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

MINUTES OF MEETING

APRIL 24-25, 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 April 24-25, 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, April 24, 2003 at 1:00 p.m. Those present, constituting a quorum of the board, were:

Margaret Soden, R.Ph. Ron Miller, R.Ph. Cindy Bueler, R.Ph. Mark Bohrer, R.Ph.

Present from the Division of Occupational Licensing was:

Barbara Roche, Licensing Examiner

Visitors present were:

Rick Younkins, Investigator (Agenda Item 6)
Julia Winchell, Senior Investigator (Agenda Item 6)
Nancy Davis, Executive Director Alaska Pharmacists
Association (Agenda Item 8)
Angie Leboeuf, Past President, Alaska Pharmacists
Association (Agenda Item 8)
Scott Tague, TelePharmacy Solutions (Public Comment)

Agenda Item 1 Review of Agenda

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

RESOLVED to approve the agenda.

Agenda Item 2 Review of Minutes

The board reviewed the minutes from the February 13-14, 2003 meeting.

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

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RESOLVED to approve the minutes of the February 13-14, 2003 meeting, as presented.

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The board reviewed the minutes from the March 19, 2003 teleconference.

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

RESOLVED to approve the minutes of the March 19, 2003 teleconference, as presented.

Agenda Item 3 Ethics Disclosure

There were no ethics violations to disclose.

Ms. Soden distributed copies of "Pharmacy Board Member Orientation", an overview of the Purpose of the Board, Structure of the Pharmacy Practice Act, Ethics Disclosure Process, Investigative Process, Open Meetings Act, and Individual Board Member Responsibilities.

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 Multistate 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

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- rooms, institutional pharmacies, home infusion pharmacies, nuclear pharmacies, sterile products, telepharmacy, etc.).
- 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 access and evaluate the growing public concern regarding abuse of prescription drugs.
- 12. The board will pursue applicants for the vacant public member board position. (Goal 12 has been accomplished with the appointment of the new public member.)

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

RESOLVED to delete Goal 12.

Agenda Item 6 Review of Proposed Regulation Changes

Ms. Soden reviewed the steps in the regulation process and stressed that the board consider the cost to private persons of any proposed regulatory action.

The board reviewed the following "draft" regulation:

- 12 AAC 52.130 Review of applications for registration of pharmacies located outside of the state.

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

RESOLVED to approve draft regulation 12 AAC 52.130 as amended. 12 AAC 52.130(b)(2) is amended to read: "pays the [PHARMACIST INTERN] license fee required in 12 AAC 02.310."

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

The licensing examiner reported that the status of other regulation projects is "ongoing." The Regulations Specialist is continuing to work on the following regulation project:

- 12 AAC 02.310 Amendment to occupational licensing fees for the Board of Pharmacy."

Agenda Item 7 Long - Term Care Facilities

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 Mr. Bohrer reported that the recent complete turnover of the Board of Nursing may make progress on proposed long-term care facility regulations uncertain. In addition, Mr. Bohrer reported that, according to the Board of Nursing Executive Administrator, the Long-Term Care Committee would be restructured.

Agenda Item 14 <u>Discuss Prescription Drug Abuse Issues</u>

- Ron Miller reported that the DEA is actively pursing Internet prescribing and noted that pharmacies can be found negligent for filling improper prescriptions.
- New Medicaid reporting regulations have helped in controlling drug abuse. Physicians are being more responsive because of oversight regulations, DEA enforcement, and drug testing of patients.
- HIPPA privacy regulations were discussed as they relate to releasing information on billing, treatment and patient care.

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

 MPJE State-Specific Review Meeting #3 will be held in Rosemount, IL on September 5-7, 2003 or in Washington, DC on September 11-13, 2003. NAPB requires all participating states to complete both an annual review of new MPJE questions and the state specific review. Ms. Soden participated in the state specific item review meeting in September 2002. The Board needs to select a delegate and notify NABP of their preferred meeting date.

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

RESOLVED to appoint Mr. Bohrer as the board's delegate to the MPJE State-Specific Review Meeting #3 to be held September 11-13, 2003 in Washington, DC.

The licensing examiner will notify NABP of the Board's official delegate.

 Foreign Pharmacy Graduate Equivalency Examination (FPGEE) will be given in June, as a paper and pencil exam.
 Mr. Miller pointed out that Foreign Pharmacy Graduate Equivalency Certification (FPGEC) is a lengthy process requiring comparison of degree programs, passing a difficult

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pharmacy exam, and taking spoken and written English language exams.

- <u>Direct Processing for NAPLEX/MPJE Registration</u> will expedite signup and licensing of pharmacists. The licensing examiner is currently working with NAPB in setting up direct processing for exam eligibility designations, registration and payment of fees. Pharmacist applications will need to be updated with new NAPLEX/MPJE registration instructions.
- NEW NAPLEX/MPJE EXAM SITE. The licensing examiner reported that NAPB is not currently interested in adding another test site in Alaska for NAPLEX/MPJE exam candidates. NABP reviewed the two Alaska testing sites in Anchorage and Fairbanks and found that most exam candidates were taking the NAPLEX or MPJE in other states and that the considerable costs involved make it unlikely that a new test site would be established. The licensing examiner noted that new exam candidates are strongly encouraged to register for the NAPLEX or MPJE before moving to Alaska, due to the 3-4 week wait to take the exam at an Alaska site.

Agenda Item 7 Investigative Report

Investigators Rick Younkins and Julia Winchell joined the meeting at 2:20 p.m.

REVIEW REPORT: The board reviewed the investigative report provided by Mr. Younkins, noting that there were 17 open cases. There were three licensing actions and 2 cases were closed. Mr. Younkins noted that of the open cases: 2 cases have pending MOAs, 4 surrenders have been delivered to respondents, 1 reinstatement of license request has been received, and there are 7 active investigations.

INVESTIGATIVE PROCESS: As part of the <u>Investigative Priorities</u> set by the board, Mr. Younkins reported that investigators have continued to make unannounced visits to pharmacies to check for compliance with counseling, licensing and facility standard requirements. Mr. Younkins reported that the pharmacies visited were in compliance with counseling, licensing and facility standards, but some were struggling with new HIPPA privacy regulations.

CASE #2606-03-004: A surrender of a pharmacy technician license was presented to the board. The case is the result of an active investigation of diversion by a pharmacy technician.

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

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RESOLVED to enter executive session in accordance with Alaska Statute AS 44.62.310(c)(2) to discuss the Surrender of Pharmacy Technician License Case #2606-03-004.

The board entered executive session at 2:40 p.m.

The board went back on the record at 2:45 p.m.

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

RESOLVED to adopt the Surrender of Pharmacy Technician License Case #2606-03-004 as presented.

For the record, Case #2606-03-004 is a voluntary surrender agreement for Susan L. Ward, Pharmacy Technician License No. 982.

Ms. Soden signed the original surrender and presented it to Mr. Younkins.

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

RE-IMPORTATION. Mr. Younkins reported that investigations are ongoing on re-importation by Canadian pharmacies that are not licensed in Alaska. The FDA and US customs agents are taking an increasingly active role in enforcement of federal laws prohibiting re-importation of pharmaceuticals from Canada.

Investigators, Mr. Younkins and Ms. Winchell departed from the meeting at 3:00 p.m.

Break Off record: 3:00 p.m.

Back on record: 3:15 p.m.

Agenda Item 8 Report by AK Pharmacists Association

Angie Leboeuf, Past President, Alaska Pharmacists Association and Nancy Davis, Association Executive Director, joined the meeting at 3:15 p.m. Ms. Davis discussed pending legislation that the Association is pursuing, including House Bill No. 32 (Uniform Prescription Drug Card) and House Bill No. 270 (Licensing of Pharmacists and Pharmacy Technicians). Ms. Leboef reported the Association has been very active in

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opposing Senate Bill 138, the proposed legislation that would annul current collaborative practice pharmacy regulations. Ms. Davis distributed copies of the current legislative report from Barry Christensen, the Association's Legislative Chair.

Ms. Davis announced that the Association Board of Directors Meeting and Retreat will be held May 3-4, 2003. Ms. Bueler will give a Board of Pharmacy update at the May 3 meeting.

Ms. Davis reported that as a result of membership vote, the Association name has changed to "The Alaska Pharmacists Association". A current list of the Alaska Pharmacists Association 2003-2004 Board of Directors was distributed.

Ms. Davis and Ms. LeBoef departed from the meeting at 3:50 p.m.

Agenda Item 9 Public Comment

Public comment period was opened at 3:30 p.m.

TELEPHARMACY SOLUTIONS representative, Scott Tague asked the board if the company's input was needed at the telepharmacy regulations discussion to be held tomorrow. The board responded that it would be better for TelePhamacy Solutions to submit comments on the regulations during the public comment period. Mr. Tague requested a mailing list of Alaska Pharmacies and Public Health Clinics. The licensing examiner noted that the mailing list can be downloaded from the division's web site.

Public comment period was closed at 4:00 p.m.

On a motion duly made by Mr. Bohrer, seconded by Mr. Miller, it was

RESOLVED to adjourn until tomorrow morning, April 25, 2003, at 9:00 a.m.

Recess

The Board recessed at 4:05 p.m., April 24.

Call to Order/Roll Call

The meeting was called to order by Margaret Soden, Chair, April 25, 2003, at 9:15 a.m. Those present, constituting a quorum of the board, were:

Margaret Soden, R.Ph. Mark Bohrer, R.Ph.

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Ron Miller, R.Ph. Cindy Bueler, R.Ph.

Present from the Division of Occupational Licensing was:

Barbara Roche, Licensing Examiner

Agenda Item 10 Review of Agenda

The discussion of Agenda Item 14, Prescription Drug Abuse Issues was covered on April 24, so can be deleted from the April 25 Agenda.

Ms. Soden added two items to Agenda Item 19, New Business: discussion of "Annual Report assignments" and discussion on "Patient Counseling."

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

RESOLVED to approve the agenda, as amended.

Agenda Item 11 Review of License Applications

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

Pharmacy Intern Applications:

- Kurt H. Byington Pharmacy Intern License Approve, pending Intern Jurisprudence Exam, Letter confirming completion of 3rd year pharmacy program.
- Elizabeth Chase Pharmacy Intern License Approve, pending Intern Jurisprudence Exam, Declaration of Sponsorship letter.
- Crystal Nichole Chilson Pharmacy Intern License Approve.
- Katherine Claxton Pharmacy Intern License Approve.
- Karen Ann Cygler Pharmacy Intern License Approve, pending Intern Jurisprudence Exam.
- Steven Garrett Darling Pharmacy Intern License Approve, pending letter confirming completion of 3rd year pharmacy program.

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- Elsbeth H. Desselle Pharmacy Intern License Approve, pending Intern Jurisprudence Exam, Declaration of Sponsorship letter.
- Megan R. Didier Pharmacy Intern License Approve, pending Intern Jurisprudence Exam, license fee.
- Karen Hoang Pharmacy Intern License Approve, pending Intern Jurisprudence Exam, Declaration of Sponsorship letter.
- Roberto Iaderosa Pharmacy Intern License Approve, pending Intern Jurisprudence Exam, license fee.
- Dennis Jackson II Pharmacy Intern License Approve, pending Intern Jurisprudence Exam.
- Christina M. Jakobowski Pharmacy Intern License Approve.
- Mark T. Johnson II Pharmacy Intern License Approve, pending Intern Jurisprudence Exam.
- Hijin Angela Kim Pharmacy Intern License Approve, pending Intern Jurisprudence Exam.
- Glenn Mathew Kulzer Pharmacy Intern License Approve.
- Angeliki Karapanos Pharmacy Intern License Approve, pending Intern Jurisprudence Exam, Declaration of Sponsorship letter.
- April Dawn Miller Pharmacy Intern License Approve, pending Intern Jurisprudence Exam.
- Annie Lorie Naramore Pharmacy Intern License Approve, pending Intern Jurisprudence Exam, Declaration of Sponsorship letter. The board approved "Yes" answer to professional fitness question, after investigator / program coordinator's review.
- Allison Perdue Pharmacy Intern License Approve, pending Declaration of Sponsorship letter.
- Jeffrey S. Taylor Pharmacy Intern License Approve.
- Tammy Thompson Pharmacy Intern License Approve.
- Emily Walsh Pharmacy Intern License Approve, pending Intern Jurisprudence Exam.

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Pharmacist Applications:

- Justin Cornett Pharmacist License- Approve, pending passing score on MPJE.
- Joyce F. Durcann-Robbins Pharmacist License- Approve, pending passing score on MPJE, Affidavits of Moral Character, Final NABP Report, License Fee.
- Robert P. Miller Pharmacist License Approve pending passing score on MPJE, Final NABP Report, Florida License Verification.
- Leah Jo Rein Pharmacist License- Approve, pending passing score on MPJE.
- Edward C. Rocha Pharmacist License Approve pending passing score on MPJE, Affidavits of Moral Character
- David C. Wendover Pharmacist License Not approved because application is not complete at this time. The board will re-review the application at the next mail ballot pending receipt of verification of one year licensed practice, passing score on MPJE, and final NABP report.

Temporary Pharmacist Applications:

• Leah Jo Rein – Temporary Pharmacist License - Approve, pending passing score on MPJE.

Pharmacy Technician Application:

• Alexander Scott Torre – Pharmacy Technician License - Denied, based on Alaska Statute (AS) 08.80.003 and Professional Regulation 12 AAC 52.140 (b)(2), which states that "the applicant has not been convicted within the five years before the date of application of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently." Based on the documentation submitted and the investigator's review, the board determined that the applicant did not meet the requirements of 12 AAC 52.140 (b)(2).

Out of State Pharmacy Applications:

 AdvanceRX.com, Ft. Worth, TX – Out of State Pharmacy Application – Approved.

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- Dr's Foster & Smith Pharmacy, Rinelander, WI Out of State Pharmacy Application – Approved.
- Integrity Healthcare Services, Inc, Louisville, KY Out of State Pharmacy Application Approved.
- Ken Drugs, Inc, Tampa, FL- Out of State Pharmacy Application – Approved pending certified true copy of facility license.
- Pharmanet, Inc., Miami, FL Out of State Pharmacy Application Approved.
- TheraCom, Inc., Richardson, TX– Out of State Pharmacy Application Approved.

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

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

2002 Renewal Continuing Education Audit:

 Richard Prine – Pharmacy Technician License No. 473 & 1085 – Approved.

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

RESOLVED to approve the action taken on the renewal application continuing education audit as read into the record.

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Agenda Item 12 Review of Protocol Applications

There were no new collaborative practice applications submitted for review at this meeting. The licensing examiner noted that a list of all currently approved collaborative practice protocols can be found in the board packets, Tab 12.

Break

Off record: 11:00 a.m. Back on record: 11:10 a.m.

Agenda Item 13 Discuss Licensing

- LICENSING FEE UPDATE At the February 13-14, 2003 meeting, the board requested that the licensing examiner resend the October 8, 2002 letter to the new Occupational Licensing Director requesting that fees listed in 12 AAC 02.310 be amended. A motion was made at the October 3-4, 2002 meeting requesting an amendment to Occupational Licensing Fees of the Board of Pharmacy as follows:
 - 12AAC 02.310(a)(5) Pharmacy Intern fee <u>\$25.</u> (lower \$25)
 - 12AAC 02.310(b)(3) In State Pharmacies \$<u>150</u>.(raise \$50)
 - 12AAC 02.310(b)(7) Out of State Pharmacies \$150. (raise \$50)
 - 12AAC 02.310(b)(8) Pharmacy Technicians <u>\$25</u>. (lower \$25)

However, after reviewing the previously proposed fees in light of the current budget report, the board feels that the original fee recommendations will not cover the pending costs of increased investigations and regulation projects. In consideration of these increased costs, the board recommends adjusting fees so that facility and pharmacist fees will increase, while pharmacy intern and pharmacy technician fees will decrease.

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

RESOLVED to approve adjusting licensing fees per Proposed Fee Schedule #2 as follows:

- 12AAC 02.310(a)(5) Pharmacy Intern, \$25;
- 12AAC 02.310(b)(1) Pharmacist, \$250;
- 12AAC 02.310(b)(2) Wholesale Drug Distributor, \$250;
- 12AAC 02.310(b)(3) Pharmacy, \$250;
- 12AAC 02.310(b)(5) Drug Room, \$250;

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- 12AAC 02.310(b)(7) Pharmacy Located outside of state, \$250;
- 12AAC 02.310(b)(8) Pharmacy Technician, \$25;

LICENSE STREAMLINING

- Several regulations that would streamline the licensing process have been submitted for public notice.
- The licensing examiner reported that revisions to applications and checklists for Wholesale Drug Distributors, Pharmacies, Out-of-State Pharmacies, Pharmacists, Pharmacy Interns, and Pharmacy Technicians are being worked on. The new applications should be available soon.
- The board discussed streamlining licensure requirements for new pharmacy graduates who seek "Licensure by Examination." 12 AAC 52.090(2)(d) Examination Requirements and Registration requires applicants for "Licensure by Examination" to wait 60 days after submitting an application, before taking the exam. This regulation was required in the past when the board wrote and administered the pharmacist license exam, and needed the 60-day period to set up the exam. Now that the exams are administered by NABP, there is no reason for the 60 day waiting period. NABP requires that exam candidates are Pharmacy program graduates, but the board could see no reason to delay the licensing of new graduates.

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

RESOLVED to revise 12 AAC 52.090(2)(d) to read "An applicant shall file with the department an [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.

Agenda Item 15 Legislative Update

• HB No. 51 ("An act requiring pharmacists to include generic drug information on containers in which brand-name drug orders are dispensed") was discussed by the Board. Ms. Soden

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pointed out that there would be costs to pharmacies associated with adding the new information to prescription labels.

- HB No. 239 ("An Act directing the Department of Public Safety to establish an Internet-based identification and tracking system relating to controlled substances that are prescribed for human use; and relating to the manner in which prescriptions for controlled substances may be filled by a pharmacists.") The board discussed concerns that this bill requires the Department of Public Safety to set up a Controlled Substances Data Base, but that the bill's statute number 08.80.305 would fall under the Pharmacy Act (AS 08.80). In addition, the board noted that there would be considerable costs in establishing such a data base project, and that funding could be a problem.
- HB No. 270 ("An Act relating to licensure of pharmacists") was discussed under Agenda Item 8.
- SB No. 41 ("An Act relating to medical care and crimes relating to medical care..."). An amended copy of the bill was handed out at the meeting.
- SB No. 138 ("An Act annulling a regulation relating to the use of collaborative practice authority...") was discussed under Agenda Item 8.

Break

Recess for Lunch at 12:15 p.m. Back on record at 1:25 p.m.

Agenda Item 16 <u>Division Updates</u>

<u>Budget Report</u> - The Board reviewed the Budget Report provided by the Division of Occupational Licensing. The licensing examiner responded to a question asked by the board at the February 14, 2003 meeting about why the 2002 Direct Costs are almost double the 2001 Direct Costs. Direct costs reflect actual billed hours by staff, including the licensing examiner, supervisors, paralegal, investigators, and regulation specialist. The rise in costs is due to increased investigations, regulation projects and training. Board members requested that the division review the board's recommendations for licensing fee adjustments to cover these increased costs.

<u>Discuss Intern Jurisprudence Exam</u> - The licensing examiner reported that revisions to the exam have been made and that pharmacy intern applicants are taking the new exam.

2003 Annual Report Assignments - Ms. Soden noted that 2003Annual Report submissions are due in June of each year. The board discussed which sections of the Annual Report need direct input and decided on the following:

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- <u>Letter</u> from the board chair will be done by Margaret Soden.
- Narrative Statement will be drafted by Cindy Bueler. The 2003 Narrative Statement can be modeled after the 2002 report, but the statement should also include a note on the board's request for an Attorney General opinion on whether Alaska Native Medical Centers are considered Federally operated institutions and are exempt from regulation under AS 08.80.475.
- <u>Statistical Overview</u> will be submitted by the licensing examiner.
- <u>Investigative Report</u> information will be submitted by the investigator.
- Budget Recommendations will be submitted by the licensing examiner based on four meeting per year, travel expenses similar to 2003, and board recommendation for licensing fee increases to cover increased costs.
- <u>Goals and Objectives</u> will be submitted by the licensing examiner.
- Recommendations for Proposed Legislation will be the same as the 2002 Annual Report, unless HB 270 amendments to AS 08.80.261 take effect.
- Recommendations for Proposed Legislation will be the same as the 2002 Annual Report.

Agenda Item 18 Correspondence

National Pharmacy Technician Association (NPTA) - Continuing Education Regulations & Guidelines. The board reviewed the NPTA regulations and guidelines for approval of continuing education for pharmacy technicians and noted that NPTA meets the guidelines and requirements set forth by the Pharmacy Technician Certification Board (PTCB), however, NPTA is not specifically cited as an approved program in 12 AAC 52.340.

In addition, the board noted that 12 AAC 52.340 lists the "Alaska Pharmaceutical Association" as an approved continuing education provider. Section 12 AAC 52.340(b)(1), as well as the Editor's Note following 12 AAC 52.325 will need to be revised to reflect the AkPhA name change to the "Alaska Pharmacists Association."

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

RESOLVED to revise 12 AAC 52.340(b)(1) to read "any program presented or approved by the Alaska [PHARMACEUTICAL] <u>Pharmacists</u> Association" and to revise 12 AAC 52.340(b)(2) to read "any

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program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA)." Revise Editor's Note following 12 AAC 52.325 to read: "The Alaska [PHARMACEUTICAL] Pharmacists Association,..."

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

<u>Pharmacy Technician Certification Board (PTCB)</u> - PTCB Video "Enhancing Pharmaceutical Care: Certified Pharmacy Technicians" For information only, no action required.

<u>APhA - ASP Standing Committee on Policy</u> - ENS Sharon M. Justin, PharmD Candidate - Resolution 2002.11 on Pharmacy Technician training. For information only, no action required.

National Association of State Controlled Substances Authorities - Findings and Recommendations of the Prescription Monitoring Standards Workgroup. The board suggested that the Workgroup's recommendation for opposing passage of federal legislation establishing the National All Schedules Prescription Electronic Reporting Act of 2002 (NASPER) be forwarded to HB 239 sponsor, Representative Chenault.

American Academy of Pain Management - State position on the legality of issuing several Schedule II prescriptions on the same date for the same medication. The Licensing Examiner will respond that because there are no Alaska Pharmacy Statutes and Regulations addressing their question, Federal law should be followed.

PeaceHealth, HID Clinical Improvement (Sharon Gurtel, RPh) & Ketchikan General Hospital (John Zahler, RPh) Approval request for inpatient pharmacist computer order entry between facilities, allowing off-site new order review and entry. The licensing examiner will respond that facilities that conduct off-site or out of state new order review and entry for Alaska patients must be licensed by the Alaska Board of Pharmacy. The board stated, per AS 08.80.158, off-site facilities that serve patients in Alaska are required to obtain Out of State Pharmacy licenses.

<u>Food and Drug Administration, Div. Of Federal-State Relations</u> - FDA Proposes Drug Bar Code Regulation - For information only, no action required.

State of Alaska DCED & Dept. of Law – "Whether or Not Alaska Native Medical Centers are Considered Federally Operated Hospitals or Institutions and Are Exempt from Regulation under

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AS 08.80.475." The division director sent a new request for an AG opinion on March 19, 2003.

<u>Food and Drug Administration, Division of Federal-State</u> <u>Relations</u> -Purchasing Medications Outside the United States -For information only, no action required.

Rosemary Sheldon, RPh, - Harry Race Pharmacy, Sitka - Patient Confidentiality question. The Licensing Examiner will respond that there are no specific Alaska Pharmacy Statutes and Regulations and that pharmacists should use their best professional judgement.

NABP, Lisa Pugliese, NAPLEX/ MPJE Manager - Time and Task Schedule for Participating Boards - Planning Questionnaire. Mr. Bohrer will attend as the Board's delegate to the MPJE State-Specific Review Meeting #3 to be held September 11-13, 2003 in Washington, DC.

<u>NABP</u>, Moira Gibbons, PharmD, JD ELT/VIPPS Manager -Letter to Dale Crawford, BScPharm, Winnipeg, MB, Canada -For information only, no action required.

<u>NABP</u> - Missouri Board of Pharmacy Survey on current state laws and enforcement governing licensure of drug distributors - For information only, no action required.

<u>NABP</u> - Importation of Foreign Prescription Medications letter from FDA Associate Commissioner, William K. Hubbard - For information only, no action required.

NABP - Resolution No. 97-2-2001: Task Force to Study the Electronic Transmission of Prescriptions and Prescription Information via Electronic Devices. The board discussed how Resolution No. 97-2-2001 would affect Alaska regulation 12 AAC 52.510(a) "A pharmacist may dispense an equivalent drug product instead of the prescribed drug if (1) the prescribing practitioner does not hand write on the prescription drug order that a specific brand must be dispensed, using language such as 'brand medically necessary' or similar wording." To allow electronic prescription transmission, the current regulation would need to be modified.

On a motion duly made by Mr. Miller, seconded by Ms. Bueler, it was

RESOLVED to revise 12 AAC 52.510(a)(1) to read: the prescribing practitioner does not [HAND WRITE] <u>indicate</u> on the prescription drug order that a specific brand must be dispensed, using

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language such as 'brand medically necessary' or similar wording."

After further discussion by the board, Mr. Miller withdrew the motion. It was noted that Medicaid payment procedures require a handwritten statement by the prescriber in order to prevent generic substitution. The board agreed to table the discussion until the next meeting to discuss whether a regulation change is in the best interest of patient safety.

<u>NABP</u> - Paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination to be administered in June - For information only, no action required.

<u>NABP</u> - Results of survey on the criteria used to approve new pharmacy permits. - For information only, no action required.

NABP - Online Scheduling Available for NAPLEX / MPJE Candidates - For information only, no action required.

<u>NABP</u> - Direct Processing for NAPLEX / MPJE Registration Forms and Fees – The licensing examiner is working on getting the new process set up.

<u>NABP</u> Constitution and Bylaws - Proposed Amendments (Copies of Constitution & Bylaws available upon request) - For information only, no action required.

NAPB - Information Request from Wisconsin Pharmacy Examining Board - Eligibility Requirements for NAPLEX and MPJE - For information only, no action required.

Rod Gordon, RPh - Sammuel Simmonds Memorial Hospital Pharmacy (PHA R 308) Licensing Question. Mr. Gordon asked the board whether a new pharmacy license would be required if this hospital sets up an additional pharmacy. The board responded that the hospital would be operating two pharmacies in separate locations and each location would require a separate license. (AS 08.80.157 Licensing of Facilities. "If operations are conducted at more that one location, each location shall be licensed by the board.") In addition, the pharmacies would be serving two different patient groups, beneficiaries and non-beneficiaries, and would have different purchasing contracts for the two groups. The board stated that the two pharmacies should be separately licensed and recommended that they review the requirements of their Federal purchasing contracts.

Kansas State Board of Pharmacy - Regulations for Central Prescription Filling Question – The Licensing Examiner will

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send response that there are no specific regulations for central prescription filling.

NABP, Melissa Madigan, HIPPA Privacy Rule: Impact on State Board of Pharmacy Inspections and Prescription Monitoring Programs - For information only, no action required.

Off the record at 3:10 p.m. Back on the record at 3:15 p.m.

Agenda Item 22 New Business

<u>TelePharmacy Ad-hoc Committee</u>.

Angie Leboeuf, Past President, Alaska Pharmacists Association joined the meeting at 3:15 p.m.

Mr. Bohrer cited that the following statutes give the board statutory authority for licensing of facilities:

- AS 08.80.157(a) "A facility engaged in the practice of pharmacy ...and a pharmacy where drugs or devices are dispensed, shall be licensed by the board,...If operations are conducted at more than one location, each location shall be licensed by the board."
- AS 08.80.157(b) "The board may by regulation determine the licensure classification of facilities and establish minimum standards for the facilities."
- AS 08.80.157(c) "The board shall establish by regulations the criteria that a facility must meet to qualify for licensure in each classification."
- AS 08.80.157(f) "The board shall specify by regulation the minimum standards..."
- AS 08.80.330(a) "Each pharmacy shall have a pharmacist-in-charge....The pharmacist –in-charge shall ensure compliance with all laws, and regulations governing the operation of the pharmacy."

Mr. Bohrer presented a review of the existing pharmacy regulations that may need to be revised to allow "TelePharmacy":

- 12 AAC 52.010(b) Classification of Licensure. Add a new license classification for a "remote" pharmacy location.
- 12 AAC 52.200(a) "Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in <u>that</u> pharmacy location as the pharmacist-in-charge of the pharmacy

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- in accordance with AS 08.80.330." The wording of this regulation may need to change to allow telepharmacy.
- 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 regarding a patient or prescription; (3) interpreting a prescription drug order; (4) determining the product required for a prescription; (5) interpreting date 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 will have to determine if a pharmacist can perform all the duties listed in 12 AAC 52.210 from a different location, and protect the public health, safety and welfare.
- 12 AAC 52.420 Security (c) "All drugs, devices, and other items or products that are restricted to sale by or under the personal supervision of a pharmacist shall be kept in the prescription department." The board discussed whether "personal supervision" could be electronic supervision via computer, two-way video and audio links.
- 12 AAC 52.420 Security (d) "The prescription department shall be locked by key or combination to prevent access when a pharmacist is not on-site.
- 12 AAC 52.420 Security (f) Prescriptions shall be stored in the prescription department and may not be removed unless a pharmacist is present..."
- 12 AAC 52.995 Definitions. (13) "direct supervision" means the visual or physical proximity that insures adequate safety controls;"

Mr. Miller distributed an outline of telepharmacy regulations, "Alaska TelePharmacy". The regulations include Purpose and Scope; Definitions; Guidelines for Pharmacies and Pharmacists; Rule Exceptions; and Suspension and Termination. Mr. Miller emphasized that "real time" computer, video, and audio monitoring, security checks, and overrides by the pharmacist-in-charge must be in place to

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insure protection of the health, welfare and safety of the public.

The Board discussed how a remote facility would be licensed and whether the regulatory authority exists to determine a new license category. The Licensing Examiner reported that the Regulations Specialist stated that the Board appears to have authority under AS 08.80.157(b) and 12 AAC 52.010 to designate a new licensing type and to define a "remote site" and to set up telepharmacy regulations. The Regulations Specialist also noted that the Department of Law does not review regulation proposals, but that the regulations would have to go through the regulation process before an official determination of regulatory authority is made.

Ms. Leboef asked whether a telepharmacy pilot project soon to be implemented by a Native Health Corporation would be under the jurisdiction of the Board of Pharmacy. The board noted that current Board of Pharmacy regulations, as well as the proposed telepharmacy regulations, apply to pharmacies and not to remote clinics and village health aids working under the supervision of a prescribing physician. (AS 08.80.390)

The TelePharmacy Ad-hoc Committee will continue to work on drafting regulations and the discussion will be continued at the next meeting. Angie Leboeuf left the meeting at 4:25 p.m.

• Patient Counseling Ms. Soden expressed concern about the occurrence and extent of patient counseling. Current Alaska pharmacy regulation 12 AAC 52.585 Mandatory Patient Counseling, requires that the pharmacist "make an offer to provide counseling." Ms. Soden noted that Washington pharmacy law requires counseling for all new prescriptions: "the pharmacist <u>must</u> orally explain to the patient or the patient's agent directions for use..." Ms Soden suggested that, for the health and safety of the public, that the board amend 12 AAC 52.585 Mandatory Patient Counseling. The wording in 12 AAC 52.585(a) "make an offer to provide" should be replaced with "shall verbally provide counseling."

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

RESOLVED to revise 12 AAC 52.585(a) Mandatory Patient Counseling to read: "With each new prescription dispensed, the pharmacist shall verbally [MAKE AN OFFER TO] provide counseling to the patient or the patient's caregiver on matters considered significant in the pharmacist's professional judgement. [THE OFFER SHALL BE MADE VERBALLY BY THE PHARMACISTS OR

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THE PHARMACIST'S AGENT]. The counseling may include..." (Leave items 1 through 10 as written.) RESOLVED to revise 12 AAC 52.585(b) [IF A PATIENT OR PATIENT'S CAREGIVER ACCEPTS THE OFFER TO PROVIDE COUNSELING] "A pharmacist shall counsel the patient or the patient's caregiver face-to-face." (Leave all other parts of the regulation as written.)

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

The board requested that Ms. Nelson include a statement in the newsletter about the proposed amendments to the mandatory counseling regulations.

Agenda Item 20 Office Business

- The board set the 2003 meeting schedule as follows: July 25, 2003. Confirmed
 October 2-3, 2003. Confirmed
- The Chair signed the approved minutes from the February 13-14, 2003 meeting and the March 19, 2003 Teleconference.
- The Board Chair signed wall certificates.
- Board members signed Travel Authorizations and provided travel receipts.
- Mr. Miller will be bringing four or five Pharmacy Interns to observe the July 25, 2003 meeting.

Adjournment

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

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

The meeting was adjourned at 4:45 p.m.

Respectfully submitted:
Barbara Roche, Licensing Examiner
Approved:
Margaret Soden, R.Ph., Chair Alaska State Board of Pharmacy
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