

**STATE OF ALASKA  
DEPARTMENT OF COMMUNITY AND ECONOMIC DEVELOPMENT  
DIVISION OF OCCUPATIONAL LICENSING  
ALASKA STATE BOARD OF PHARMACY**

**MINUTES OF MEETING  
FEBRUARY 5-6, 2004**

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held on February 5-6, 2004, at the State Office Building, 333 Willoughby, 9<sup>th</sup> Floor, Conference Room "A," Juneau, Alaska.

**Thursday, February 5, 2004**

**Call to Order/Roll Call**

The meeting was called to order by Margaret Soden, Chair, February 5, 2004, at 1:02 PM. Those present, constituting a quorum of the board, were:

Margaret Soden, R.Ph.  
Bill Altland, R.Ph.  
Cindy Bueler, R.Ph.  
Mark Bohrer, R.Ph.  
Laura Lee Nelson, R.Ph.  
Michael Pauley

Present from the Division of Occupational Licensing were:

Barbara Roche, Licensing Examiner

Kurt West, Regulation Specialist, Division of Occupational  
Licensing (Agenda Item 5b)

Steve Winker, Paralegal, Division of Occupational  
Licensing (Agenda Item 6)

Present from the Department of Law were:

Gayle Horetski, Assistant Attorney General (Agenda  
Item 5a)

Dave Brower, Assistant Attorney General (Agenda  
Item 5b)

Present telephonically was:

Colin Matthews, Sr., Investigator (Agenda Item 6) via  
Teleconference

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Visitors present were:

Terry Babb, President-elect, Alaska Pharmacists Association (Agenda Item 8 & Public Comment)

Nancy Lewis, Purdue Pharma

Teresa Bruce

Louise Kressly, Alaska Primary Care Assoc. – (Public Comment)

Marilyn Kasmar, Alaska Primary Care Assoc. – (Public Comment)

**Agenda Item 1 Review of Agenda**

**On a motion duly made by Ms. Bueler, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to approve the agenda as presented.**

Mr. Bohrer noted that election of a new Vice President should be added to Agenda Item 19, New Business.

**Agenda Item 2 Review of Minutes**

The board reviewed the minutes from the October 2-3, 2003 meeting. The following corrections were noted:

- Page 9 – change “Review of Agenda” from Agenda Item 10 to Agenda Item 12. Change “Review of License Applications” from Agenda Item 10 to Agenda Item 11.
- Page 12 – delete “is” in first paragraph to read “for a continuing education audit”. Change “Discuss Licensing” from Agenda Item 12 to Agenda Item 13.
- Page 20 – change “questions” to “question” on the last line of page 20.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to approve the minutes of the October 2-3, 2003 meeting, with the corrections noted.**

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**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to approve the minutes of the October 21, 2003 Teleconference.**

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to approve the minutes of the November 20, 2003 Teleconference.**

**Agenda Item 3 Ethics Disclosure**

There were no ethics violations to disclose.

**Agenda Item 4 Review of Goals and Objectives**

Ms. Soden referred to the Goals and Objectives under Tab 4 of the board packets. There were no changes to the Goals and Objectives. In the interest of time, the board agreed to not read the Goals and Objectives at this meeting.

**Agenda Item 5a Legal**

Ms. Horetski stated for the record that she is the State of Alaska attorney defending the Board of Pharmacy in the lawsuit (Case No. 3AN-03-10587CI) brought by the Alaska State Medical Association (ASMA) regarding collaborative practice regulations. She stated that discussion regarding the lawsuit falls under attorney-client privilege and recommended that the board go into executive session.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to enter executive session in accordance with Alaska Statute (AS) 44.62.310(b) and (AS) 44.62.310(c)(1) to discuss the legal case of Alaska State Medical Association v. State of Alaska, Board of Pharmacy.**

The board entered executive session at 1:20 PM

The board went back on the record at 2:20 PM

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Ms. Horetski announced that Dr. Malter, President of the ASMA, would present a redraft of the collaborative practice regulations for the board's consideration Friday afternoon.

**Agenda Item 5b Review of Proposed Regulation Changes**

Mr. Brower and Mr. West joined the meeting at 2:25 PM

Mr. Brower discussed the following regulation changes that had been withdrawn from regulation project 993-03-0139 (pt. 2):

1. 12 AAC 52.990 Display of license certificate. Mr. Brower noted that changes to 12 AAC 52.990 were withdrawn because the Department of Law felt that the proposed changes were unclear and that a web posting of license certificate could be susceptible to fraud. The board noted that the information contained on the Division web site: <http://www.dced.state.ak.us/occ/> is the same information contained on the original license certificate. The current regulations require that the original license certificate be conspicuously displayed at the practice site. The board explained that the reason for the proposed regulation change was to allow a recently licensed person or facility to begin practicing between the time that the license is issued and the time that it actually arrives in the mail. There may be several days or even weeks delay from the time that a license is issued (and licensing information appears on the Division web site) to when the license arrives in the mail. Mr. Brower suggested that an editor's note could more clearly explain which specific "web posting" would be acceptable and also noted that the board might want to consider adding a penalty for fraudulent display of license certificate. Mr. Brower stated that he would work on revisions to the proposed regulation.
2. 12 AAC 52.130 Review of Application for registration of pharmacies located outside of the state. Proposed regulation changes to 12 AAC 52.130 were withdrawn by the Department of Law because of inconsistencies in language, specifically "license" vs. "registration" and unnecessary duplication of AS 08.80.158 REGISTRATION OF FACILITIES LOCATED OUTSIDE OF STATE. Mr. Brower noted that the regulation should not repeat the statute and that the board "registers", but does not "license" out of state facilities. Mr. Brower stated that he would make some revisions to the proposed regulations for the board to review and suggested that the Out of State Pharmacy applications be reviewed to assure consistency with the statute.

Mr. Brower left the meeting at 2:40 PM

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Mr. West presented the following regulation changes as amended in the October 27, 2003 "Notice of Proposed Changes in the Regulations of the Board of Pharmacy." The board discussed public comment received by December 3, 2003:

1. 12 AAC 52.090 EXAMINATION REQUIREMENTS AND REGISTRATION will be amended to alter the application requirements for applicants applying for a pharmacist license by examination. No public comments were received.

**On a motion duly made by Ms. Nelson, seconded by Mr. Bohrer, and approved unanimously, having considered public comment and cost to private persons, it was**

**RESOLVED to adopt regulation 12 AAC 52.090 as amended in the October 27, 2003 "Notice of Proposed Changes in the Regulations of the Board of Pharmacy."**

2. 12 AAC 52.325 CONTINUING EDUCATION REQUIREMENTS FOR PHARMACY TECHNICIANS, will be amended to alter the editor's note in this section to reflect a more current name and address for obtaining information on the certification process. No public comments were received.

**On a motion duly made by Ms. Bueler, seconded by Ms. Nelson, and approved unanimously, having considered public comment and cost to private persons, it was**

**RESOLVED to adopt regulation 12 AAC 52.325 as amended in the October 27, 2003 "Notice of Proposed Changes in the Regulations of the Board of Pharmacy."**

3. 12 AAC 52.340 APPROVED PROGRAMS, will be amended to reflect the new names of continuing education providers in this section. The board discussed public comment by a pharmacist who stated that completing 15 credit hours per year of Accreditation Council for Pharmacy Education (ACPE) approved continuing education was difficult for pharmacists living and working in bush areas. The board noted that there are many ACPE approved on-line, correspondence and pharmacist publications that offer continuing education courses, and that opportunities for completing ACPE approved continuing education are widely available. Mr. West stated that the ACPE name change from "American Council on Pharmaceutical Education" to

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“Accreditation Council for Pharmacy Education” would have to be taken care of in a future regulation project.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, having considered public comment and cost to private persons, it was**

**RESOLVED to adopt regulation 12 AAC 52.340 as amended in the October 27, 2003 “Notice of Proposed Changes in the Regulations of the Board of Pharmacy.”**

4. 12 AAC 52.585 MANDATORY PATIENT COUNSELING, will be amended to alter the requirements for counseling patients regarding prescriptions. Public comment was received from the National Association of Chain Drug Stores urging the board to not make patient counseling mandatory, but instead to allow pharmacists to use professional judgment to ensure counseling when appropriate. Mr. Altland stated that one of the board’s Goals and Objectives is to “promote effective patient counseling by licensees.” The board considered that there could be increases in costs to private persons, but that the board has acted in the interest of public health and safety in proposing this regulation change.

**On a motion duly made by Ms. Bueler, seconded by Ms. Nelson, and approved unanimously, having considered public comment and cost to private persons, it was**

**RESOLVED to adopt regulation 12 AAC 52.585 as amended in the October 27, 2003 “Notice of Proposed Changes in the Regulations of the Board of Pharmacy.”**

Ms. Soden thanked Mr. West on behalf of the board for his support and hard work on the many Pharmacy Board regulation projects.

Mr. West left the meeting at 3:00 PM.

**Break**

Off record: 3:00 PM

Back on record: 3:10 PM

**Agenda Item 6 Investigative Report**

Senior Investigator Colin Matthews, joined the meeting telephonically at 3:15 PM.

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REVIEW REPORT: The board reviewed the investigative report noting that there were 13 open cases and 4 cases were closed since the last report. Three pharmacy inspections have been completed since the last report.

Mr. Matthews reviewed the investigator report on a license application submitted by a pharmacist (Case #2650-03-002).

**On a motion duly made by Ms. Bueler, seconded by Mr. Bohrer, and approved unanimously, it was**

**RESOLVED to enter executive session in accordance with Alaska Statute AS 44.62.310(c)(2) to discuss Case #2650-03-002.**

The board entered executive session at 3:20 PM.

The board went back on the record at 3:45 PM.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Bueler, and approved unanimously, it was**

**RESOLVED for denial of pharmacist application. Because the applicant was convicted of multiple felonies, as listed in the Ohio State Board of Pharmacy Findings of Fact (Docket No. D-990218-029), the application is denied on the basis of AS 08.80.261 DISCIPLINARY SANCTIONS (a) "The board may deny a license to an applicant...when the board finds that the applicant...:  
(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services...;  
(4) has been convicted of a felony or has been convicted of another crime that affects the applicant's...ability to practice competently and safely;  
(8) engaged in conduct involving moral turpitude or gross immorality;  
(11) violated state or federal laws or regulations pertaining to drugs or pharmacies;  
(14) engaged in unprofessional conduct, as defined in regulations of the board.  
In addition, the application is denied on the basis of 12 AAC 52.075 GOOD MORAL CHARACTER.**

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

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**RESOLVED to amend the preceding motion to delete denial on the basis of AS 08.80.261(11) because the convictions were for fraud relating to laboratory services, not pharmacies. The remainder of the motion is unchanged.**

For the record, Case #2650-03-002 is the result of an investigation regarding a pharmacist application submitted by Mr. Colin E. Bayliss.

Senior Investigator Colin Matthews disconnected from the meeting at 3:50 PM.

Mr. Winker, Paralegal, joined the meeting at 3:50 PM.

CONTINUING EDUCATION AUDIT: Mr. Winker requested that the board resolve an issue regarding a fine for late payment in Case # 2600-03-005 Memorandum of Agreement (MOA) for Christian I. Duruji, Pharmacists License No. 1112. Mr. Winker stated that the MOA includes a provision for suspending part of the fine if all the conditions of the MOA have been met, but due to extenuating circumstances, payment was received late. Mr. Duruji acted in good faith in notifying Mr. Winker and making payment of the \$2000 fine.

**On a motion duly made by Ms. Nelson, seconded by Mr. Pauley, and approved unanimously, it was**

**RESOLVED to suspend the \$500 penalty for late payment in Case # 2600-03-005 Memorandum of Agreement.**

Mr. Winker departed from the meeting at 3:55 PM.

**Agenda Item 7 Long - Term Care Facilities**

Mr. Bohrer stated that there was nothing to report regarding Long-term Care facilities. He suggested that either the committee needs to be renamed the "Nursing Board Liaison Committee" or that it be dissolved. The board agreed that the committee would be reinstated in the future if warranted.

**Agenda Item 8 Report by AK Pharmacists Association**

Terry Babb, Association President-Elect and Pharmacy Director of Valley Hospital presented a report from the Alaska Pharmacists Association (AKPhA).

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- Mr. Babb announced that AKPhA has contracted with a new lobbyist, Caren Robinson, who will assist the association in pursuing their legislative priorities.
- AKPhA legislative priorities are: 1) Uniform Prescription Card; 2) Opposing SB 138 – introduced to annul collaborative practice; 3) Monitor / oppose anti-pharmacy bills.
- Mr. Babb announced upcoming continuing education opportunities co-sponsored by the association and invited board members to participate in the February 27-29, 2004 AKPhA Convention in Anchorage.
- AKPhA is actively promoting pharmacy technician training and is working with UAA and Kathi Baldwin, RPh, in the development of a pharmacy technician certification program. The UAA program involves developing distance learning modules, a certification program, and would provide training for technicians to pass the Pharmacy Technician Certification Board (PTCB) exam. The board discussed the feasibility of PTCB certification as a requirement for pharmacy technician licensing and noted that the board has considered adding a higher level of technician licensing.

**Agenda Item 9    Public Comment**

Public comment period opened at 4:15 PM.

TERRY BABB, PharmD, expressed his support to the board regarding the collaborative practice regulations and urged the board not to compromise to the extent that the original regulations become ineffective. Mr. Babb asked the board whether the ASMA lawsuit would fall under the provisions of the Public Litigant bill passed last year. Mr. Pauley noted that the ASMA lawsuit was filed under the old rules that required the public interest litigant not to have a financial interest in the outcome of the case.

MARILYN KASMAR, RNC, MBA, Executive Director and LOUIS KRESSLY, ANP, MSN, Clinical Specialist of Alaska Primary Care Association. Ms. Kasmar presented an overview of the Alaska Primary Care Association (APCA), a membership organization of federally funded community health centers, rural health clinics, other “safety net providers” and Associate Members who support the APCA’s efforts to develop and enhance health care for underserved populations in Alaska. Ms. Kasmar noted that the Alaska Pharmacists Association has recently become a member of APCA. APCA provides networking and various services to members including technical assistance, information and education services, legislative advocacy and community development.

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Ms. Kressly gave an overview of the Alaska Practice Management Network (APMN), a nine-member organization comprised of Section 333 Health Center personnel who work to integrate and coordinate functions among Community Health Centers. Ms Kressly discussed APMN efforts in replicating the Anchorage Native Medical Center (ANMC) pilot project model of pharmacy service delivery. Several of the non-federal APMN members have expressed interest in improving pharmacy services to rural areas by adopting the ANMC telepharmacy model and urged the Board of Pharmacy to adopt telepharmacy regulations. Ms Kressly asked the board to clarify whether a provider site could currently employ more than one type of delivery system for pharmacy services. The board noted that either a site is licensed by the Board of Pharmacy as a pharmacy/drug room or it is a dispensing provider site regulated by the Medical Board; the site is either/or and can not be both. The board is currently formulating telepharmacy regulations recognizing the need for flexibility in rural Alaska. Ms. Bueler stressed that the board is currently writing telepharmacy regulations, but that regulations can take up to a year to go through all the steps in the regulation process. Ms. Kressly reported that funding is available for a telepharmacy demonstration project and asked the board if there is a way to proceed with the project. The board responded that a telepharmacy demonstration project is not authorized under current regulations and that third-party reimbursement would not be available for an unlicensed facility. Ms. Kressly offered her assistance in answering questions or providing input in crafting telepharmacy regulations. The APC representatives invited board members to participate in the Alaska Rural Health and Primary Care Conference to be held March 2-5, 2004 in Anchorage.

Public comment was closed at 4:50 PM

**On a motion duly made by Ms. Nelson, seconded by Mr. Bohrer, it was**

**RESOLVED to recess and return at 9:00 AM,  
February 6, 2004.**

Recess

The board recessed at 4:55 PM.

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**Friday, February 6, 2004**

**Call to Order/Roll Call**

The meeting was called to order by Margaret Soden, Chair, February 6, 2004 at 9:02 AM. Those present, constituting a quorum of the board, were:

Margaret Soden, R.Ph.  
Bill Altland, R.Ph.  
Cindy Bueler, R.Ph.  
Mark Bohrer, R.Ph.  
Laura Lee Nelson, R.Ph.  
Michael Pauley

Present from the Division of Occupational Licensing were:

Rick Urion, Director  
Barbara Roche, Licensing Examiner

Present from the Department of Law was:

Gayle Horetski, Assistant Attorney General (Agenda Item 5a)

Visitors present were:

Terry Babb, President-elect, Alaska Pharmacists Association

Caren Robinson, Lobbyist, Alaska Pharmacists Association

Nancy Lewis, Purdue Pharma

Louise Kressly, Alaska Primary Care Assoc.

Marilyn Kasmar, Alaska Primary Care Assoc.

Dr. Alex Malter, President, Alaska State Medical Association

**Agenda Item 10 Review of Agenda**

Election of new board vice president was added under new business.

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Discussion by Dr. Malter of the ASMA was added after new business, at 4:00 PM.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to approve the agenda as amended.**

**Fire Alarm**

Off record: 9:10 AM

Back on record: 9:35 AM

Mr. Urion joined the meeting at 9:35 AM.

Mr. Urion, Division of Occupational Licensing Director, expressed his appreciation to the board for their service. Mr. Urion stated that he has an "open door policy" and welcomed input by board members. Ms. Soden, board chair thanked Mr. Urion for his support and contributions to the Board of Pharmacy.

Mr. Urion departed from the meeting at 9:40 AM.

**Agenda Item 11 Review License Applications**

The board reviewed the following applications and their recommendations were read into the record:

Pharmacy Technician Application:

- Deborah Coolidge - Pharmacy Technician License – Application with "Yes" answer was denied on the basis of 12 AAC 52.075 Good Moral Character, and 12 AAC 52.140(b)(2). Because the applicant refused to submit to chemical test and was "convicted within five years before date of application of a felony or other crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently", the board voted to deny this pharmacy technician license. The application was previously considered in the December 1, 2003 mail ballot, where the vote was: 1-approved; 1-denied; 1- vote pending further discussion at February board meeting. The vote at this meeting was 3-denied.

Pharmacist Applications:

- Colin E. Bayliss - Pharmacist – Reviewed under Agenda Item 6, Investigative Report. The Board denied the application.

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- Stephen P. Calloway – Pharmacist – Approved pending passing score on MPJE.
- Patrick J. Casey – Pharmacist – Approved pending passing score on MPJE and NABP final report.
- Doreen M. Hinsz – Pharmacist – Approved pending passing score on MPJE and receipt of original Verification of Alaska Internship hours.
- Doreen M. Hinsz – Temporary Pharmacist License - Application withdrawn.
- Shirley J. Isbell – Pharmacist – Approved pending passing score on MPJE, NABP final report, and license fee.

Out of State Pharmacy Applications:

- Accredo Health Group, Inc., Kent, WA – Change Name Application, was license #431 – Approved.
- The Compounding Shop, St. Petersburg, FL– New Application – Approved.
- EZRx, LLC., Union, NJ – New Application – Approved.
- PMSI, Inc., Tampa, FL – Change Ownership Application, was license #357 – Approved.
- TheraCom, Rockville, MD – Change Location Application, was license #100 – Approved.
- United HealthCare Products, LLC., Tampa, FL – New Application – Approved pending verification of pharmacy name.

Pharmacy Application:

- Alaska Infusion Therapy, Juneau, AK – Change Location Application, was license #358 – Approved.
- Wal-Mart Pharmacy 10-2722 – New Application – Approved pending receipt of names of corporation owners/officers. Self-inspection report will be submitted within 14 days of opening.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Bueler, and approved unanimously, it was**

**RESOLVED to approve the action taken on the license applications as read into the record.**

**Agenda Item 12 Review Protocol Applications**

The board reviewed the following applications and their recommendations were read into the record:

- Safeway Pharmacy # 0548 (Karen Maples, RPh – Colleen Murphy, MD) Emergency Contraception – Approved.

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- Safeway Pharmacy # 1808 (John Davis, RPh – Colleen Murphy, MD) Emergency Contraception – Approved.
- Susitna Professional Pharmacy (Mary Mundell, RPh and Dave Zuck, RPh – Colleen Murphy, MD) Emergency Contraception – Approved.
- Chief Andrew Isaac Health Center Pharmacy – (Daniel P. Nelson, RPh – Donna Galbreath, MD) Hypertension Collaborative Practice Agreement – Not approved. Application needs to be clarified. Ms. Soden will contact the pharmacy.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to approve the action taken on the protocol applications as read into the record.**

The board discussed a question posed by Mr. Altland regarding whether signatures for all participating pharmacists should be required. Some protocols that list the principal pharmacist and “all pharmacists employed by ...” are signed only by the principal pharmacist. Mr. Bohrer noted that this question had been discussed at length in the original drafting of the collaborative practice regulations. The board agreed that it would be impractical for a new application to be filed every time there was a change of personnel in the pharmacy and that the principal pharmacist is responsible to assuring that all pharmacists have completed the prescribed training before participating in the protocol.

**Agenda Item 13 Discuss Licensing**

- Renewal Applications. The board reviewed the draft revisions to June 30, 2004 renewal applications and approved the changes, including the addition of “Schedule of Continuing Education Completed” and a note on “Disciplinary Action for Late Renewal.”

**Agenda Item 14 Discuss Prescription Drug Abuse Issues**

- Medical Board / Committee Update - Ms Soden stated that the Board’s Prescription Drug Task Force continues to work on coordinating efforts between prescribers, law enforcement, pharmacists and others involved in the misuse and abuse of prescription drugs.
- HB 239 (ID System for Prescriptions) - Ms Soden noted that the board packets contain copies of letters to Representative Chenault and Commissioner Gilbertson expressing the

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board's concern about elements of HB 239. Ms. Lewis stated that Representative Chenault said he would be submitting a new bill.

- HB 408 / HJR 33 (Oxycodone Prescription Tracking / Oxycontin Request to Remove from the Market). The board discussed the recently introduced House Bill and House Joint Resolution and noted that targeting specific drugs does not effectively accomplish control of prescription drug abuse. Mr. Pauley stated that a Joint Resolution is not binding but could end up being introduced as a House Bill. If there are concerns with either HB 408 or HJR 33, the board should state, in a timely manner, their position to the House sponsors. Ms. Soden and Mr. Altland will draft a letter to the House sponsor, Representative Wolf, stating that the board supports prescription monitoring of all controlled substances, and feels that singling out just Oxycodone would not be effective. In addition, the letter will clarify usage of the terms Oxycodone and Oxycontin. Mr. Altland pointed out that Board of Pharmacy Goal Number 2 is "to provide input and comment on any proposed legislation/regulations involving medications or pharmaceutical care."

**Agenda Item 16 Division Updates**

- Budget Report - The board reviewed the Budget Report provided by the Division of Occupational Licensing. Board members requested that the division review the board's recommendations for licensing fee adjustments. The Licensing Examiner stated that renewal fees would likely be higher due to added legal expenses and an increase in the number of regulation projects and licensing actions. The board budget is currently being reviewed, and increased costs will be reflected in the renewal and licensing fees.
- Newsletter - The Board of Pharmacy will no longer be mailed out, but will be available online on the National Association of Boards of Pharmacy (NABP) web site: <http://www.nabp.org>. There will also be a link to the newsletter on the Board of Pharmacy web page: <http://www.dced.state.ak.us/occ/ppha.htm>. Ms. Soden will include an announcement of the online only newsletter in the Board of Pharmacy write-up she submits to the Alaska Pharmacists Association Newsletter. Ms. Soden suggested that Pharmacists in Charge print out copies for their pharmacy staff.

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**Agenda Item 17 National Association of Boards of Pharmacy (NABP) Update**

MPJE State-Specific Review Meeting was attended January 23-25, 2004 in Scottsdale, AZ by Ms. Soden and Mr. Bohrer. Mr. Bohrer reported that they reviewed approximately 1600 questions, eliminated 300 confusing or out-dated questions, and wrote 30 new questions. Ms. Soden mentioned that the exam scores for the Alaska MPJE fall in the 80% range, which gives the Alaska MPJE high "validity" (scores are not too high or too low). Mr. Bohrer and Ms. Soden definitely recommended that two board members attend the review meetings and suggested that either the Licensing Examiner or the Investigator go to next year's meeting along with one board member. Ms. Soden noted that many of the Review Meeting attendees were Board of Pharmacy Executive Directors or Investigators, and that it was a great opportunity to network with other state Board of Pharmacy staff.

**Break** Recess for Lunch at 11:45 PM.

Back on record at 1:10 PM.

**Agenda Item 15 Legislative Update**

- HB 51 (Generic Labeling) Ms Soden noted that the board's concerns about this bill were presented to Representative Seaton's aide during the last legislative session. The generic labeling regulation 12 AAC 52.48(12) became effective January 14, 2004. Ms. Robinson stated that she gave a copy of the new generic labeling regulation to Senator Seaton's staff, who said that HB 51 would probably not progress.
- SB 138 (Collaborative Practice) Ms. Soden noted that there has been no activity on SB 138 since April 8, 2003 and that if the bill doesn't pass in this legislative session, it would have to be reintroduced.
- HB 306 / SB 197 (Pharmaceutical Use by Optometrists) Copies of these bills are in the board packets.
- HB 374 / SB 259 (Senior Care Program) Ms. Robinson presented information handouts on "Senior Care". If passed, this legislation would provide funding for a prescription drug benefits for eligible seniors starting April 2004 until full Medicare prescription drug coverage begins in January 2006. Ms. Robinson noted that this bill is on the "fast track".

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**Agenda Item 18 Correspondence**

Nevoca, Patient Information & Prescription System, P.I.P.S., Prescription Monitoring Program. For information only, no action required.

Sharon Hamrick, Alaska Dept. of Health & Social Services. Question on "declared emergencies". "In the event of a declared emergency, can pharmacists assist with processes that provide medications for the public good without fear of retribution from the State Board of Pharmacy?" The Board stated that current regulations don't directly address "declared emergencies, but that specific protocols to "administer" are regulated under 12 AAC 52.240 "Pharmacist Collaborative Practice Authority". However, "drug administration" is included under the scope of practice of pharmacy. AS 08.80.480(27) "practice of pharmacy" means interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research;..." The board stated that pharmacists have authority under AS 08.80.480(27) "practice of pharmacy" to "administer" medications, and that in the event of a declared emergency, pharmacists may assist with processes that provide medications for the public good without fear of retribution from the State Board of Pharmacy. Because "drug administration" is already within the scope of practice of pharmacy, there does not appear to be a need for additional legislation. The board noted that the currently a lawsuit filed by the Alaska State Medical Association (ASMA) v. The State of Alaska Board of Pharmacy, is related to collaborative practice regulations 12 AAC 52.240, and pharmacist authority under AS 08.80.480. The Licensing Examiner will respond to Ms. Hamrick.

Juneau Empire, November 25, 2003. FDA considers over-the-counter morning-after pill. For information only, no action required.

Bill Altland. Email regarding scheduling Pharmacy Board meeting during AKPha Convention. Mr. Altland stated that holding the Board of Pharmacy meeting at the same time as the AKPha Convention would be an opportunity for pharmacists attending the convention to participate in the board's meeting. Mr. Babb announced that the next AKPha Convention will be held in Anchorage at the Captain Cook February 25-27, 2005.

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Rick Urion, Director, Division of Occupational Licensing - State of Alaska DCED Procedures - Staff Travel. For information only, no action required.

Charles N. Holmes, Question on refilling time limits. 12 AAC 52.470(b) and 12 AAC 52.920(11). The board answered that interpretation of refilling time limits is subject to 12 AAC 52.470(b) and 12 AAC 52.920(11), as well as professional choice and interpretation of the regulation by the pharmacist. The board noted that in the case presented by Mr. Holmes, some pharmacists would have filled the whole prescription and some would have filled only the 9 days. The Licensing Examiner will respond to Mr. Holmes.

Claudia Palacios, Coordinator, Alaska Practice Management Network. Telepharmacy for Non-Tribal Entities. Copy of NABP Model Automation Regulations. Mr. Altland noted that the Telepharmacy Model Regulations referred to in the letter are actually NABP Model Automation Regulations. Mr. Altland said that there is more current information available and that he will be attending The Alaska Rural Health and Primary Care Conference in March.

Roger F. Holmes, Letter to Gayle A. Horetski, RE: ASMA v. Pharmacy Board, request for meeting. Ms. Soden, Ms. Horetski and Ms. Roche met with Dr. Malter, ASMA President on February 4, 2004 to discuss the ASMA v. SOA lawsuit and review proposed collaborative practice regulation language. Further discussion will be held at 4:00pm at today's meeting.

NABP - 100th Annual Meeting, April 24-27, 2004, The Fairmont Hotel, Chicago, IL. A representative of the board will not attend the Annual Meeting, but will plan to attend the Fall District VII meeting. The District VII meeting date and location has not yet been announced.

NABP - Annual Active Membership Dues for 2004. \*Motion to pay.

**On a motion duly made by Ms. Bueler, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to approve payment of NABP Annual Membership dues for 2004.**

Baker & Hostetler, LLP, - Andrew J. Murray - Letter and emails RE: Valley Hospital - PHA R 404; MyDoktors Pharmacy - PHA R 405; Valley Hospital - AIC Medical Clinic - PHA G 24; Valley Hospital - Susitna Surgery Center - PHA G 25 license issue date. Tennessee & Texas Regulations. The board discussed whether it

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had the authority to change the license issue date and answered that the license was issued on the date that notification was received by the Licensing Examiner.

State of Alaska - Office of the Governor, Board and Commissions Office. Membership Roster Pharmacy Board; Reappointment Letter to Cindy Bueler; Michael Pauley; Appointment Letter to Gary Givens. Ms. Soden announced that Ms. Bueler and Mr. Pauley have been reappointed to 4-year terms to the board. Mr. Gary Givens, Pharmacy Director of Alaska Native Medical Center has been appointed to replace Mr. Bohrer, whose term expires March 1, 2004. Ms. Soden expressed appreciation to Mr. Bohrer for his service to the Board of Pharmacy.

Dr Alex Malter, President, Alaska State Medical Association (ASMA) - fax; Memorandum from Roger F. Holmes, Attorney for ASMA - RE: Redraft of Regulations. Discussion will be held at 4:00pm at today's meeting.

US Food and Drug Administration, Letter to State Boards of Pharmacy, Acetaminophen Hepatotoxicity and Nonsteroidal Anti-Inflammatory Drug (NSAID)-related Gastrointestinal and Renal Toxicity. Ms. Bueler distributed copies of a FDA cautionary letter raising awareness about the danger of unintentional overdoses of NSAID products. Mr. Altland recommended downloading the FDA brochure for distribution to patients. Ms. Bueler suggested that an article in the Anchorage Daily news would reach a wide audience and agreed to contact the newspaper.

NABP - 2004 MPJE Time and Task Schedule for Participating Boards. Mr. Bohrer pointed out that the original Time and Task Schedule needs to be corrected to show that the board will participate in the Review of New Items, June 15 to August 16, 2004. The Licensing Examiner will notify NABP.

NABP - "Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine Products by Retail Distributors". For information only, no action required.

NABP - NABP/FDA: Public Safety is at Risk with Foreign Drug Importation. For information only, no action required.

**Agenda Item 19 New Business**

- Substitution 12 AAC 52.10(a)(1).

The board discussed possible changes to electronic prescribing regulations, specifically substitution provisions. The board packets contain copies of proposed electronic prescription

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regulations from Massachusetts. Ms. Bueler noted that the NABP is developing model regulations for electronic prescription transmission through Resolution (97-2-2001). The board agreed to follow the lead of NABP and revisit the issue when model regulations are finalized.

- Election of Board Vice-President

The board held election for Vice President to fill the position left vacant from Mr. Bohrer's expiring term. The change in officer will be effective March 1, 2004.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to nominate and elect Cindy Bueler for board Vice-President.**

**Break**

Off record: 2:30 PM

Back on record: 2:40 PM

**Agenda Item 20 Office Business**

- The board set the 2004 meeting schedule as follows:  
April 22-23, 2004, Anchorage at Atwood Building.  
July 22-23, 2004, Anchorage at Atwood Building.  
October 21-22, 2004, Anchorage at Atwood Building.
- The Chair signed the approved minutes from the October 2-3, 2003 meeting, October 21, 2003 and November 20, 2003 teleconferences.
- The Board Chair and Secretary signed wall certificates.
- Board members signed Travel Authorizations and provided travel receipts.

**Agenda Item 22 New Business**

- TelePharmacy Ad-hoc Committee.

Mr. Bohrer distributed copies of "Telepharmacy Project Phase I", which includes a list of the regulations discussed at the April 24-25 meeting that would need to be revised in order to move forward with telepharmacy practice. Mr. Bohrer identified problem areas in the existing regulations and came up with proposed language to address these problems. In addition to amending existing pharmacy regulations, new regulations would need to be written to provide the framework for telepharmacy.

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Mr Bohrer and Mr. Altland presented a review of existing pharmacy regulations that need to be revised to allow telepharmacy. The board discussed recommendations from the April 24-25, 2003 meeting minutes and Telepharmacy Project document distributed by Mr. Bohrer.

Problem #1 – “New Regulation Classification”

- 12 AAC 52.010(b) Classification of Licensure. Add a new classification of licensure under 12 AAC 52.010(b)(6) “remote site”. “The board noted that each remote site would be separately licensed, and each remote site would have a unique DEA and NCPDP number. The Licensing Examiner noted that a new License Type letter designator for “remote site” would need to be assigned by the division and cross-referenced in the licensing data base to the central pharmacy site. The board agreed that remote site license should list the central pharmacy site and the central pharmacy license should list all the remote sites. An application and self-inspection form for a remote site pharmacy would have to be drawn up based on the new regulations.
- 12 AAC 52.010(a) Facility License. Add under 12 AAC 52.020(a)(5) “for a remote site, the license number and name of the central pharmacy.”

Problem #2 - Amend 12 AAC 52.200(a)

- 12 AAC 52.200(a) is amended to read: “Before the board will issue a license to a pharmacy, the owner of a pharmacy must designate a pharmacist [WHO PRACTICES IN THAT PHARMACY LOCATION] as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330 and comply with either (1) or (2) below. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.
  - (1) The pharmacist-in-charge must practice in that pharmacy location; or
  - (2) For remote sites, the pharmacists-in-charge must ensure that all practice in that location is under the direct supervision of a pharmacist.

Problem #3 – Pharmacist Duties

- 12 AAC 52.210 “Pharmacist Duties. Except as provided in 12 AAC 52.220, the following duties may be performed only by a pharmacist: (1) receiving an oral prescription drug order, including refill approval or denial that includes any change to the original prescription drug order; (2) consulting with a prescriber

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regarding a patient or prescription; (3) interpreting a prescription drug order; (4) determining the product required for a prescription; (5) interpreting data in a patient medication record system; (6) making a final check on all aspects of a completed prescription and assuming the responsibility for a filled prescription, including the accuracy of the drug prescribed and of the prescribed drug's strength, labeling and proper container; and (7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system." The board determined that, with computer, video and audio links in place, bar-code technology and security regulations, a pharmacist could perform all the duties listed in 12 AAC 52.210 from a different location, and protect the public health, safety and welfare.

Problem #4 – Security

- 12 AAC 52.240(c) "Security" should be amended to read: All drugs and devices and other items or products that are restricted to sale by or under the [PERSONAL] direct supervision of a pharmacist shall be kept in the prescription department. Mr. Boher pointed out that "personal supervision" is changed from the current regulation to "direct supervision".
- 12 AAC 52.995(13) should be amended to read: "direct supervision' means [VISUAL OR PHYSICAL PROXIMITY] supervision that ensures adequate safety controls either by physical proximity or by computer, video and audio link."

Problem #5 – Security

- 12 AAC 52.420(d) should be amended to read: "The prescription department shall be [LOCKED BY KEY OR COMBINATION] secured to prevent unauthorized access when a pharmacist is not [ON-SITE] available to provide direct supervision."

Problem #6 – Security

- 12 AAC 52 420(f) should be amended to read: "Prescriptions shall be stored in the prescription department and [MAY NOT BE REMOVED UNLESS A PHARMACIST IS PRESENT] may be removed only under the direct supervision of a pharmacist and the removal is for immediate delivery to the patient, the patient's agent or the person delivering the prescription to the patient or the patient's agent."

Definitions to add to 12 AAC 52.995:

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- “Remote Site” Definitions included in other states telepharmacy regulations were presented, including the following: “Remote site” means a site staffed by a registered pharmacy technician, with access to its main pharmacy and registered pharmacist by computer video and audio link”

The board discussed whether a remote site would be required to have a licensed technician and acknowledged the problems of finding and training qualified staff for remote sites. The board suggested that the distance learning program being developed by UAA for Pharmacy Technician training and certification could be a solution for technician training in remote areas. Mr. Altland stated that Washington and North Dakota established higher standards for pharmacy technicians working in remote sites and noted that initial training approved by the board and a continuing education component was also required. The board acknowledged that different locations and populations in Alaska require different approaches in the regulations. Before telepharmacy regulations can be finalized, a decision needs to be made on training, education and examination requirements for personnel staffing remote sites. Ms. Kressly noted that she supports an examination requirement for remote pharmacy technician licensing and suggested that a specific pharmacy technician-training module be developed for health aids.

Mr. Bohrer agreed to help Mr. Altland and other interested parties to form a technician work group to generate a regulation proposal on pharmacy technician qualifications, classifications, and training. The Telepharmacy ad hoc committee will continue to work on crafting regulations, and discussion will be continued at the next meeting. Definitions of the following terms also need to be written:

- “Remote Site”
- “Central Pharmacy”
- “Telepharmacy”

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**Agenda Item 5a Legal**

Ms. Horetski and Dr. Malter joined the meeting at 4:00 PM.

Dr. Alex Malter, ASMA President addressed the board regarding collaborative practice lawsuit brought by the Alaska State Medical Association against the State of Alaska, Board of Pharmacy. Dr. Malter stated that it was unfortunate to have to meet the board under strained circumstances. Dr. Malter noted that the ASMA pursued many avenues to get this issue addressed and to pressure the state to revise the collaborative practice regulations before filing the lawsuit. ASMA felt compelled to file the lawsuit in the Fall of 2003 because of some pending changes in Alaska law. Dr Malter stated that the lawsuit is not about a turf issue, or about emergency contraception, but has been filed out of the ASMA's concern for public safety. Dr. Malter expressed concerns that the regulations allow the Pharmacy Board to gradually and potentially be making decisions that the ASMA believe are clinical, medical decisions. ASMA concerns are spelled out briefly in the overview and "Redraft of Regulations" January 20, 2004 memo presented to the board. Dr. Malter asked if any board members had questions regarding his introduction or the regulation redraft.

Mr. Pauley asked if any discussions had taken place with the State Medical Board encouraging them to enact their own set of regulations addressing prescriber participation in collaborative practice. Mr. Pauley cited 12 AAC 52.240(a) "A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08..." Mr. Pauley noted that the State Medical Board obviously has jurisdiction over some of those practitioners and wondered to what extent concerns could be resolved by changes to Medical Board regulations. Dr. Malter answered that some of the concerns could have been resolved if the Medical Board had been more willing to work with the Pharmacy Board when these regulations were brought forward four years ago. Dr. Malter has spoken several times more recently with the State Medical Board encouraging them to become more engaged, not just to support the ASMA position, but also to work with the Pharmacy Board to see if some joint regulations could be devised. The Pharmacy Board acknowledged receipt of a Medical Board Resolution passed at the January 15-16, 2004 State Medical Board Meeting requesting and supporting removal of collaborative practice regulations as currently written.

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Dr. Malter stated that the ASMA proposed "Redraft of Regulations" would go 90% of the way to getting pharmacists and patients the benefits that can come from collaborative practice. Mr. Pauley asked Dr. Malter what barriers prevent the Medical Board from unilaterally adopting the regulations as suggested by ASMA and implementing some of the language as a Medical Board regulation. Dr. Malter noted that the ASMA could not make the State Medical Board do anything, but could attempt to make the Pharmacy Board do something because the pharmacy regulations have already been adopted. The ASMA believe that they have some valid legal issues and see the lawsuit as their only recourse for now.

Dr. Malter stated that, whether or not the ASMA concerns are legally founded, there are concerns within the membership that it is not good to have the Pharmacy Board do something which ASMA sees as a unilateral action where folks are moving potentially into the practice of medicine. Some members of the ASMA perceive that if the Pharmacy Board can do this, then other boards can do it as well. For example, other boards, with ancillary providers, have proposed and may even have regulations adopted which ASMA perceives as moving into the field of medicine or getting very close to it. The Association is concerned with the legal precedent. Dr. Malter added that even if the Medical Board did make some of these proposed changes, he is not sure that the Association would be completely satisfied, because they are still concerned that the Pharmacy Board overstepped its statutory authority by adopting these regulations. In addition, Dr. Malter expressed concern that pharmacists are setting themselves up where they could get into clinical decision making.

Ms Bueler stated that as a hospital pharmacist, she participates daily in collaborative practice. She pointed out that, just as the P&T Committee is a joint committee of physicians and pharmacists overseeing protocols, Collaborative Practice protocols are joint protocols between a physician and a pharmacist or a group of pharmacists. Dr. Malter said that the concern of the Association membership is that, unlike some Collaborative Protocols signed off by only one physician, hospital P&T committees contain multiple physicians and pharmacists, and that protocols are reviewed and signed off by two or three doctors and pharmacists. Ms. Bueler asked whether additional oversight could be written into the regulations, rather than just annulling the entire collaborative practice program. Dr. Malter stated that 50% of their concerns could be satisfied if agreement could be reached on one of the ASMA general provisions (2) "All protocols must be approved not only by the Pharmacy Board but also by a board of physicians, or the practitioner's relevant board. We believe that the State Medical Board is the optimal body for this responsibility,...)."

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Ms. Bueler asked if the ASMA could have gone forward with its regulation suggestions without filing a lawsuit? Dr. Malter stated that these suggestions were circulated for one to two years to a variety of folks including the current Occupational Licensing Director, his predecessor, the Department of Law, the Governor's transition teams, the Senate, the Legislature, with no result. Mr. Bohrer stated that back when the regulations were initially introduced, he went to the State Medical Board Meeting. Mr. Bohrer presented the draft collaborative practice regulations and he did not receive a cordial or respectful reception. Mr. Bohrer requested the Medical Board consider having some oversight of collaborative protocols. They answered Mr. Bohrer that the Medical Board does not regulate how their clinicians practice clinically. Mr. Bohrer noted that neither a member of the ASMA or the State Medical Board has attended one of 4 yearly Pharmacy Board meetings to express any opinion on these regulations.

Ms. Bueler asked Dr. Malter to speak to ASMA general provisions point 1 ("ASMA would be satisfied with new regulations based on the following general provisions: (1) An approved protocol may only be applied to individual patients specifically enrolled by prescription of a collaborating physician.") Dr. Malter stated that the concern is that you could have one physician set up a protocol that any patient who had a blood pressure of 145/90 could be started by a pharmacist on anti-hypertensives. Dr. Malter noted that this is the way ASMA reads the regulations. This interpretation is evidenced by some of the approved protocols, specifically emergency contraception (EC), which allow a patient to be started on a medication without a previous physician-patient relationship. Dr. Malter stated that EC makes the point that the regulations are broad enough that similar protocols could be approved for hypertension, for example. Mr. Bohrer noted that protocols similar to what Dr. Malter has suggested have not been approved and that every protocol requires a physician willing to authorize the protocol, a pharmacist willing to participate, and a Pharmacy Board that would approve the protocol. Dr. Malter stated that because the regulations appear to be broad enough to allow such protocols, a medical board, or medical group needs to be looking at the protocols and there needs to be a prior physician-patient relationship. Ms. Bueler pointed out that EC medications would likely be going over the counter and that requiring an initial diagnosis by a physician would preclude EC and immunization protocols. Dr. Malter referred to the proposed "Redraft of Regulations" (2)(c) "With the exception of immunizations/vaccinations...a referral to the pharmacist occurs only after the patient has been evaluated by the practitioner and a practitioner/patient relationship has been established. Dr. Malter stated that ASMA believes that a carve-out for

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immunizations may be appropriate, that they don't have a position on EC, and that the Pharmacy board could decide how they want to handle that. Dr. Malter stated that the legal action is not about EC, and that the lawsuit is a separate issue from the legislative action. Further, Dr. Malter said that if the board is interested in working with ASMA and settling the lawsuit, he believes that EC is not going to be an issue.

Ms. Bueler asked if there could be some cooperation in oversight of the protocols, understanding that ASMA can not speak for the Medical Board. Dr. Malter stated that if the Medical Board refused to provide oversight of protocols, then between AMSA counsel and the Pharmacy Board counsel, a satisfactory compromise could be reached where ASMA would offer names of several physicians that could sit on an advisory board to review protocols.

Ms. Soden thanked Dr. Malter for speaking to the board.

Ms Horetski asked if the board wanted to discuss Dr. Malter's comments, the proposed "Redraft of Regulations, or litigation strategy.

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to enter executive session in accordance with Alaska Statute (AS) 44.62.310(b) and (AS) 44.62.310(c)(1) to discuss the legal case of Alaska State Medical Association v. SOA.**

The board entered executive session at 4:45 PM

The board went back on the record at 5:15 PM

**Adjournment**

**On a motion duly made by Mr. Bohrer, seconded by Ms. Nelson, and approved unanimously, it was**

**RESOLVED to adjourn the meeting of the Alaska State Board of Pharmacy.**

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The meeting was adjourned at 5:15 PM.

Respectfully submitted:

\_\_\_\_\_  
Barbara Roche, Licensing Examiner

Approved:

\_\_\_\_\_  
Margaret Soden, R.Ph., Chair  
Alaska State Board of Pharmacy

Date: \_\_\_\_\_