedicine and pro-telepharmacy.

A discussion then ensued about the propensity for litigation over the regulation, former courses of action taken by the board in order to move the regulation project forward and the actual objectives. Meeting the intent of the regulation, without simultaneously creating a distorted and skewed pharmacy service (primarily in urban areas) that could technically pass the remote services regulation litmus-test, was an obstacle that could not be overcome in the day's discussion.

Mr. Johnson exited at 3:45.

The *Community Health Centers in Alaska by Census Area* was discussed.

Mr. Johnson returned at 3:50.

Several specific examples of potential and known distortion telepharmacy programs were reported by board members, further highlighting the obstacle present. It was noted the current regulation project would become stale on August 14th, 2010. Ms. Mundell felt it would ultimately become a federal issue but that should not halt the effort to move forward. Mr. White offered to provide additional telepharmacy data for the May board meeting. Mr. Holm said the board would consider any options to make the service work as intended. Mr. Johnson made the point it was ultimately an issue of enforcing existing federal regulations. Ms. Mundell asked Mr. Branch if he would locate the federal regulation that prohibits a pharmacy to mix inpatient and outpatient medications. This, she said, was pertinent to the telepharmacy issue because it was a description of the federal issue lying at the foundation of the regulation project. It was decided to table the issue until the May board meeting so further work and re-drafting could be done in the interim.

Mr. Branch exited.

Mr. Maiquis disconnected.

Agenda Item 11

Correspondence

The board reviewed the NABP correspondence.

NABP-State News Roundup-September, 09, 2009-No action required.

NABP-letter to ICPT re Credentialing Program-October 30, 2009-No action required.

NABP-Alaska Board of Pharmacy State Newsletter-January, 10, 2010-No action required.

NABP-e-News 5000 Websites Selling Rx Drugs Outside of Pharmacy Laws and Practice Standards-January 6, 2010-No action required.

NABP e-News USP Issues Recall of National Formulary 28-January 21, 2010-No action required.

MPJE Item-Writing Workshop April 8-9, 2010-No action required.

NABP e-News Rx Warning Label Research Reveals Elements That Increase Patient Understanding-February 3, 2010-No action required.

The board reviewed the General correspondence.

Letter from Center for Lawful Access and Abuse Deterrence (CLAAD)-November 6, 2009-No action required.

Report of Theft or Loss of Controlled Substances-November 23, 2009- No action required.

Statistics re Pharmacy Technician Certification and Model Rules for Registration and Certification of Pharmacy Technicians-November 24, 2009-No action required.

Letter from Nancy Davis re Pharmacy Technician Certification-January 13, 2010-No action required.

Correspondence from Dan Branch re Nevada Court Decision-January 21, 2010-No action required.

The board recessed until 9:00 a.m. on Friday.
Off the record at 3:55 p.m.

Friday, February 19, 2009

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:

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

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

Sher Zinn, Records and Licensing Supervisor
Mary Kay Vellucci, Licensing Examiner

Visitors present:

Margaret Soden
Robert Gruszynski
Bill Altland, Whale Tail Pharmacy
Sarah Altland, Whale Tail Pharmacy
Catherine W. Karnski, Petersburg Rexall
Lisa Gore
Paul Gione
Lis Houchen, NACDS

Agenda Item 14 **Review of Agenda**

No changes were made to the agenda.

Agenda Item 15 **Public Comment**

Mr. Altland inquired about the status of the telepharmacy regulations, the pending opinion from the AG's Office and the PDMP. The board collectively updated him and the audience on the status of those projects. Ms. Vellucci agreed to scan the PDMP timeline documents to Mr. Altland.

Mr. Miller initiated a discussion about Collaborative Practice Agreements. He stated the Board of Nursing was considering changing their regulations to ban Advanced Nurse

Practitioners from signing off on Collaborative Practice Agreements as the prescribing practitioner. Ms. Vellucci agreed to check with the Board of Nursing to determine the status of this. The requirements and regulations of other states regarding pharmacists and immunizations were discussed. Mr. Miller asked the board to consider a regulation project to authorize pharmacists to administering immunizations.

Agenda Item 16 **Medical Marijuana**

Mr. Holm provided a brief history regarding medical marijuana in Alaska. He informed the group a DEA memo issued last fall stated they would not be enforcing or prosecuting medical marijuana shops which now exist in other states. Mr. Holm described the outcome of the lack of enforcement in California, as well as other states. He further noted there was no means for pharmacies in Alaska to acquire medical marijuana in Alaska. Acquisition and distribution methods in other states were discussed. The Alaska Statutes described the circumstances under which a person can grow their own medical marijuana, as was brought to the attention of the group by Ms. Handley. Ms. Mundell stated medical marijuana should be regarded as any other medication, i.e. provided by pharmacies and thereby afforded the same safeties and oversight as any other medication. Mr. White spoke of a period of time in Sitka during which street marijuana was laced with potent and hallucinogenic illicit substances of abuse. He cited this as further justification for licensed pharmacies to offer safe medical marijuana in a controlled setting. Additional comments supporting the regulation of medical marijuana were made by multiple audience members. Mr. Holm said creating regulations for the distribution of medical marijuana could be done but regulations alone would not resolve the primary issue, i.e. lack of product supply or vendor. Mr. Miller asked if the NABP had model rules for medical marijuana. No one was certain. Ms. Vellucci agreed to check into it prior to the next board meeting. Ms. Houchen agreed to provide information pertaining to medical marijuana from Washington and other states in her area of responsibility. The consensus was the board would continue to work the subject and it would be revisited during the May board meeting.

Agenda Item 18 **Legislative Updates**

The board reviewed and discussed legislative projects. Mr. Holm clarified the following bills were a continuation of last legislative session:

HB 284 Pioneer Home Rx Drug Benefit
SB 38 Pharmacy Benefits Managers
HB 277 Certify Emergency Use of Epinephrine
HB 282 Naturopaths

SB 247 Extending Board of Pharmacy: Per Mr. White, one committee hearing had occurred and another was being planned. The legislative audit was discussed at the initial hearing. Mr. White did not foresee any obstacles with legislative approval.

SB 197 Emergency Contraceptives/Pharmacist Right of Conscience: Mr. Holm summarized the content of the presentation by Mr. Kopp of Senator Dyson's office on February 18th for the benefit of the audience. He added the goal was to have the scope of the regulation broadened so it did not address only emergency contraception, but rather

allowed for the many other valid circumstances and issues which justified a pharmacist to refuse service.

HB 327 Rescheduling Dextromethorphan: Ms. Gore informed the group this bill was currently in the house. The intention of it was to put dextromethorphan behind the pharmacy counter and required the patient to be at least eighteen years old to purchase it. A difficulty with the bill was remodeling most pharmacies to create sufficient behind the counter space to store all these products. Mr. White remarked this was most of the cough and cold aisle.

Agenda Item 18 **Office Business**

The board signed the TA forms.

Mr. Holm requested Ms. Vellucci mail the wall certificates to him for signature. He would then forward them by postal mail to Mr. Johnson for signature. Mr. Johnson would sign them and return them by postal mail to Ms. Vellucci.

The board adjourned at 10:45 a.m.

Respectfully Submitted:

Mary Kay Vellucci, Licensing Examiner

Approved:

Dick Holm, Chair
Alaska Board of Pharmacy

Date: _____