

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

**MINUTES OF MEETING
OCTOBER 2-3, 2003**

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 October 2-3, 2003 at the Atwood Building, 550 West 7th Ave. Suite 602, Anchorage, AK.

Call to Order/Roll Call

The meeting was called to order by Margaret Soden, Chair, October 2, 2003 at 1:10 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
Gerry Knasiak

Present from the Division of Occupational Licensing was:

Barbara Roche, Licensing Examiner

Visitors present were:

Jason M. Hooley, Legislative Aide for Senator Dyson
Julia Winchell, Senior Investigator (Agenda Item 6)
Rick Younkens, Investigator (Agenda Item 6)
Nancy Davis, Executive Director Alaska Pharmacists Association (Agenda Item 8)
Nancy Lewis, Purdue Pharma – (Agenda Item 14)
Kathi Baldwin, UAA – (Public Comment)
David High, Walmart/Sams – (Public Comment)

Agenda Item 1 Review of Agenda

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

RESOLVED to approve the agenda as presented.

Agenda Item 2 Review of Minutes

The board reviewed the minutes from the July 25, 2003 meeting. The following corrections were noted:

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- Page 9 – change “AMNC” to “ANMC” and correct the spelling of “Commissions”
- Page 10 – change “certain federal contracts” to “certain contracts” and change “diversion of federally purchased pharmaceuticals” to “diversion of the purchased pharmaceuticals”
- Page 12 – change “AMA” to “ASMA” for the Alaska State Medical Association.

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

RESOLVED to approve the minutes of the July 25, 2003 meeting, with the corrections noted.

Agenda Item 3 Ethics Disclosure

There were no ethics violations to disclose.

Agenda Item 4 Review of Goals and Objectives

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). Ms. Soden suggested that the board consider administering the Intern Jurisprudence exam to pharmacy technicians.
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 their affiliation with NABP and send one board member to the District VII NABP meeting and two members to the annual NABP meeting. The Division's budget currently allows one out-of-state travel per fiscal year; this is generally used for attendance at the District VII NABP meeting.
8. The board will continue to evaluate the need for regulations specific to facility activities (i.e.; retail pharmacies, drug rooms, institutional pharmacies, home infusion pharmacies, nuclear pharmacies, sterile products, telepharmacy, etc.).

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9. The board will continue to evaluate regulations regarding the electronic transmission of prescriptions.
10. The board will continue to evaluate regulations regarding collaborative practice and to establish procedures for reviewing/approving appropriate protocols for collaborative practice.
11. The board will assess and evaluate the growing public concern regarding abuse of prescription drugs.

Agenda Item 5 Review of Proposed Regulation Changes

The board discussed the following regulation changes:

1. 12 AAC 52.240 PHARMACIST COLLABORATIVE PRACTICE AUTHORITY. Ms Bueler presented a “Draft” of wording changes to the Collaborative Practice Agreement, emphasizing that this is a “working draft” and that the current language was developed after looking at regulations from several other states. Ms. Bueler pointed out that collaborative agreements for vaccines are singled out by many other state’s regulations and vaccine collaborative agreement regulations specifically address training and education. Malpractice insurance is another issue addressed by other state’s collaborative agreements. During the original drafting of Alaska’s collaborative practice regulations, an opinion from the Alaska State Medical Board noted that the prescribers’ insurance covered delegated individuals within the scope of the collaborative agreement.

Ms. Bueler noted that the first paragraph of the “Draft” is an attempt to be very specific about the physician/patient relationship, which would in effect exclude emergency contraception, and vaccinations, unless specifically addressed, from collaborative practice agreements.

Mr. Bohrer noted that his presentation to the Alaska State Medical Board in 2000 of the original draft of collaborative practice regulations was met with strong but mixed opinions from the Medical Board members. Mr. Bohrer noted that nationally, more and more states are approving collaborative practice agreements or modeling agreements after the federal model and public health service practices.

Ms. Bueler questioned whether clarifying the physician/patient relationship in the regulations would result in Senator Dyson’s withdrawal of SB 138 and/or withdrawal of the ASMA’s legal action. Mr. Bohrer noted that in the case of vaccine collaborative agreements, medical records are transmitted to the primary care physician, if there is one. However, many of those vaccinated for flu did not have a primary care physician and would not have spent the money

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or time to be vaccinated if the pharmacy vaccination program had not been available.

The Board discussed their options for proceeding on writing new collaborative practice regulations or amending existing regulations in light of the recently filed "Complaint for Permanent Injunction": Alaska State Medical Association vs. The State of Alaska, DCED, Division of Occupational Licensing, Board of Pharmacy. The Board has not been contacted by the Department of Law and was uncertain which attorney would be answering the complaint. The licensing examiner will talk to the Occupational Licensing Director about contacting the Department of Law for guidance on public comment relating to the lawsuit, and on how to proceed with amending the collaborative practice regulations.

Ms. Bueler and Mr. Bohrer will continue to work on wording for collaborative practice regulation changes. Ms. Bueler will draft a letter to be sent to Senator Dyson and the Alaska State Medical Board stating that the Pharmacy Board is continuing to work, in good faith, on amending the collaborative practice regulations. Ms. Soden suggested that a representative of the Board of Pharmacy attend the next Medical Board Meeting.

The Board discussed the effects of changes to the current collaborative practice regulations. SB 138 would annul the entire collaborative practice regulation. The proposed "draft" regulation change would eliminate any collaborative agreements including emergency contraception and immunizations, where there was no referral by a licensed practitioner. Mr. Altland wanted to state for the record that it is unfortunate to change the original intent of the regulations to exclude emergency contraception from collaborative agreements. Many board members agreed that many pharmacies entered emergency contraception collaborative agreements at the request of licensed practitioners and that excluding Emergency Contraception collaborative protocols may not be in the best interests of the public.

Break

Off record: 2:25 AM

Back on record: 2:30 AM

2. 12 AAC 52.480 and HB 51 (GENERIC LABELING).
Discussion of the proposed regulation change was continued from the last meeting. Mr. Altland reported on correspondence received from Bill Lockwood of Computer Talk Magazine, a technology publication for retail pharmacies. Mr. Lockwood stated that changing existing software to add the generic name to the prescription label could be a difficult and expensive to implement. The Board noted that it did not

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adopt the proposed generic labeling regulation change to 12 AAC 52.480, because of the public comment received.

Ms. Nelson reported the survey results received from the posting the following question on the NABP web mail site: "1.) Does your state have regulations requiring, on the prescription label, a listing of the equivalent generic drug name when dispensing a brand-name prescription drug order?" "2.) If yes, how does the generic labeling regulation read?" Out of the fourteen responses received, ten states answered that they had no regulations. Two states require labeling of generic name, one state's regulations "encouraged" generic labeling, and one state regulations say that the "label may" include the generic name.

HB 51 is currently in the Rules Committee, which is the last stop before the bill hits the floor for debate at the upcoming session. Mr. Pauley suggested that a representative of the Board meet before the next Legislative session with Senator Therriault, Senate President, to suggest changes to the current bill. Mr. Bohrer noted that at the last meeting Senator Dyson suggested that the bill could be referred back to his committee if the board presented alternate wording. Mr. Pauley suggested contacting the HB 51 sponsor, Representative Seaton, to present copies of the public comments received by the board and discuss changes to the bill. Mr. Bohrer and Ms. Soden will draft improved language and discuss during tomorrow's meeting.

Discussion of the remainder of the Regulations for Review and "Draft" Regulations will continue at tomorrow's meeting.

Agenda Item 6 Investigative Report

Senior Investigator Julia Winchell and Investigator Rick Younkens joined the meeting at 2:35 PM.

REVIEW REPORT: The board reviewed the investigative report provided by Mr. Younkens, noting that there were 14 open cases and 2 cases were closed.

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

**RESOLVED to enter executive session in
accordance with Alaska Statute AS 44.62.310(c)(2)
to discuss Case #2600-02-003 and 2602-02-006.**

The board entered executive session at 2:40 PM.

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The board went back on the record at 3:10 PM.

CASE #2600-02-003: Memorandum of Agreement for a pharmacist was presented to the board. The case is the result of an active investigation of abuse by a pharmacist. Ms. Soden recused herself from voting on this case because of a financial relationship and personal knowledge of the pharmacist.

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

RESOLVED to adopt the Memorandum of Agreement for a pharmacist Case #2600-02-003 as presented.

For the record, Case #2600-02-003 is a Memorandum of Agreement for David L. Swanson, Pharmacists License No. 292. Mr. Bohrer, Board Vice-President signed the M.O.A and presented it to Mr. Younkins

CASE #2602-02-006: License Surrender for Out of State Pharmacy was presented to the board. The case is the result of an active investigation of a license application problem.

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

RESOLVED to adopt the License Surrender for Out of State Pharmacy, Case #2602-02-006 as presented.

For the record, Case #2602-02-006 is License Surrender for Out of State Pharmacy, Urgent Care Pharmacy, Inc. Spartanburg, SC - License No. 319. Ms. Soden signed the surrender and presented it to Mr. Younkins.

Mr. Younkins presented the results of an investigation regarding a pharmacist's application. The board will consider the application under Agenda Item 11.

Case # 2600-03-005 and #2600-03-003 Memoranda of Agreement for continuing Education will be presented by Steve Winker, Paralegal under Agenda Item 11.

LICENSE ACTIONS ARE PUBLIC RECORD. The board noted that, as a matter of public record, case numbers and names of licensees with revoked, suspended or restricted licenses will be listed in the Board of Pharmacy Newsletter.

Senior Investigator Julia Winchell and Investigator Rick Younkins departed from the meeting at 3:15 PM.

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Break Off record: 3:15 PM
 Back on record: 3:25 PM

Agenda Item 13 Long - Term Care Facilities

- Mr. Altland reported that new distance technology Pyxis equipment is being used to service a long-term care facility on the Kenai Peninsula and that he has a video available for viewing by board members.

Agenda Item 8 Report by AK Pharmacists Association

Nancy Davis, Association Executive Director distributed a report from the Alaska Pharmacists Association (AKPhA). Ms. Davis announced that AKPhA is in the process of amending its constitution and bylaws with the Association name change, and the addition of Business Memberships. Ms. Davis noted that AKPhA now has a full time lobbyist for the 2004 Legislative session. Ms. Davis announced that the February 27-29 Association Convention is in the planning stages and listed upcoming Continuing Education opportunities. Ms Davis requested a report from the Board of Pharmacy to be included in the upcoming AKPhA Quarterly Newsletter. Ms. Soden will submit a report for the Newsletter.

Agenda Item 9 Public Comment

Public comment period opened at 3:30 PM.

NANCY LEWIS, Purdue Pharma Representative distributed copies of "RxPatrol" (**R**x **P**attern **A**nalysis **T**racking **R**obberies & **O**ther Losses) an information clearinghouse about pharmacy robberies and thefts of controlled substances. Ms. Lewis pointed out that the online theft reports (www.rxpathrol.org) assist law enforcement efforts in apprehending and successfully prosecuting those engaged in pharmacy theft.

KATHI BALDWIN, RPh, University of Alaska, Anchorage, Allied Health Programs, distributed copies of a statement about the UAA Pharmacy Technician Certificate of Completion program. Ms. Baldwin outlined the need for quality education for pharmacy technicians and pharmacist assistants and noted incentives must be in place for pharmacy technicians to pursue education and training beyond the current minimum requirements. Ms. Baldwin emphasized that the University is interested in partnering to provide the best training for pharmacy technicians and is considering including distance delivery programs. Ms. Baldwin requested that the Board

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consider adding a certification requirement or establishing graduated levels of licensing of pharmacy technicians. The Board will discuss Ms. Baldwin's request under Agenda Item 19 New Business.

DAVID HIGH, Walmart/Sams, asked the Board for advice in situations where pharmacists are asked to fill prescriptions for what they consider excessive quantities. Mr. High reported that the prescribing physician was unwilling to provide an explanation of why quantities prescribed were outside established practice. Mr. High asked if the physician is required to give an answer to the pharmacist. The Board responded that there is a corresponding responsibility between the prescriber and the pharmacists, but that the Medical board regulates Physicians. The Board emphasized that the pharmacist's duty is to the safety of the patient and that the pharmacist must use professional judgement in dispensing. Mr. Bohrer noted that 12 AAC 52.920 specifies that "dispensing drugs to an individual or individuals in quantities, dosages, for periods of time that grossly exceed standard of practice" is considered unprofessional conduct and is a basis for disciplinary action.

Public comment was closed at 4:00 PM

On a motion duly made by Ms. Knasiak, seconded by Mr. Pauley, it was

**RESOLVED to recess and return at 9:00 AM,
October 3, 2003.**

Recess

The Board recessed at 4:15PM.

Call to Order/Roll Call

The meeting was called to order by Margaret Soden, Chair, October 3, 2003 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
Gerry Knasiak

Present from the Division of Occupational Licensing was:

Barbara Roche, Licensing Examiner

Present telephonically were:

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Steve Winker, Paralegal, Division of Occupational Licensing
Robert Young, PharmD, Mt. Edgecumbe Hospital

Visitors present were:

Senator Fred Dyson (Agenda Item 15)
Jason M. Hooley, Legislative Aide for Senator Dyson
Terry L. Marquart, DEA – (Agenda Item 14)
Nancy Lewis, Purdue Pharma – (Agenda Item 14)
Gary Givens, ANMC – (New Business – Telepharmacy)
Doug Herring, ANMC – (New Business – Telepharmacy)
Erica Wessel, ANMC – (New Business – Telepharmacy)

Agenda Item 10 Review of Agenda

Teleconference with Steve Winker for review of continuing education MOA's will be scheduled under Agenda Item 11 Review License Applications.

Discussion of the remainder of Regulations from Agenda Item 5 will be added to Agenda Item 15 Legislative Update.

Add discussion of SB 156 to Agenda Item 15 Legislative Update.

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

RESOLVED to approve the agenda as amended.

Agenda Item 11 Review License Applications

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

Pharmacy Intern Applications:

- Marnie Bay - Pharmacy Intern License – Approved.
- Andrew Funk - Pharmacy Intern License - Approve, pending Intern Jurisprudence Exam.
- Martha Healy - Pharmacy Intern License – Not Approved. Need more information on completion of 3rd year pharmacy program. Also need Intern Jurisprudence Exam, and certificates of moral character. Review completed application at next mail vote.

Pharmacy Technician Application:

- Edwin Patrick Ebona - Pharmacy Technician License – Application with “Yes” answer approved.

Pharmacist Applications:

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- Jimmie L. Asher - Pharmacist – Review disciplinary action and application “Personal Data” Questions #1. After consideration of the Investigators report under Agenda Item 6, the Board approved the application.
- Edward Joseph Bako – Pharmacist – Approved pending passing score on MPJE and receipt of License Fee.
- Brian K. Bevins – Pharmacist – Application not complete. Board requested that completed application be reviewed at next mail ballot.
- Kirby Alan Drawbaugh – Pharmacist – Approved pending passing score on MPJE and receipt of Certificates of Moral Character, Verification of 1-year practice, and License Fee.

Out of State Pharmacy Applications:

- Clinical Supplies Management Inc., Fargo, ND – New Application – Approved.
- Innovative Healthcare, Inc., Davie, FL – New Application – Approved.
- Motto Pharmacy, Inc., Riviera Beach, FL – New Application – Approved.
- MP Totalcare Supply Inc., New Albany, OH – Change Name & Ownership Application, was license #173 – Approved.
- National Diabetic Pharmacies, Inc., Salem, VA – New Application – Approved.
- Prestab Co., Miami, FL – New Application – Approved pending Certified True Copy of the Facility License.

Pharmacy Application:

- ImmediateCare / Jasper Wethington – I-Care., Anchorage, AK – New Application – Approved.

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

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

Mr. Winker, Paralegal joined the meeting telephonically at 9:15 AM.

CASE #2600-03-003: Memorandum of Agreement for a pharmacist was presented to the board. The case is the result of a pharmacist continuing education audit. The board reviewed the MOA and the list of continuing education submitted by the Paralegal.

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

RESOLVED to accept the Memorandum of Agreement for a pharmacist Case #2600-03-003 as presented.

For the record Case #2600-03-003 is a Memorandum of Agreement for Stephen A. Fenick, Pharmacists License No.1025. Ms. Soden, Board Chair, signed the M.O.A.

CASE #2600-03-005: Memorandum of Agreement for a pharmacist was presented to the board. The case is the result of a pharmacist continuing education audit. The board reviewed the MOA and list of continuing education submitted by the Paralegal.

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

RESOLVED to accept the Memorandum of Agreement for a pharmacist Case #2600-03-005 as presented.

For the record Case #2600-03-005 is a Memorandum of Agreement for Christian I. Duruji, Pharmacists License No. 1112. Ms. Soden, Board Chair, signed the M.O.A.

The Board discussed adding a requirement to list Continuing Education completed on the Pharmacist and Pharmacy Technician renewal application forms. The Board felt that fewer licensing actions would result if renewal applicants were required to list the name, date, sponsor and number of credit hours on the renewal form as well as signing the "Affidavit of Completion of Continuing Education." The licensing examiner will submit a draft of the revised renewal forms for review at the next meeting.

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

RESOLVED to require renewal applicants for pharmacists and pharmacy technicians to submit a list of continuing education completed including course name, date, credit hours and APCE #. Copies of certificates of completion will not need to be submitted with the renewal, but will be required if the licensee is selected for a continuing education audit.

Break

Off record at 10:05 AM.

Back on record at 10:20 AM

Agenda Item 12 Review Protocol Applications

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

- Fred Meyer Pharmacy #668 (Cheryl Fowler, RPh; Dawn Woods, RPh; Juby Thomas, RPh – Jessica Spayd, ANP) Administration of Vaccines – Approved.

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

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

Agenda Item 13 Discuss Licensing

- NABP Final Report. Copies of the NABP License Transfer Application were included in the board packets. The Board requested that the licensing examiner find out from NABP what original documentation is required to be submitted for NABP License Transfer.

Agenda Item 14 Discuss Prescription Drug Abuse Issues

- Ms Soden noted 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.
- Ms Soden reported that she gave Grand Jury testimony for a case involving prescription fraud in Fairbanks
- Mr. Altland discussed his experience of being robbed while working at a pharmacy in Wasilla. Mr. Altland stated that the armed robber asked specifically for Oxycontin. After the robbery, Mr. Altland visited eight other pharmacies in the area and found that most of these pharmacies, who do not stock Oxycontin, post signs stating that fact. Mr. Altland found that three other pharmacists he surveyed had also been recently robbed and he expressed concerns that this is a public health problem and security problem for pharmacy personnel. Mr. Altland noted that abuse of Schedule II drugs in general, and Oxycontin in particular, seems to be more widespread in Alaska than in other areas of the country.
- Ms. Soden distributed copies of "Model State Prescription Monitoring Programs" and a memo with "Notes on HB 239". HB 239, sponsored by Representative Chenault, is pending legislation that would establish an Internet database for

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tracking controlled substances. Although the Board supports a tracking system for controlled substances, they felt that there are some areas that HB 239 does not address and recommends that the bill be more in line with the NABP Model Regulations and state prescription monitoring programs adopted or being looked at by many states. Ms. Soden noted that the current HB 239 does not require prescriber participation in the tracking database and that prescriber buy-in is critical for a prescription monitoring program to be effective. Ms. Soden stated that starting up a state online tracking system is costly, noting that for a similar system in Kentucky, the start up costs was \$415,000 with yearly operating costs of \$500,000. On the other hand, the Board noted that there are costs to the public health and safety in not committing resources to the prescription drug abuse problem. Ms. Soden noted that the Model Regulations recommend a combined effort by all members of the health care community to achieve an effective prescription-monitoring program. In addition the Board noted that the responsibility for the online tracking system by Department of Health and Social Services instead of the Department of Public Safety could result in greater participation by the whole health care community. The Board discussed effective ways to make recommendations to Representative Chenault for changes in HB 239. Mr. Pauley suggested that representatives of the Board contact the Department of Community and Economic Development Legislative Liaison and Department of Health and Human Services Commissioner Gilbertson, as well as sending proposed rewording of the bill to Representative Chenault. Mr. Pauley noted that the bill is at the stage where the sponsor may file a "Sponsor Substitute" of a reworded bill. Ms. Soden and Mr. Altland will draft a letter recommending proposed language based on the Prescription Monitoring Program Model Regulations for HB 239 to be sent to Representative Chenault and the DCED Legislative Liaison.

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

RESOLVED that the Board of Pharmacy recommend proposed legislative language relating to HB 239 that would state that the Department of Health and Social Services develop the data base and that the language of the legislation be amended to provide access to the data base by both prescribers and dispensers, and that the language follow the criteria included the NABP Prescription Monitoring Program Model

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Regulation. The Board will contact the DCED Legislative Liaison and Representative Chenault, the bill sponsor, to express these concerns.

Mr. Altland stated that the Substance Abuse Counselors will be meeting in Fairbanks at the end of the month and suggested that a board member attend. Ms. Knasiak suggested that Pam Watts, the Executive Director of the Alcoholism and Substance Abuse Board be contacted. Ms. Soden will contact Ms. Watts.

Discussion of prescription drug abuse issues and presentation by DEA Agent Terry Marquart will continue after lunch.

Agenda Item 5 Regulations (Continued from October 2, 2003 Discussion)

2. 12 AAC 52.480 (GENERIC LABELING) Will be tabled to Agenda Item 19, New Business.
3. 12 AAC 52.130 REVIEW OF APPLICATIONS FOR REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. The regulation, which was included in the May 9, 2003 "Supplemental Notice of Proposed Changes in the Regulations of the Board of Pharmacy", was adopted by the Board at the July 25, 2003 meeting. Original language ("A pharmacy located outside the state that ships, mails, or delivers prescription drugs more than twice annually to individual patients in the state shall register with the board.") was inadvertently deleted from the "Supplemental Notice...." The Board stated that its intention was to keep the original language that defined "regularly" and to add the checksheet regulation as stated in the "Supplemental Notice....", not to repeal the first sentence of 12 AAC 52.130. Mr. Brower of the Dept. of Law stated in an email that a new public notice would not be required.

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

RESOLVED that in 12 AAC 52.130, the original definition of “regularly” (“A pharmacy located outside the state that ships, mails, or delivers prescription drugs more than twice annually to individual patients in the state shall register with the board.”) should be included in the final regulation along with the checksheet regulation (a) and (b).

4. 12 AAC 52.510 (Brand Medically Necessary) Discussion will be tabled until next meeting.
5. 12 AAC 52.090(d) (Exam Requirements) The board reviewed the “draft” regulation.

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

RESOLVED to approve “draft” regulation 12 AAC 52.090(d) as amended. 12 AAC 52.090(d) is amended to read: “An applicant shall file with the department an [A COMPLETED] application for a pharmacist license by examination and the application and examination fees established in 12 AAC 02.310 [AT LEAST 60 DAYS BEFORE THE DATE OF THE EXAMINATION].

The board noted that adopting these regulations would not result in any cost to private persons.

6. Changes (from the Alaska Pharmaceutical Association to the Alaska Pharmacists Association) to the Editor’s note after 12 AAC 52.325 were reviewed and the Board noted that the address for the Alaska Pharmacists Association is: 4107 Laurel Street, Suite 101, Anchorage, AK 99508

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

RESOLVED to approve “draft” regulation Editor’s Note: Information on the certification....The Alaska Pharmacists [PHARMACEUTICAL] Association, 4107 Laurel Street, Suite 101, Anchorage, AK 99508 [P.O. Box 10-1185, Anchorage, AK 99510] also provides certification information.

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The board noted that adopting these regulations would not result in any cost to private persons.

7. 12 AAC 52.340(b)(1) & (b)(2) Changes to correct the name of the Alaska Pharmacists Association and to add NPTA under the "Approved Programs" for pharmacy technician continuing education were reviewed by the Board. The numbering on the draft regulation should be corrected to (b)(1) & (b)(2), not (b)(2) & (b)(3).

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

RESOLVED to approve "draft" regulation 12 AAC 52.340(b)(1) & (b)(2) as amended. 12 AAC 52.340(b)(1) is amended to read: "...any program presented or approved by the Alaska Pharmacists [PHARMACEUTICAL] Association. 12 AAC 52.340(b)(2) is amended to read: "...any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

The board noted that adopting these regulations would not result in any cost to private persons.

8. 12 AAC 52.585(a) and (b) MANDATORY PATIENT COUNSELING. Changes to clarify that patient counseling is required were discussed by the board. The board suggested that the "patient's agent" should be substituted for "patient's caregiver."

A motion was made by Mr. Bohrer to approve "draft" regulation 12 AAC 52.585(a) and (b) as amended.

Mr. Pauley asked if there really would be no cost to the public, since it appeared that this regulation would require pharmacists to spend additional time counseling the patient. Mr. Bohrer withdrew his motion. After discussion, the board noted that, in fact, there may be "cost to private persons", but that the provision of Patient Counseling is part of the "practice of pharmacy" as defined in AS 08.80.480 and the intent of 12 AAC 52.585 is shown in its title: "Mandatory Patient Counseling".

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

RESOLVED to approve "draft" regulation 12 AAC 52.585(a) and (b) as amended following. 12 AAC

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52.585(a) is amended to read: “With each new prescription dispensed, the pharmacist shall verbally [MAKE AN OFFER TO] provide counseling to the patient or the patient’s agent [CAREGIVER] on matters considered significant in the pharmacist’s professional judgment. [THE OFFER SHALL BE MADE VERBALLY BY THE PHARMACIST OR THE PHARMACIST’S AGENT] The counseling may include....” 12 AAC 52.585(b) is amended to read: [IF A PATIENT OR PATIENT’S CAREGIVER ACCEPTS THE OFFER TO PROVIDE COUNSELING, A] A pharmacist shall counsel the patient or the patient’s agent [CAREGIVER] face-to-face. If face-to-face counseling is not possible....”

The Board noted that they considered the cost to private persons when adopting these regulations and acted in the interest of public health and safety. The Board requests that the Notice of Changes to regulations above be sent to all pharmacies and pharmacists (license types R, P, and O).

Break Recess for Lunch at 12:05 PM.

Back on record at 1:02 PM.

Agenda Item 14 Discuss Prescription Drug Abuse Issues (Continued)

Terry Marquart, DEA, spoke to the Board on pharmaceutical narcotic drug trends in Alaska and nationwide. The DEA monitors all pharmaceuticals, paying special attention to Schedule II, which tend to be the drugs abused. Mr. Marquart noted that Alaska ranks in the top five in the nation for per capita use of Oxycontin, oxycodone, hydrocodone, meperidine and fentanyl and methadone. Methodone use in Alaska is almost four times the national average. Mr. Marquart discussed DEA policy cornerstones: 1) Controlled substances have useful and legitimate medical purposes. 2) Practitioners are not limited in their ability to administer and prescribe medications for patients with intractable pain. 3) Prescriptions must be for legitimate medical purpose, by a practitioner acting in the usual course of professional practice. 4) Corresponding responsibility rests with the filling pharmacist.

Agenda Item 15 Legislative Update

Senator Dyson and Jason Hooley joined the meeting at 1:15PM

SB 156 (“An Act relating to the posting and giving of certain warnings about drinking alcohol during pregnancy when selling or dispensing pregnancy testing kits, birth control devices, or

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birth control prescriptions”) was discussed by the Board. Senator Dyson stated that he is pursuing the interstate commerce issues related to product labeling and is contacting manufacturers and retailers. Ms. Soden suggested a standardized sign could be distributed to retailers. Mr. Altland distributed a letter from a grocery storeowner commenting on SB 156.

HB 51 (“An act requiring pharmacists to include generic drug information on containers in which brand-name drug orders are dispensed”). Mr. Bohrer distributed a memo and outlined the “key points” relating to HB 51.

- Public comment noted that several pharmacies would not be able to comply with the regulation.
- Software changes would be expensive and take time.
- HB 51 does not deal with multiple ingredients and compounded products.
- Generic labeling is better dealt with under the 12 AAC 52.480 the labeling regulation.

Ms Soden noted that these concerns were presented to Representative Seaton's aide during the last legislative session. Mr. Pauley recommended that the board contact Representative Seaton again with their concerns about HB 51. Mr. Bohrer agreed to contact Representative Seaton. Senator Dyson noted that if the Board could get the regulation done, he would appeal to Representative Seaton to drop the bill.

On a motion duly made by Mr. Bohrer,

RESOLVED to accept regulation 12 AAC 52.480(12) as amended in the May 9, 2003 “Supplemental Notice of Proposed Changes in the Regulations of the Board of Pharmacy.” 12 AAC 52.480 is accepted and amended by adding a new paragraph to read: (12) the accepted generic drug name and strength of the drug dispensed. If the drug product dispensed has multiple ingredients, the pharmacist shall provide this information in writing to the patient or the patient’s agent.

Mr. Pauley noted that there would likely be a cost to the public in adopting this regulation. Mr. Bohrer withdrew the motion and the board discussed the public comment and possible cost to the public.

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

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RESOLVED to adopt regulation 12 AAC 52.480(12) as amended in the May 9, 2003 “Supplemental Notice of Proposed Changes in the Regulations of the Board of Pharmacy.” 12 AAC 52.480 is accepted and amended by adding a new paragraph to read: (12) the accepted generic drug name and strength of the drug dispensed. If the drug product dispensed has multiple ingredients, the pharmacist shall provide this information in writing to the patient or the patient’s agent.

The Board noted that they have considered public comment and have made adjustments to the regulations based on that comment. The Board also considered the cost to private persons and has determined that there may be some cost to the public.

SB 138 (“An Act annulling a regulation relating to the use of collaborative practice authority...”) discussion is continued from yesterday. Ms. Bueler summarized the “draft” rewording of 12 AAC 52.240 and noted that the section on vaccinations needs to be worked on further. Ms. Bueler asked Senator Dyson what he thought of the “draft” rewording. Senator Dyson responded that he was pleased with the “draft” wording because it reestablished the relationship between a specific physician and a specific patient. The Board noted that it would need to get advice and verification from the Department of Law about moving forward with regulation changes to collaborative practice.

Break

Off record: 2:40 PM

Back on record: 2:45 PM

Agenda Item 18 Correspondence

Stephanie Magill - fda.gov - FDA Initiates Seizure of Potentially Dangerous Drugs from Repackager. For information only, no action required.

Stephanie Magill - fda.gov - FDA Letter to State of California regarding drug import policy. For information only, no action required.

Chris Eyler - Alaska Dept of Law - Pharmaceuticals Purchased over the Internet. For information only, no action required.

U.S. Department of Justice, D.E.A., - Rule entitled "Allowing Central Fill Pharmacies and Retail Pharmacies to Fill Prescriptions for Controlled Substances on Behalf of Retail Pharmacies. For information only, no action required.

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Governor Murkowski - Letter to Senator Fred Dyson re: Collaborative Agreement Regulations. For information only, no action required.

Lawrence H. Mokhiber - New York State Board of Pharmacy - Regulations on Mandatory Patient Counseling. For information only, no action required.

Rick Urion, Director, Division of Occupational Licensing - State of Alaska DCED Procedures - Newsletters / Publications and Mail Outs. The Board discussed the new Division policy replacing hard copy mail outs with web posted newsletters. The Board noted that the Newsletter is an important means of informing licensees and requested that at least one more Newsletter be published and mailed out informing licensees of the change. The licensing Examiner will send a letter from the Board to the Division Director requesting approval for a final Newsletter mail out. The Board also requested that the renewal forms ask for email addresses from licensees so that an email database could be used to replace the mailed out newsletter.

NABP - Web-only Newsletter & State Board Newsletter Expenses. For information only, no action required.

NABP - MPJE State Roster - Test Period January 01, 2003 - June 30, 2003 and May 1, 2003 - August 31, 2003. - For information only, no action required.

NABP - Accreditation of Lebanese American University School of Pharmacy Doctor of Pharmacy Program & Recognition of Canadian Accreditation. Discussion tabled until the next meeting.

NABP - Response to Governor Blagojevich's Study to Investigate Canadian Drug Purchases. - For information only, no action required.

NABP - Launch of the Pre-FPGEE. - For information only, no action required.

Bill Altland - Labeling Changes / HB 51 emails. Discussed under Agenda Item 15.

Robert Young, PharmD, Mt. Edgecumbe Hospital, Question for the Alaska Board of Pharmacy. The Board contacted Mr. Young by phone and discussed the question: If, in the absence of a pharmacist, could a physician fill and dispense medications from the Pharmacy?

The Board of Pharmacy considered the question and noted that in "AS 08.80.390 PHARMACISTS REQUIRED IN HOSPITALS AND CLINICS. (a) A hospital, clinic, nursing home, infirmary, or related facility that dispenses drugs for outpatient treatment shall have a licensed pharmacist in charge of the dispensary, except that prescriptions may be compounded and dispensed by or under the supervision of the prescribing

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physician." The first part of AS 08.80.390 requires that a pharmacy has a licensed pharmacist in charge. The second part of AS 08.80.390 refers to "physician/prescriber dispensing". The board emphasized that "physician/prescriber dispensing" is dispensing only for the prescriber's own patients, not dispensing other prescriber's prescriptions. In addition, Mr. Altland noted that the hospital pharmacy can not be both a pharmacy and a clinic setting, or change back and forth between the two facilities. In other words the situation suggested would imply that, when there is a pharmacist dispensing, the facility is a pharmacy, and when there is a physician dispensing, the facility is a clinic. In addition AS 08.80.330 (a) states that: "Each pharmacy shall have a pharmacist-in-charge." and AS 08.80.157 (j) this section does not apply to the offices of physicians," The board understands the hospital's difficulty in finding permanent and/or temporary pharmacists, but there is no provision in the Alaska Pharmacy Statutes & Regulations for operating a pharmacy without a pharmacist-in-charge. This is a question that has come up on several occasions in the past, and because the board may not operate outside the existing statutes and regulations, the board has offered the same recommendation to other pharmacies in the same situation. The board recommends that, until a pharmacist is found that the physicians dispense under their own licenses with their own drug stocks, and/or that prescriptions be filled via mail order.

The Board also noted that a pharmacy technician must work under the direct supervision of a person who is licensed as a pharmacist and that a pharmacy technician may not perform any of the duties listed in 12 AAC 52.210" (Pharmacist Duties). The licensing examiner will send a response to Mr. Young.

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 to cover increased costs.
- Travel Expense Estimate – The board reviewed the Travel Expense Estimate included in the board packets and noted that holding a board meeting in Juneau would be slightly more expensive than Anchorage meetings. Actual costs may vary depending on the composition of the board and time of year that the meeting is held. Because of all the pending legislative issues involving pharmacy, the Board agreed that holding a meeting during the legislative session in Juneau would be worthwhile. The Board agreed to hold the February 2004 meeting in Juneau.

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

MPJE State-Specific Review Meeting scheduled for September 11-13, 2003 in Washington, DC was attended by the board's delegate, Mr. Bohrer. Mr. Bohrer reported that he reviewed approximately 2700 questions, and definitely recommended that two board members attend the next review meeting to be held January 23-25, 2004 in Phoenix.

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

RESOLVED to appoint Mr. Bohrer and Ms. Soden as the Board's delegates to the next MPJE Review meeting to be held January 23-25, 2004 in Phoenix.

Agenda Item 22 New Business

• TelePharmacy Ad-hoc Committee.

Guests from Alaska Native Medical Center (ANMC), Gary Givens, Doug Herring, and Erica Wessel distributed copies of a presentation "Using Technology to Provide Pharmaceutical Care to Remote Locations" and product information from the PickPoint Corporation. Mr. Herring discussed ANMC's current levels of service and their efforts to provide an equivalent level of care in remote villages. New technology and equipment allows for pharmaceutical care with increased control of medications, real time dispensing and counseling by a pharmacist, reports of dispensing, and real time inventory control. Most rural clinics are staffed with health aides, many of whom have limited educational backgrounds. Mr. Givens noted that in current educational requirements, High School Graduation or G.E.D., eliminate many health aides from becoming licensed as pharmacy technicians. Mr. Givens encouraged the Board to consider the challenges and realities of providing pharmaceutical care in remote villages when crafting regulations for telepharmacy.

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 seven 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. Several suggested areas that need to be addressed in new regulation include:

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- Definitions and types of licensing for telepharmacy sites.
- Licensing of personnel dispensing at telepharmacy sites.
- Can an out of state pharmacy practice telepharmacy in Alaska? Could only pharmacists licensed in Alaska be the Pharmacist in charge of a telepharmacy site?
- Inspections

Mr. Bohrer noted that telepharmacy regulations are very difficult to write because of all the variables of location and changing technology and still maintain the protection of the public health and safety. The TelePharmacy Ad-hoc Committee will continue to work on drafting regulations and the discussion will be continued at the next meeting.

- UAA Pharmacy Technician Training.

The Board discussed current pharmacy technician training and licensing requirements, including graduated licensing of pharmacy technicians. Testimony was given earlier in the meeting by representatives of ANMC regarding their rural telemedicine and telepharmacy programs and current educational requirements for pharmacy technicians. Representatives of ANMC stated that in many cases even current educational requirements (High School Diploma or GED) eliminate many rural health aides from becoming licensed as pharmacy technicians. The board also discussed the Pharmacy Technician survey results and concluded that there was not an overwhelming interest on the part of either pharmacists or pharmacy technicians for regulation changes that would increase pharmacy technician duties. Several board members noted that current Pharmacy Technician Certification has not been a reliable predictor of increased training or knowledge by newly hired pharmacy technicians. The board acknowledged that effective Pharmacy Technician education would require buy-in by employers in the form of increased technician salary and compensation for training. The board is not, at this time, going forward with regulations that would expand technician duties or add certification or educational requirements for licensing. The Board also noted that the telepharmacy regulations are a "work-in-progress" and these regulations could change education and training requirements for Pharmacy Technicians.

Agenda Item 20 Office Business

- The board set the 2004 meeting schedule as follows:.
February 5-6, 2004 meeting will be held in Juneau at the State Office Building.

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- The Chair signed the approved minutes from the July 25, 2003 meeting.
- The Board Chair and Secretary signed wall certificates.
- Board members signed Travel Authorizations and provided travel receipts.

Adjournment

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

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

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:_____