STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOP.M.ENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

ALASKA STATE BOARD OF PHARMACY

MINUTES OF MEETING
February 17-18, 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 February 17, 2011 at the Atwood Building, 550 West 7th Ave., Suite 602 and February 18, 2011 in the Juneau Ballroom of the Anchorage Downtown Marriott.

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:06a.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.

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

Quentin Warren, Chief Investigator
Brian Howes, Investigator & PDMP Program Manager
Gary Keiser, Investigator
David Newman, Investigator
Deborah Stovern, Executive Director, Medical Board
Sara Chambers, Program Coordinator
Mary Kay Vellucci, Licensing Examiner

Present from the Department of Law - via telephone

Dan Branch, Assistant Attorney General

Visitors present:

Chris Kennedy, Office of Administrative Hearings
Ron Miller, Safeway Pharmacies
Daniel Essim, Wal-Mart Pharmacies
Meredith Wolpert, Wal-Mart Pharmacies
Lis Houchen, NACDS
William McCormick, Walgreens Pharmacies
Kay Gouwens, Attorney for Prime Therapeutics
Laura Watkins, Prime Therapeutics
Susan Ratner, Prime Therapeutics

Duane Barnes, Prime Therapeutics

Agenda Item 1 **Review of Agenda**

CE Audits were moved to the May agenda and the ExcellRx Administrative Law Judge Decision was added in its place.

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 2 **Review of Minutes**

The board reviewed the minutes from the September 23-24, 2010 full board meeting. No editing was required.

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

RESOLVED to approve the minutes of the September 23-24, 2010 Board of Pharmacy Board Meeting minutes.

The board reviewed the minutes from the October 6, 2010 teleconference. No editing was required.

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

RESOLVED to approve the minutes of the October 6, 2010 Board of Pharmacy teleconference.

The board reviewed the minutes from the January 7, 2011 teleconference. No editing was required.

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

RESOLVED to approve the minutes of the January 7, 2011 Board of Pharmacy teleconference.

The board reviewed the minutes from the January 28, 2011 teleconference. No editing was required.

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

RESOLVED to approve the minutes of the January 28, 2011 Board of Pharmacy teleconference.

All minutes were signed on the record by the board chair.

Agenda Item 3 **Ethics Disclosure/Goals and Objectives**

There were no ethics violations to report.

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.

Chair Holm noted Lori DeVito has been appointed to the board by the governor to fill the vacant pharmacist position. She is a former president of the Alaska Pharmacists Association, operates a home infusion and home health care agency in Soldotna and is Alaska born and raised.

Ms. Vellucci reported Boards and Commissions have opened an inquiry with the Department of Law regarding Ms. Handley's continued participation on the board as a public member given her employment. Ms. Handley then reported she has since resigned her employment due to personal circumstances. Boards and Commissions will be notified by Ms. Handley.

Agenda Item 4 Expense Report

The members were provided with a Schedule of Revenues and Expenditure as of February 1, 2011. Ms. Vellucci summarized a recent conversation with Katherine Mason, Administrative Officer II. The board's total surplus was $223,718 noting the surplus was cumulative since FY 08. Definitions were provided for line items Personal Services, Contractual Expenditures and Indirect Expenditures. These figures did not include billing from the Department of Law since September, 2010.

Agenda Item 6 Correspondence

Pharmacy Technician CEUs: The board was provided with several documents about Pharmacy Technicians who took CE courses designated for pharmacists only to meet their CE requirement. The ACPE and AkPhA did not regard these courses as acceptable for certification and licensure. The March 2, 2007 letter to the Board of Pharmacy from AkPhA described the ACPE Changes, stating in part "*if a technician attends and receives a statement of credit for a program designated for pharmacist only, the Board should NOT accept this as hours toward the CPE requirement for licensure of the technician."* The ACPE and AkPhA took this position due to scope of practice parameters between pharmacists and technicians.

Mr. White stated pharmacist-based training for technicians was desirable because it helped them learn about side effects and disease processes. Ms. Mundell stated any training was beneficial and technicians were capable of understanding pharmacist-based training. Ms. Handley stated technicians should not be penalized for taking the courses and others agreed.

Ms. Vellucci informed the board she called several technicians who took pharmacist courses to ask them their reasons for doing so. She was told technicians licensed for 4-5 years or longer have taken most or all of the technician courses

available from their CPE provider. Therefore, some technicians took pharmacist courses for new content. Other technicians stated they were not aware they could not take pharmacist courses. This was particularly true of technicians who were not affiliated with AkPhA, ACPE or other similar associations. Of the 120 Technician CE Audits completed, 18 had taken some or all pharmacist only CEs reported.

The board then referred to and discussed 12 AAC 52.325 Continuing Education for Pharmacy Technicians, 12 AAC 52.340 (CE) Approved Programs and 12 AAC 52.350 Audit of Records by the Board.

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

> **RESOLVED to accept, under 12 AAC 52.325(a) (1), pharmacist-only ("P" courses) and/or pharmacy technician CE courses ("C" courses) as qualifying for the continuing education requirements of pharmacy technicians.**

Nuclear Chemistry Lab/Langdon Engineers: Mr. Holm informed the board Mr. Swank of Langdon Enterprises was moving a modular nuclear lab to Anchorage for producing radioactive doses for PET. With short notice, Mr. Swank asked for time on this agenda to speak to this topic. The plan was for board members to review the data prior to the May meeting and notify Ms. Vellucci if the topic should be added to the May agenda. The facility was going to be run by a physician under the purview of the medical board. Mr. Swank did not reply to a February 6th email asking, in part, if they were going to apply for any licensing from the Board of Pharmacy.

Ms. Mundell stated these materials are currently being flown in from Washington, taking into account their half-life. It was stated a PET imaging facility in Anchorage holds a Drug Room License. Ms. Mundell stated this may be required because the facility has a crash cart.

Agenda Item 5 **Investigative Report**

David Newman informed the board he was now an investigator for the Medical Board. Quentin Warren was now the Senior Investigator for the Board of Pharmacy. Gary Keiser, the current Board of Pharmacy Investigator, was introduced and provided the board with his background and credentials.

Mr. Keiser provided an Investigator's Report on February 1st, which was included in the board packets. He summarized his recent work as follows:

- An additional case was closed and subsequently re-opened due to jurisdictional considerations.
- He has consulted with Mr. Holm on several cases.
- Pharmacy Investigations, across categories, were very nearly up to date.

The board made positive comments about the current status of pharmacy investigations.

Break: Off record at 10:00
On record at 10:15

Agenda Item 6 Correspondence (con't.)

Physician Dispensing From a Drug Room: Prior to the board meeting, the Division received an inquiry from Krieg/Devault in behalf of The Fairbanks Surgery Center. This facility had a drug room license and automatic dispensing system. The prescribing physicians want to prescribe full courses of medication from this facility.

Mr. Holm stated he did not want to be part of the decision making process on this question because the inquiry originated in his locale. Board members made the following comments and recommendations:

- A twenty four hour course of therapy was the limit for physician dispensing from a facility with Drug Room License.
- Other physicians who performed the same surgeries wrote post-op prescription(s) prior to the day of surgery. The patient then filled the prescription(s) in advance and had them available. This was a common, standard operating procedure.
- The pharmacy that filled the prescriptions for the patient had a record of his/her current and former medications as well as allergies. This information was used to counsel the patient about potential interactions and side effects. The patient also had an opportunity to ask questions in response to the pharmacist's counsel. This, the board stated, was the essence of patient pharmaceutical safety.
- It was suggested a pharmacy could supply the medications ahead of time in the following manner: pharmacist received the patient's prescription(s), pharmacist filled the prescription(s), courier employed by the pharmacy delivered the filled prescription(s) to the surgery center, the surgery center then began acting as the patient's agent, surgery center stored the medications in the drug room, surgery center dispensed medications to the patient after the surgery. If the medication was never dispensed to the patient, but remained in the controlled environment of the surgery center drug room, it could be returned to pharmacy inventory. Narcotics and Class IIs were handled in this manner in hospitals.
- The Surgery Center's address could not appear on the prescription because legally they did not have a dispensing pharmacy.

- Automatic Dispensing Systems were not an option at The Fairbanks Surgery Center, based on the description provided in Mr. Rickert's five page letter dated January 25, 2011. This presumed "Automatic Dispensing System" was not synonymous with an automatic *unit dose* dispensing system, which delivered unit doses administered by a licensed professional.

The statutes and regulations referenced by the members include:

- 08.80.390 Pharmacists Required in Hospitals and Clinics
- 08.80.400 Other Licenses Not Affected
- 12 AAC 52.800 Drug Room License
- 12 AAC 52.850 Emergency Distribution

DEA Diversion Control Program: The board reviewed a January 6, 2011 email from Christopher Hatscher, Senior Analyst, Homeland Security and Justice Team. The board said more information was needed to identify what the DEA program entails before a reply can be given. The board requested this information in writing so it could be reviewed prior to the May 12-13 meeting.

Agenda Item 11 License Applications

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

A discussion ensued about the role of the pharmacist's initial state of licensure as it relates to reciprocity applicants.

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

RESOLVED to approve the following pharmacist applications as read into the record:
Jennifer Cole, score transfer, pending proof of internship hours.
William Decker, credentials, pending transcripts, passing MPJE score, verification of UT & NE licenses.
Erin Narus, credentials, pending passing MPJE score.
Matthew Weatherly, credentials, pending passing MPJE score.

Agenda Item 7 PDMP

Mr. Howes and Mr. Warren joined the meeting. The board reviewed the 10/06/10 Draft Regulations and Public Comments. It was noted there were several comments about waivers, the frequency of reporting, the advisory board and real time access. The Relay Health data parameters had been changed to accommodate those who have only a PO Box address and not a street address.

Mr. Howes replied real time access to data for those who were not registered with Relay Health would greatly increase the cost of the program. Inquiries made by non-registered persons would be addressed by certified mail. The investigator would verify the identity and authenticity of the person making the inquiry, which could not be done via telephone. However, once access was established with Relay Health, the data was immediately available. A monthly reporting requirement, vs. daily or weekly reporting, would greatly reduce the cost of the program. Providers could, however, report more frequently if they choose to do so. Some facilities would have automatic upload. Ms. Mundell added it was common for persons who abuse narcotics to have a long history of doing so. This would be identifiable even with monthly reporting.

Mr. Howes stated the waiver requests he received were primarily from facilities that did not dispense any controlled substances. Mr. White asked how it would become known if a waivered facility began dispensing controlled substances after the waiver was issued, for example, due to a merger. Mr. Howes stated he would check to see what other states were doing.

The waiver application denial for Department of Corrections was discussed. Mr. Holm stated it was denied because the pharmacist needed to know the patient's history when s/he was released from custody. Ms. Mundell asked if a person living at a halfway house was classified under the Department of Corrections and Mr. Howes replied "yes." Ms. Mundell stated this was relevant and further supported the denial of the waiver for Department of Corrections. Others agreed.

Mr. Holm asked what measures were in place to monitor overall compliance with the PDMP. How would a facility's monthly reporting requirement be verified? What policies were in place to address a facility that did not report monthly? Would those with waivers renew their waiver on a regularly scheduled basis? Mr. Howes stated the board could establish regulations to address these situations.

A discussion about controlled substances dispensed from veterinary clinics occurred. The consensus was controlled substances used in house for office use, surgeries and procedures did not need to be reported. Controlled substances dispensed to the pet's owner or agent from the veterinary pharmacy, such as Phenobarbital, did need to be reported.

Advisory Board: The members agreed the Advisory Board for the PDMP needed to move forward. The role of the Advisory Board needed to be clarified, members selected and their role defined. These initial tasks needed to be done by the Board of Pharmacy because the PDMP was under their scope per statute.

Membership was planned to consist of a practitioner or board member representing the Medical, Nursing, Veterinary, Dental professions, Pharmacist board member, Brian Howes and possibly a public member.

A letter needed to be drafted to the Medical, Nursing, Veterinary, Dental boards to solicit Advisory Board members. Based on discussion, content of the letter was to include solicitations for PDMP Advisory Board membership.

The tasks of the PDMP Advisory Board were envisioned to be completed in conjunction with Brian Howes, Program Coordinator and included:

- Providing opinions on PDMP tasks, policies and decisions from the point of view of your profession.
- Providing input into PDMP policies, regulations and waivers.
- Assisting in the preparation of PDMP reports, to be distributed at full Board of Pharmacy meetings in February, May and Sept. Reports need to include frequency of use by law enforcement.
- Making recommendations to BOP regarding PDMP policies and waivers

Other Advisory Board factors were:

- A teleconference for orientation to the Advisory Board, introduction of the PDMP, role of the Advisory Board and general orientation was likely.
- The time commitment would be greater in the initial phases of the Advisory Board, but would level out over time.

Upon a motion duly made by Mr. Holm it was

> **RESOLVED to go into Executive Session in accordance with Alaska Statute 44.62.310 (c) (2) to discuss PDMP management.**

Board members, Quentin Warren and Brian Howes to remain.

Mr. Holm stated the group will break for lunch after this discussion.

Off the record at 11:30 am
On record 1:13 p.m.

Agenda Item 8 **Prime Therapeutics**

The following Prime Therapeutics audience members were introduced:

- Dwayne Barnes, Sr. VP of Consumer Affairs
- Laura Watkins, RPh, Director of Quality Mail Operations
- Sara Ratner, Chief Compliance Officer
- Kay Gouwens, Attorney representing Prime Therapeutics.

Ms. Horetski joined the meeting telephonically and identified herself as the Attorney General assigned to this case. She stated there were two Prime Therapeutics Out

of State Registration Renewals denied by the board during the September 2010 full board meeting. Inadvertently, the board received incorrect information during the renewal process. The board, as would be expected, acted on the information it had available at that time. This information was presented in the Joint Statement Supporting Consent Agreement and Proposed Consent Order provided to the board.

Ms. Horetski stated there were two corrections to the Joint Statement:

1. The board did not meet telephonically on August 20, 2010 to consider the Prime Therapeutics renewals as stated on page 3, lines 4 and 5. The Board first acted on the 2010 license renewal applications via mail ballots. The last mail ballot was received on August 20, 2010.

2. The subsequent teleconference occurred on October 6, 2010. The October 8, 2010 date in the Joint Statement was not correct.

Ms. Horetski made handwritten comments about the current status of each violation reported by Prime Therapeutics on the July 2, 2010 Summary of Violations from Prime Therapeutics to the Division. The proposed Decision and Order included a fine of $1000 per license and a retroactive license renewal date of July 2, 2010.

Ms. Gouwens stated Prime Therapeutics regarded this matter seriously and brought key management personnel with them so the board members have an opportunity to address any questions to them. She expressed her appreciation to the Division and the Board for the "spirit in which the Division worked with us to identify the problems and bring this to a timely conclusion in a very cooperative manner."

Mr. Barnes and Mr. Warren initialed the changes above to the original Joint Statement.

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

RESOLVED to accept the Consent Agreement for Prime Therapeutics, License numbers PHAO 679 and PHAO 790 in case number 2010-001022 and 2010-001014.

Agenda Item 5 **<u>Investigations</u> (cont'd)**

Upon 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) for the purpose of discussing the cease and desist order.

Board, staff, Mr. Warren and Mr. Keiser to remain.
Off record at 1:37 p.m.
On record at 2:10 p.m.

Agenda Item 9 **Regulations**

Mr. Branch and Mr. Maiquis joined the meeting telephonically.

Remote Pharmacies: The board received in their board packets the 1/5/11 draft per Dan Branch addressing 12 AAC 52.423 Remote Pharmacy License. The Resolution in Support of Changes to Remote Pharmacy Regulations was acquired during the meeting and distributed to the members. The board will review this document during the May 2011 meeting with the public comments to be acquired between now and then.

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

RESOLVED to approve for public notice 12 AAC 52.423 Remote Pharmacy License.

Thirty Day Violation Reporting: The board members reviewed the proposed addition to 12 AAC 52.920 Disciplinary Guidelines (a) (22) which would require licensees to report to the board any disciplinary decisions within thirty days. Mr. Branch suggested a revision to the draft to account for receipt of notices of disciplinary actions from other jurisdictions. The board agreed with his suggestion and the draft will be revised to account for the same.

Expired Pharmacist License: The board reviewed 12 AAC 52.310, Reinstatement of Expired Pharmacist or Pharmacy Technician License, email correspondences addressing the subject, the 1/28/11 draft and subsequent revision per Dan Branch. The board reiterated the purpose of this project was to identify violations or convictions which occurred during the time a pharmacist license was lapsed. The board decided to require Verifications of Licensure from each jurisdiction where the applicant held a license during the time the Alaska license was lapsed or an NABP Application for License Transfer. The regulation would also require good standing of the initial pharmacist license issued by exam or score transfer. The draft regulation would be revised to reflect these board member comments.

Temporary Pharmacist License: Mr. Branch noted a statutory change to 08.80.150 would be required to repeal the temporary pharmacist license regulations. The board opted to put this project on hold.

Changes to Schedule II CS Prescriptions: The board reviewed the draft amendment to 12 AAC 52.460 Prescription Drug Order Information. The new information outlined the allowed changes to Schedule II Controlled Substances as outlined by the DEA. The members stated licensees had frequent questions, contradictory information and difficulty locating the requirements for these prescription changes in the

available DEA reference materials. The purpose of this regulation was to assist pharmacists in this regard, without conflicting with DEA regulations and/or guidelines. The regulation text was acquired from DEA reference materials. Board members cited examples of the direct link between patient safety and implementation of this regulation.

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

> **RESOLVED to approve for public notice new sub sections (c) and (d) to 12 AAC 52.460 Prescription Drug Order Information which describe the allowed Changes to Controlled Substances Schedule II Prescriptions.**

A discussion occurred about the options for public noticing regulations. Mr. Maiquis explained the minimum requirements. He added the board can decide to send the information to all licensees.

Mr. White added the Division should establish a method to record the email address of licensees for purposes such as this, noting the cost savings between email and postal mail. Mr. Maiquis confirmed email correspondence was a legal method of contact. Mr. Branch added email could not be the only method of advertising. Mr. White asked what it would take to amend applications and renewals to require email addresses. Ms. Vellucci stated she would research this prior to the next meeting in May.

The board decided to advertise all regulation projects discussed during this meeting to all licensees in addition to the minimum legal standards.

Federal Facilities: The board received a memo from Peter Putzier Assistant Attorney General Office describing his assignments since the September 2010 meeting and the reasons he was unable to address this topic. He added this project remained a high priority and he plans to address it in the very near future.

Medical Marijuana: The chair noted this project would not make it into the current legislative session. However, groundwork was being laid between board members and potential sympathetic legislators to hopefully bring this to the legislative table in 2012.

Break: Off record at 3:07 p.m.
On record at 3:24 p.m.

Agenda Item 10 **<u>ExcellRx Administrative Law Judge Decision</u>**

Administrative Law Judge Chris Kennedy joined the meeting and was introduced by the chair. Judge Kennedy stated ExcellRx had three out of state pharmacy registration renewals during the last cycle. The board denied the renewals at the September 2010 meeting with a follow up procedure in October. ExcellRx went to hearing and a proposed decision was created and provided to the board in the

board packets. No objections to the proposed decision were filed by either party. Judge Kennedy then stated any discussion about the merits of the case should be done in Executive Session

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

> **RESOLVED to go into executive session in accordance with AS 46.62.310 (c)(2), to discuss the ExcellRx case.**

Board members and Judge Kennedy to remain.
Off record at 3:37 p.m.
On record at 4:04 p.m.

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

> **RESOLVED to adopt the ExcellRx Decision as final in case numbers 10-0582-PHA, 10-0583-PHA, 10-0583-PHA (Consolidated) and renew the out of state pharmacy registrations effective immediately.**

This motion addressed license numbers PHAO 698, PHAO 930 and PHAO 684. Judge Kennedy stated he will notify the pharmacies by email on February 18th that the licenses were renewed effective immediately. Ms. Vellucci stated the licenses will be issued on Tuesday February 22nd with a February 17, 2011 effective date.

Agenda Item 11 **<u>License Applications</u> (con't.)**

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

> **RESOLVED to approve the Out of State Pharmacy Renewal for Walgreens Mail Service, PHAO 796**

Recess until 9:00 a.m. Friday, February 18, 2011
Off the record at 4:40 p.m

Friday, February 18, 2011

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:08 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:

Not Applicable

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

Deborah Stovern, Executive Director, Medical Board
Mary Kay Vellucci, Licensing Examiner

Visitors Present**:**

Stephen Tarbell III
Chad Hope
Justin Kirsch
Valerie Carol King
Julie McDonald
Kevin McDonald
Margaret Soden
Lis Houchen
Daiana Huyen
Debora Stovern
Nancy Davis
Daniel Essim
Sarah Altland
Chuck Kopp
Senator Fred Dyson
Sara Doran-Atchinson
Renee Robinson
Dan Nelson

Agenda Item 12 Review Agenda

There were no changes to the agenda.

Agenda Item 13 Old Business

Licensing Out of State Wholesalers: The board revisited the topic of licensing out of state wholesalers. Mr. Holm stated the board tried to accomplish this several years ago but was not successful because it required a statutory change, which involved approaching the legislature. This content would be included in the annual report. He added the licensing of out of state wholesalers would provide further control over inventory management of Automatic Dispensing Systems. Mr. Holm requested the historical information regarding licensing out of state wholesalers be provided in the May board packets and this item added to the May agenda.

Automatic Dispensing Systems: For the benefit of the audience, Ms. Mundell described the appearance, purpose and design of an Automatic Dispensing System (ADS). It was noted an ADS was not the same as a Pixes machine and ADSs were most likely to appear in medical clinics and/or physician offices. The board's primary concern was that a clinic with an ADS cannot represent themselves as having a pharmacy or pharmacist based on the presence of an ADS. The chair noted the board of pharmacy has been working with the Medical Board on this issue and introduced Debora Stovern, the Executive Director of the Medical Board.

Ms. Stovern stated some of the medical board members were not aware of the existence of ADSs until recently. For that reason, the medical board was still in the information gathering phase of this project. She added they were concerned about how an ADS would be stocked, prescribing based on the ADS contents vs. best practice, patient counseling, controlled substances in ADSs and the misrepresentation of pharmacy services. The DEA will be providing information to the medical board about how this issue was being addressed in the lower 48.

Ms. Mundell asked Ms. Stovern for the definition of "Physician Dispensing," explaining this was requested in the past specifically for the purposes of evaluating the ADS issue in clinics dispensing under this criteria. The response was a short regulation citation, which did not provide a definition. Ms. Stovern stated the medical board was somewhat resistant to provide this, as the board of pharmacy did not have purview over the medical board. The Medical Board, during their January 2011 meeting, offered to send a blast letter to all licensees about the Board of Pharmacy's regulatory concerns regarding the appropriate use of ADSs. Mr. Holm asked Ms. Vellucci to create a draft of this letter for board review at the May, 2011 Board of Pharmacy meeting.

Ms. Vellucci stated an idea for consideration was to have the medical board create their own regulations regarding the use of ADSs in clinics that operate under the "physician dispensing" criteria.

Mr. Holm added the Board of Pharmacy extended their hand to the Medical Board and offered to have a Pharmacist Board Member available to consult with the Medical Board on this subject.

Agenda Item 14 **Legislative Update**

HB 7: Synthetic Cannabinoids. This bill would classify certain synthetic cannabinoids as Schedule IIA controlled substances for non-medical use. Mr. White stated this bill was currently in committee review.

HB 28: Requiring Temporary Licenses. It was clarified this bill had already been amended to specifically apply to the military personnel and spouses and extended to licenses of plumbers, electricians as well as other professional licenses.

HB 42: Drug Pricing. This bill had been re-introduced for several years by Representative Guttenberg. There were no co-sponsors and the bill appeared to be stagnant.

HB 43: Requiring Generics. It was noted pharmacists already consistently use generics and therefore it was unclear why this would need to be put into statute. Mr. White stated having this in statue could potentially cause problems in practice and cited an example to that effect.

HB 44: Prescription Discounts. This bill appeared to be stagnant.

HB 45: Prescription Marketing Costs. This bill appeared to be stagnant.

HB 46: Prescription Drug Task Force. No information provided.

Ms. Davis provided information from AkPhA's lobbyist, Caren Robinson, regarding legislative activity. HB 7: Synthetic Cannabinoids had been referred to Judiciary and Finance. HB 28 was currently in Labor and Commerce. HB 78 had no movement. Ms. Davis stated AkPhA submitted a letter of support for HB 78. HB 122 Establishes a Naturopath Board and was currently stagnant.

SB 14: Conscience Objection by Health Care Providers. Senator Fred Dyson and his chief of Staff, Chuck Kopp, spoke on this bill. Senator Dyson gave an account of the bill's evolution, cited examples of implementation and clarified several points. Mr. Kopp noted the bill applies to various health care providers and provided numerous examples of the range of the bill.

In the case of a single practitioner in a given geographic area, the practitioner would have a limited right to refuse service in the proposed legislation. Advance written notice stating practitioner's conscience objection would be required in all cases.

Ms. Mundell asked if Federal Law would override this bill. She cited the case of a corporate hospital that received federal money for its services from Medicare, thereby obligating its practitioners to abide by federal Medicare guidelines. Mr. Kopp stated "*Yes, this bill protects the individuals working in those institutions as long as they give advance written notice and it allows the employer to specifically assess their employee pool by going back to their pre-employment interviews*..." Senator Dyson and Mr. Kopp stated as far as they knew, in the example cited, federal moneys were not lost.

Mr. White added "*If this legislation was passed and there was a challenge to Medicare/Medicaid funds...because nationally States Attorneys General are actually standing up to the Feds, it would give our State Attorneys a much better chance of pushing our state's rights*."

Ultimately, though, as stated by Senator Dyson, Federal Law did trump State Law.

The board noted on one level, this bill was not "*plowing new ground*" because there was an existing regulation which allows a pharmacist to refuse to fill a prescription. The bill had, however, evolved significantly because it was broader in scope. The board stated they had no reason to oppose the bill.

This discussion allowed for an easy segue for the board to inform Senator Dyson and Mr. Kopp about their goal of creating legislation for the safe control of dispensing prescription medical marijuana. Members provided a summary of the project to Senator Dyson and Mr. Kopp, emphasizing the following points:

- The board does not want Alaska to have a dispensary system like California.
- The goal was to introduce legislation next year.
- The system envisioned would be 100% controlled by pharmacists, dispensed in a pharmacy and produce a clean source.
- This would create a taxable resource.
- Currently patients with a medical marijuana card have no vendor to provide the product.
- It can be grown but the allowable quantity was not sufficient for genuine medical use.
- Purchases from the street were unsafe because they frequently contain harmful or lethal additives.
- The current statutes (unintentionally) promote an illegal system.

Senator Dyson requested model legislation from other states and/or the National Association and agreed to "turn our legislative legal resources loose on it."

Break: Off record at 10:30 a.m.
On record at 10:47 a.m.

Ms. Mundell made the following motion to complete the discussion regarding legislation.

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

RESOLVED to support Senator Dyson's Senate Bill 14, Conscience Objection by Health Care Providers.

Agenda Item 15 **New Business**

IHS Retail Pharmacies: Sara Altland stated the Ketchikan Indian Corporation was opening a retail pharmacy in Ketchikan. This induced questions about licensing of the Indian Health Service facility and staff members, dispensing to non-beneficiaries and apparent complications with the process of purchasing pharmaceutical products in IHS facilities.

Ms. Vellucci was asked to respond to licensing questions. She stated the PIC from the Ketchikan Indian Corporation Health Center, who is licensed as a pharmacist in Alaska, called the Division in January and inquired about licensing requirements for the new retail facility in Ketchikan. A phone appointment was scheduled two weeks later with the PIC, an administrator of the facility under construction and Ms. Vellucci. In the interim, Ms. Vellucci researched the existing Board of Pharmacy Statutes and Regulations to determine if any statutes or regulations existed which may preclude the licensure of an IHS retail facility and consulted with her supervisor. This research confirmed there were no existing statutes or regulations which specifically preclude the licensure of an IHS retail facility. During the phone appointment, an emphasis was made about the licensure requirements for retail facilities, particularly 08.80.157 Licensing of Facilities, and the facility's obligation to comply with the governing statutes and regulations.

A discussion ensued regarding federal guidelines which required separate pharmaceutical inventories for beneficiaries and non-beneficiaries as well as separate inventories for 340B purposes. Mr. Holm stated the request from the DEA was working toward changing the existing statutes so all federal facilities and employees become licensed by the Board of Pharmacy

Medicaid Reimbursements: Ms. Mundell initiated a discussion about recent reimbursement changes for filling patient medisets. This change resulted in one single filling pay provision per 28 days. Any additional mediset filling services during that time would not be reimbursed. She stated mediset services were essential for the well-being of the most severely challenged in our communities, such as patients who are mentally ill, disabled or otherwise impaired. She cited common reasons why medisets needed to be adjusted by a pharmacist during the 28 day cycle: change in or additional course of antibiotics, adjusting Warfarin or Phenobarbital dose based on lab results, 14-day pain contracts and changes in blood pressure medications. She read an excerpt of a letter from Terry Marquardt, former Alaska DEA Investigator, in which he fully supported the ongoing funding of full mediset services and reimbursement per episode for reasons of patient safety and well-being. Ms. Mundell provided a draft letter summarizing these concerns and

requested the board review it, critique it and route to persons in positions of authority at DHHS and Alaska state government.

A discussion ensued about Medicaid's minimum notification for regulatory changes and whether the opportunity for public comment was sufficient in this case. It was noted this regulation had been passed however, there was an implementation delay due to technology issues.

Continuing Pharmacy Education: Sara Atchison was introduced as the CE Director at AkPhA. She informed the audience ACPE and the NABP were working together to establish a data base for all ACPE-accredited CEs. Since AkPhA was an accredited CE provider, they would submit CE credits to ACPE who would store the CEs in their database. Providers would no longer be sending out paper statements. These changes would be implemented later this year. Access to the database would be available to pharmacists, technicians, providers and boards of pharmacy. Pharmacists and technicians would have the option of enrolling for a fee to get reminders about CE courses that were due in their multiple states of licensure. Ms. Davis stated ultimately the CPE Monitoring Program would save money for the state association, largely because data would be electronically transferred.

There was a discussion regarding how to inform technicians about the CPE Monitoring Program, particularly those who were not working but want to maintain their license. Since the last CE Audit for Alaska licensing occurred in the fall of 2010, there appeared to be sufficient time to convey this information. Ms. Atchison requested the board notify pharmacists and technicians of the CPE Monitoring Program after the Division's participation was confirmed. Pilot programs were occurring presently in several states and enrollment was projected to be available in March.

Mr. White informed the audience the board made a motion yesterday to accept pharmacist-level CEs ("P" courses) taken by technicians. He acknowledged the ACPE did not agree with that stand and asked how this would be managed within the CPE Monitoring Program. Ms. Atchison said she did not know if it would be possible for the ACPE to allow that. AkPhA may lose its status as an ACPE provider if they allowed this. She offered to create a second set of objectives for technicians who take pharmacist level CEs, but that would only address CEs offered by AkPhA. The core issues with CE content are scope of practice and patient counseling parameters.

Mr. White asked if the board should address their dissatisfaction about this in the form of a written letter to the ACPE. Ms. Davis responded that would be up to the board and reminded them they do not have to participate in the CPE Monitoring Program if the terms were not acceptable.

Ultimately, it was agreed the board would draft a letter to the ACPE informing them 1) Alaska will accept pharmacist courses for technicians 2) the board does not want to jeopardize AkPhA's provider status because of this 3) how can this be accommodated with the CPE Monitoring Program?

It was emphasized technicians and pharmacists would first have to enroll and create their own individual log in information.

Agenda Item 16 **Public Comments**

Mr. Holm summarized yesterday's board activity on regulations in response to a request.

An audience member asked if the Alaska board has a licensing category for retired pharmacist licenses and was told they do not.

Ron Miller asked about the current regulations for electronic and scanned prescriptions, which state these must be printed in hard copy. Mr. Miller stated their computer system was backed up daily. The board agreed to look into this during the May meeting.

Ms. Houchen stated the Health Care Reform Bill had lead to rapid use of electronic prescribing and requested time at the May meeting to address this with the board. Walgreens had a presentation they would like to make at the May meeting on this topic and movement toward paperless system. The board chair agreed to add this to the agenda.

Agenda Item 17 **Office Business**

The board confirmed the May meeting dates to be the 12th and 13th. Wall certificates and Travel Authorizations were signed.

The board adjourned at 12:24 p.m.

Respectfully Submitted:

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Mary Kay Vellucci, Licensing Examiner

Approved:

_____
Dick Holm, Chair
Alaska Board of Pharmacy

Date:_____