

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

**MINUTES OF MEETING  
APRIL 22-23, 2004**

By authority of AS 08.01.070(2) and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held on April 22-23, 2004 at the Atwood Building, 550 West 7<sup>th</sup> Ave. Suite 602, Anchorage, AK.

**Call to Order/Roll Call**

The meeting was called to order by Margaret Soden, Chair April 22, 2004 at 1:02 PM. Those present, constituting a quorum of the board, were:

Margaret Soden, R.Ph.  
Bill Altland, R.Ph.  
Cindy Bueler, R.Ph.  
Gary Givens, R.Ph.  
Laura Lee Nelson, R.Ph.  
Gerry Knasiak

Present from the Division of Occupational Licensing were:

Barbara Roche, Licensing Examiner  
Rick Younkens, Investigator (Agenda Item 6)

Present telephonically from the Department of Law was:

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

Visitors present were:

Nancy Lewis, Purdue Pharma  
Nancy Davis, Alaska Pharmacist Association (Agenda Item 7)  
Jim Towle, Alaska Dental Society – (Public Comment)

**Agenda Item 1      Review of Agenda**

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

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

Ms. Soden welcomed new Pharmacy Board member, Gary Givens.

**Agenda Item 2      Review of Minutes**

Bar/ 8/24/04

The board reviewed the minutes from the February 5-6, 2004 meeting. The following corrections were noted:

- Page 9 – in first complete paragraph, change “LOUIS” to “LOUISE”
- Page 15 – change “The board noted that the currently” to “The board noted that there is currently” in the third to last line under Agenda Item 18.
- Page 20 – change “12 AAC 52.240” to “12 AAC 52.420” on Problem #4 – Security.

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

**RESOLVED to approve the minutes of the February 5-6, 2004 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).
5. The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.
6. The board will continue to assess and evaluate the licensing of pharmacy technicians.
7. The board will continue its affiliation with NABP and send one board member to the District 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, **remote sites**, sterile products, 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 5a**

**Legal**

Ms. Horetski joined the meeting telephonically at 1:30 PM.

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

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

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

The board entered executive session at 1:35 PM

The board went back on the record at 1:45 PM

Ms. Soden thanked Ms. Horetski for her report and work on the lawsuit.

Ms Horetski disconnected from the meeting at 1:45 PM

**Agenda Item 5b**

**Review of Proposed Regulation Changes**

The board discussed the following regulation projects:

1. 12 AAC 02.310 Board of Pharmacy. The board discussed the 4/14/2004 Notice of Proposed Changes in the Regulations of the Department of Community and Economic Development dealing with Board of Pharmacy occupational licensing fees. The Licensing Examiner stated that pharmacy renewal forms would not be mailed in early May as requested by the board. Licensing fees were not reviewed by the Division in sufficient time to allow for early mailing of the renewal forms. Renewal forms will likely be mailed in late May

after the required 30-day public notice and signature by the Lt. Governor. The board expressed extreme displeasure and dismay at the late public notice of the fees and requested that a letter be sent to the Division Director.

2. 12 AAC 52.990 Display of license certificate. The board discussed Department of Law changes to 12 AAC 52.990.

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

**RESOLVED to adopt regulation 12 AAC 52.990 as amended by the Department of Law.**

3. 12 AAC 52.130 Review of Application for registration of pharmacies located outside of the state. The board discussed proposed regulation changes to 12 AAC 52.130, which were previously withdrawn by the Department of Law.

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

**RESOLVED to adopt regulation 12 AAC 52.130 as amended by the Department of Law.**

The board discussed regulation changes needed to update the name of the American Council on Pharmaceutical Education to their new name: Accreditation Council for Pharmacy Education.

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

**RESOLVED to submit regulation project to change “American Council on Pharmaceutical Education” to “Accreditation Council for Pharmacy Education” in 12 AAC 52.070(1) and Editor’s Note following: 12 AAC 52.080(c) and 12 AAC 52.340(1).**

The licensing examiner announced that the following regulation changes will be effective May 15, 2004:

- 12 AAC 52.090(d) – Examination Requirements
- 12 AAC 52.340(b)(1) and (2) - Continuing Education Approved Programs
- 12 AAC 52.585(a) and (b) – Mandatory Patient Counseling.

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**Break**

Off record: 2:20 PM

Back on record: 2:30 PM

**Agenda Item 6**

**Investigative Report**

Investigator Rick Younkings, joined the meeting at 2:30 PM.

REVIEW REPORT: Mr. Younkings reviewed the investigative report noting that there were 11 open cases and 5 cases were closed since the last report. Two pharmacy inspections have been completed since the last report.

Mr. Altland asked the investigator to explain the process of consulting with board members in open investigations. Mr. Younkings noted that board members could provide technical consultation to the investigator, but that ex parte communications are prohibited in ongoing investigations in order to ensure that the board members remain impartial.

Mr. Younkings noted that Out of State Pharmacies SelectRx.com - PHA O 502 and Prestab Co. - PHA O 524 will be closing.

Mr. Younkings reviewed the investigator report on a license application submitted by a pharmacist (case #2650-03-002) and discussed open case #2600-04-003.

**On a motion duly made by Mr. Givens, 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 #2650-03-002 and Case #2600-04-003.**

The board entered executive session at 2:55 PM.

The board went back on the record at 3:25 PM.

For the record the Case #2650-03-002 is the result of an investigation regarding a pharmacist application submitted by Mr. Colin E. Bayliss. Case#2650-03-002 was discussed at the Feb. 5-6, 2004 meeting at which time the board resolved to deny the pharmacist application. Mr. Bayliss did not submit a request to initiate a hearing within the required 15 -days, but sent a letter to each board member asking if the board could re-examine their decision. The investigator noted that the board does not need to take further action on this application.

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

**RESOLVED to adopt the surrender of pharmacist license, Case #2600-04-003 as presented.**

For the record, the surrender is the result of an active investigation, Case #2600-04-003 of Pharmacist Sarah Martin, License #1135.

Investigator Rick Younkings departed from the meeting at 3:35 PM.

**Agenda Item 7**

**Report by AK Pharmacists Association**

Nancy Davis, Association Executive Director presented a report from the Alaska Pharmacists Association (AKPhA).

- Ms. Davis announced upcoming AKPhA continuing education presentations and noted that several courses will be co-sponsored with Providence and Alaska Native Medical Center. Ms Davis pointed out that the list of continuing education offered at the February AKPhA Convention is included in the board packets.
- The AKPhA web site has been updated to include links to the Alaska Board of Pharmacy, Board of Pharmacy Newsletter, Alaska Statutes, Alaska Medicaid, and Asthma Coalition web sites.
- Ms. Davis discussed the pending introduction of the Medicare Prescription Card and stated that the AKPhA Board agreed to not endorse any specific Medicare card at this time.
- Legislative Update by Caren Robinson – AKPhA Lobbyist reports on various bills affecting the practice of pharmacy. The Legislative Report by Barry Chritensen, AKPhA Legislative Committee Chair noted that the Association is actively monitoring bills that would establish a narcotic tracking system and enlarge the prescriptive authority of Naturopathic Physicians.

Mr. Altland asked if the AKPhA would consider working to foster cooperation with other associations like the Alaska State Medical Association and The Alaska Dental Society. Mr. Altland noted that several bills introduced in the last legislative session would affect all the medical professions, and that resources could be shared with the other medical associations for lobbying, grants, etc. Ms Davis noted that the AKPhA has a cooperative relationship with national pharmacist associations.

Ms. Soden thanked Ms. Davis for her report and for the opportunity to represent the Board of Pharmacy as a speaker at the AKPhA Convention.

**Break**

Off record: 3:40 PM

Back on record: 3:45 PM

**Agenda Item 8      Public Comment**

Public comment period opened at 3:45 PM.

JIM TOWLE Alaska Dental Society Executive Director, noted that the various medical associations share common interests and that cooperation should be encouraged involving various licensing and public policy issues. Mr. Towle distributed copies of HB 530 and Fact Sheet for HB-530 Dental Disciplinary and Accountability Bill and noted that the proposed bill would establish a process where grievances and complaints are investigated and reviewed first by the Alaska Board of Dental Examiners instead of by the Division Investigators. HB 530 would put the Board of Dental Examiners in the complaint and investigation process earlier. Passage of HB 530 would allow the Board to direct serious allegations directly to a disciplinary committee comprised of practicing dentists and be more involved in crafting disciplinary agreements. Mr. Towle stated that the proposed bill would enhance public safety and improve the quality of dentistry.

Public comment was closed at 4:15 PM

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

**RESOLVED to recess and return at 9:00 AM, April 23, 2004.**

**Recess**      The board recessed at 4:20 PM.

**Call to Order/Roll Call**

The meeting was called to order by Margaret Soden, Chair, April 23, 2004 at 9:02 AM. Those present, constituting a quorum of the board, were:

Margaret Soden, R.Ph.  
Bill Altland, R.Ph.  
Cindy Bueler, R.Ph.  
Laura Lee Nelson, R.Ph.  
Gerry Knaskiak

Present from the Division of Occupational Licensing was:

Barbara Roche, Licensing Examiner

Present telephonically from the Division of Occupational Licensing were:  
Kurt West, Regulations Specialist

Jennifer Strickler, Administrative Manager

Visitors present were:

Nancy Lewis, Purdue Pharma

Mark Bohrer, Former Alaska Board of Pharmacy Member and  
Telepharmacy Ad Hoc Committee Member

**Agenda Item 9**

**Review of Agenda**

Discussion of Licensing Fees was added to Agenda Item 12 and 15  
Licensing and Division Updates.

Discussion of the new Generic Labeling regulations, 12 AAC 52.480(12)  
was added to Agenda Item 12, Discuss Licensing.

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

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

**Agenda Item 10**

**Review License Applications**

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

Pharmacy Technician Application:

- Alexandrea C. Brown - Pharmacy Technician License – Application  
with “Yes” answer was approved.

Pharmacist Intern Applications:

- Shannon Lane Hanson – Pharmacist Intern – Application with “Yes”  
answer was approved pending Intern Jurisprudence Exam.
- Heather Johnson – Pharmacist Intern – Application with “Yes” answer  
was approved pending Intern Jurisprudence Exam.
- Amanda Rae Nelson – Pharmacist Intern – Application with “Yes”  
answer was approved pending Intern Jurisprudence Exam and receipt  
of one certificate of moral character.
- Charles P. Semling – Pharmacist Intern – Application with “Yes”  
answer was approved.

Pharmacist Applications:

- William Scott Claunch - Pharmacist – Approved pending passing  
score on MPJE, NABP final report and transcripts.



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- Lucy Galloway – Pharmacist – Approved pending passing score on MPJE and NAPLEX Score Transfer, final transcripts, license verification from Washington, and \$180 license fee.
- Robert Sim Guy – Pharmacist – Application with “Yes” answer approved pending passing score on MPJE and receipt of NABP final report.
- Joshual Lee Mark - Pharmacist – Application with “Yes” answer approved pending passing score on MPJE and \$180.00 license fee.
- Paul T. Michaud – Pharmacist - Approved pending NABP final report.
- James Blake Richardson – Pharmacist – Application with “Yes” answer approved pending receipt of NABP final report.

Out of State Pharmacy Applications:

- Accredo Health Group, Inc., Memphis, TN – New Application – Approved.
- Health Solutions Pharmacy, Inc. – Pet Express Pharmacy, Corvallis, OR– New Application – Approved.
- RxUSA PBM, Inc., Port Washington, NY – New Application – Approved.
- Simplex Medical Pharmacy, Ft. Meyers, FL – New Application – Approved.
- Target Mail Order Pharmacy T-1899, Columbus, OH – Change Location Application, was license #245 – Approved pending receipt of Certified True Copy of Facility License.
- Universal Rx., Tampa, FL – New Application – Approved pending list of pharmacists working in the facility.

Wholesale Drug Distributor:

- Hospira Worldwide, Inc c/o AFF Distribution, Anchorage, AK – Change Ownership Application, was license #38. - Approved pending original application, and fees.

Drug Room Application:

- Dialysis Services of S.E. Alaska, Reifenstein Dialysis Center, AK, Juneau, 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.**

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**Agenda Item 11**

**Review Protocol Applications**

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

- Fred Meyer #00017, 200 W. Dimond, Anchorage (Charles W. Barnett, RPh – Kami Hutchins, ANP) Emergency Contraception – Approved.
- Ron’s Apothecary Shoppe, Juneau (Scott E. Watts, RPh – Carolyn V. Brown, MD) Emergency Contraception – Approved.
- Hewitts Drug Store, 1068 W. Fireweed Lane, Anchorage (Robert Niebert RPh – Colleen Murphy, MD) Emergency Contraception – Approved.
- Chief Andrew Isaac Health Center Pharmacy – (Daniel P. Nelson, RPh – Donna Galbreath, MD) Hypertension Collaborative Practice Agreement – Approved.

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

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

**Break**

Off record: 10:30 AM

Back on record: 10:40 AM

**Agenda Item 12**

**Discuss Licensing**

- Problem Prescribers. The board discussed problems with identifying whether prescribers have valid authority to prescribe and whether there is a current M.O.A. that places restrictions on the prescriber. The licensing examiner noted that information on current licensing actions, MOA’s and restrictions, is available on the Division web site (<http://www.dced.state.ak.us/occ/ppha.htm>) under “Occupational License Search”. In addition, a pharmacist could call the Medical Board or the Investigator for licensing actions or MOA restrictions on prescribing. The board pointed out that calling the Division is only an option during business hours and noted that obtaining current information is often difficult. The board requested that MOAs for problem prescribers include required notification to Pharmacists.
- Regulation Changes by other boards. The board discussed possible regulation changes that would expand dispensing authority of other licensees, for example Naturopaths. In order to monitor regulation changes by other boards that would affect pharmacy, the board requested that it be notified. The licensing examiner will request that the Board of Pharmacy be added to the “interested parties list” for

regulation changes by the Medical Board, Dental Examiners, Board of Nursing, and Naturopathy.

- Licensing of Federal Facilities. The board discussed the past request for an AG Opinion on whether or not Alaska Native Medical Centers are considered federally operated and thus exempt from licensing by the Board of Pharmacy. Telepharmacy regulations currently being written by the board require licensing of both central and remote facilities, many of which are operated by Native Corporations. According to the licensing examiner, the original board request for AG Opinion in 2002 and a follow-up request in March 2003 are still pending. The board requested an update and directed the licensing examiner to send a letter to the Division Director asking about the status of the AG opinion.

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

**RESOLVED to request an update on the pending AG Opinion on licensing of federal facilities operated by Native Corporations.**

Kurt West, Regulations Specialist and Jennifer Strickler, Administrative Manager joined the meeting telephonically at 11:15 AM.

- Renewal Forms & Licensing Fees. The board expressed frustration and displeasure that the renewal forms could not be sent out early as requested many times in several communications to the Division. Ms Soden noted that because of increased legal and regulation project costs, the board had anticipated an increase in licensing fees. Ms. Soden stated that the board addressed increasing licensing fees in the FY 2003 Annual Report. In addition, the issue of fees was covered in board minutes and several letters were sent to the Division Directors starting in 2002 and continuing up to the present. Because pharmacy licensees are required to post current license certificates at the practice site, early mailing of renewal information is critical if licensees are to be in compliance with the regulations. Ms. Strickler said that the public notice of increased licensing fees was delayed. The board asked if renewals could be mailed out before the fees were effective. Kurt West stated that May 19 is the last day for public comment that the renewals could go out May 20. Ms. Strickler said she would ask the Director if renewal forms could be sent out early with a statement regarding possible increase in fees. Ms. Strickler noted that this could be confusing to licensees and could result in issuing large numbers of refunds.

Ms. Strickler and Mr. West disconnected from the meeting at 11:30.

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

**RESOLVED to direct the Board President to write a strongly worded letter to Director, Rick Urion, cc: Jennifer Strickler, Barbara Gabier, Carol Whelan, and Kurt West expressing our frustration and displeasure with the tardy response to our request to adjust licensing fees. Also, the letter should include two recommendations: 1) Renewal forms for the Board of Pharmacy should be mailed out in early May in compliance with 08.01.050(11) "Notify Licensees of renewal date at least 30 days before the expiration date of their licenses. 2) Any change in fees should take place after July 1, 2004.**

- Generic Labeling regulations, 12 AAC 52.480(12) The Generic Labeling regulation, requiring that the accepted generic drug name appear on the label, went in to effect on January 14, 2004. Ms. Nelson outlined the problems her pharmacy has had in complying with the new generic labeling regulation. After extensive consultation with the pharmacy software manufacturer, Ms. Nelson was able to get her pharmacy software to print the generic name on the label, but "dummy records" had to be set up in the system requiring very time consuming entry of false information. Ms. Nelson noted that the process is very cumbersome and may add to, rather than reduce confusion by patients. In addition, each pharmacy software system is different and requires reprogramming, extensive debugging and new data entry to comply with the regulation. The board acknowledged that there are software issues beyond the control of many pharmacies, which means that many facilities are not in compliance with the new regulation. Implementing the regulation will require expenditures of considerable time and money. Mr. Altland will correspond with other pharmacies to determine if they have encountered similar problems. The board will discuss the issue again at the next meeting.

### **Agenda Item 13**

#### **Discuss Prescription Drug Abuse Issues**

- Medical Board / Committee Update - Ms Soden stated that the Board's Prescription Drug Task Force continues to work on coordinating efforts between prescribers, law enforcement, pharmacists and others involved in the misuse and abuse of prescription drugs.
- HB 239 (ID System for Prescriptions) – Ms. Soden noted that Committee Hearings for HB 239 are scheduled for today during the board meeting. Ms Soden has been tracking the numerous Committee Hearing schedule changes for HB 239 and has made several attempts at testifying, only to have the hearing canceled or rescheduled. A new version of the bill has not been available for review. Mr. Altland asked if potential federal funding for prescription tracking systems

could be used to help in setting up the prescription database. Ms. Soden noted that legislation and regulations to implement the tracking system had to be in place to take advantage of that funding.

- SB 306 / HB 434 (Practice of Naturopathic Medicine) – The board discussed a pending bill that would expand prescriptive authority for naturopaths. The board shared concerns expressed by the AKPhA that passage of the bill could result in additional potential for doctor shopping by narcotic abusers.

**Agenda Item 14**      **Legislative Update** (Discussed under Agenda Item 13).

**Agenda Item 15**      **Division Updates**

- Budget Report - The board reviewed the Budget Report provided by the Division of Occupational Licensing.
- Licensing Fees - (Discussed under Agenda Item 13)

**Break**                      Recess for Lunch at 11:45 AM  
Back on record: 1:05 PM

**Agenda Item 16**      **National Association of Boards of Pharmacy (NABP) Update**

NABP District 7 & 8 Meeting will be held October 27-30th, 2004 in Las Vegas. Ms. Soden noted that the FY 2003 Annual Report budgets for one board member to attend the District NABP Meeting

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

**RESOLVED for Ms. Nelson or Ms. Bueler to attend the NABP District 7 & 8 Meeting in Las Vegas on October 17-30, 2004.**

**Agenda Item 17**      **Correspondence**

FDA, Division of Federal-State Relations, Health Alert!- February 6, 2004 - FDA and Johnson & Johnson Warn Public about Counterfeit Contraceptive Patches Sold Through Foreign Internet Site. For information only, no action required.

Rep. Kelly Wolf, cc: Rick Urion, Director, Division of Occupational Licensing - February 15, 2004 - Letter RE: HB 408 and HJR 33 For information only, no action required.

KOMO4 - "Birth Control Pills May Now be Added to Shopping Lists" - University of Washington School of Pharmacy Pilot Project. For information only, no action required.

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Alaska Board of Pharmacy - March 2004 Newsletter - now on: <http://www.nabp.net/>. The board questioned whether pharmacists and technicians are aware of the web posting of the newsletter, and how many actually read it. The board suggested that the newsletter be sent out via email using the AKPhA email list or that an email list be collected from the renewal. The Licensing Examiner will check into creating an email list.

FDA, Division of Federal-State Relations, - March 3, 2004 - FDA Launches New Easy-to-use Drug Information Web Site: <http://www.fda.gov>. For information only, no action required.

SureScripts "Electronic Prescribing Overview" and "Electronic Transmission of Prescriptions" - Points to consider when drafting new regulations. For information only, no action required. The board noted that NABP and others are working on model regulations for electronic prescriptions.

U.S. Department of Health and Human Services, CMS Public Affairs - "HSS Gives Seal of Approval to Medicare Drug Discount Cards". For information only, no action required.

U.S. Department of Health and Human Services, CMS Public Affairs - Antonett Lysen email re: 28 Sponsors of Medicare Drug Discount Cards Announced". The Licensing Examiner noted that of the 17 discount card sponsors, only 4 are licensed as Out of State Pharmacies and authorized to ship to Alaska. Correspondence has been sent to Ms. Lysen regarding licensing of the sponsors, and a response from the CMS is pending.

U.S. Department of Health and Human Services, CMS Public Affairs - Overview: Medicare Prescription Drug Discount Card and Transitional Assistance Program. For information only, no action required.

National Council on Patient Information and Education (NCPPIE) - "Surgeon General 'speaks' to Consumers about Over-the Counter Medicines in New Ad Campaign". For information only, no action required.

U.S. Department of Health and Human Services, FDA Letter to Governor of New Hampshire regarding "endorsing purchase by citizens of New Hampshire of unapproved, illegal drugs from a foreign pharmacy..." For information only, no action required.

NABP - February 13, 2004 - "Task Force on Limited Distribution and Shortage of Medications" - Resolution No: 99-3-03. For information only, no action required.

NABP - February 20, 2004 - "Web Sites Offering Dangerous or Restricted Drugs". For information only, no action required.

NABP – MPJE - State Roster - Test Period July 01, 2003 to December 31, 2003. For information only, no action required.

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NABP - February 20, 2004 - "Model Rules for Licensure of Wholesale Distributors". Ms Soden suggested that the board review current Alaska Wholesale Distributor regulations in light the new Model Rules.

Pharmaceutical Distributors Association - PDA- March 16, 2004 - Comments on "Model Rules for Licensure of Wholesale Distributors"

NABP Newsletter - March 2004 - "State and Federal Governments Target Rogue Internet Pharmacies". For information only, no action required.

NABP - March 8, 2004 - Membership - California and Florida. For information only, no action required.

NABP - April 2, 2004 - FPGEC Program Requirements regarding proof of licensure. For information only, no action required.

NABP - April 2, 2004 - Proposed Resolutions - NABP's 100th Annual Meeting & Centennial Celebration April 24-27, 2004" - Copies available on request - 25 pages. For information only, no action required.

NABP - April 2, 2004 - FPGEC Program Requirements regarding proof of licensure. For information only, no action required.

Alaska Pharmacists Association - April 19, 2004 - "Free Regional Training Sessions: Medicaid PDL". For information only, no action required.

American Pharmacists Association - April 16, 2004 - FDA Notice on Compounded Veterinary Medications. For information only, no action required.

NABP - April 16, 2004 - Expanded Class I Recall of Duragesic (fentanyl transdermal system) 75mcg/hour. For information only, no action required.

NABP - April 14, 2004 - NABP Constitution and Bylaws - Proposed Amendments (Copies Available upon request). For information only, no action required.

**Agenda Item 18**

**New Business**

Mark Bohrer joined the meeting at 1:30 PM.

- Generic Labeling. Mr. Bohrer reported that PDX, the software manufacturer for the system used at Fred Meyer pharmacies, made a programming change to accommodate the new generic labeling regulation. He noted that there were many difficulties, but that most of the bugs had been worked out.
- TelePharmacy Ad hoc Committee

The Telepharmacy ad hoc Committee, composed of Pharmacy Board members Mr. Altland and Mr. Givens; Mr. Bohrer and Terry Babb met several times to discuss recommendations to the board when writing the

telepharmacy regulations. The ad hoc committee consulted with many pharmacists and health professionals and referenced the Texas and North Dakota regulations in writing up recommendations contained in the 4/12/2004 Telepharmacy Project paper. Copies of the Telepharmacy Project (4/12/2004) are included in the board packets.

Mr. Bohrer noted that the 4/12/2004 Telepharmacy Project paper is just a starting point for consideration by the board. Mr. Bohrer stated that his participation in the discussions, as former board member, is only advisory and that the board needs to address several issues and make decisions on the following issues before going forward with a telepharmacy regulation project:

- Licensing and qualifications for personnel staffing remote pharmacy locations.
- Automated vs. community pharmacist model
- Frequency and requirements for inspections of remote locations
- Incorporation of new regulations into existing regulations.
- Requirements for security and monitoring

Mr. Altland recommended that the board emphasize the following general principals in crafting the telepharmacy regulations:

- Importance of direct continuous supervision of the remote facility by a Pharmacist-in-charge (PIC).
- Prescriptions should not be removed from the remote pharmacy when the PIC is not present to monitor.
- Requirements and frequency of inspections and inventory should be clearly defined.
- Both audio and video monitoring systems are necessary to ensure patient and public safety. If either system is “down”, the whole system is “down”.
- Licensing and training requirements for remote facility staff need to be defined.
- Regulations need to be flexible enough to accommodate the wide range of conditions and populations that would be served.

The board discussed and agreed upon the following amendments and additions to current regulations:

12 AAC 52.010 CLASSIFICATIONS OF LICENSURE is amended to read:

- (b) The board will issue the following categories of licenses or registration to a qualified facility:

**(6) Remote Pharmacy License**



12 AAC 52.020 FACILITY LICENSE is amended to read:

(c) An application for a pharmacy license **or a remote pharmacy license** must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.

**(d) An application for a pharmacy license must include the name and specific location(s) of all remote pharmacies under that pharmacy's control.**

**(e) An application for a remote pharmacy license must include the name and license number of the central pharmacy.**

“Central Pharmacy” needs to be defined under 12 AAC 52.995 DEFINITIONS.

12 AAC 52.200 Pharmacist-in-Charge is amended to read:

(a) Before the board will issue a license to a pharmacy, the owner of a pharmacy must designate a pharmacist as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330 **and comply with either (1) or (2) below.** The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

**(1) The pharmacist-in-charge must practice in that pharmacy location; or**

**(2) For remote pharmacies, the pharmacist-in-charge must ensure that all practice in that location is under the direct supervision of a pharmacist.**

“Direct Supervision” is defined under 12 AAC 52.995 DEFINITIONS.

12 AAC 52.420 Security is amended to read:

(c) All drugs and devices and other items or products that are restricted to sale by or under the [PERSONAL] **direct** supervision of a pharmacist shall be kept in the prescription department.

(d) The prescription department shall be [LOCKED BY KEY OR COMBINATION] **secured** to prevent unauthorized access when a pharmacist is not [ON-SITE] **available to provide direct supervision.**

(f) Prescriptions shall be stored in the prescription department and may [NOT] be removed [UNLESS A PHARMACIST IS PRESENT] **only under the direct supervision of a pharmacist**

and the removal is for the immediate delivery to the patient, the patient's agent or the person delivering the prescription to the patient or the patient's agent.

12 AAC 52.480 Labeling is amended to read:

- (1) Name, address and phone number of the **dispensing** pharmacy.

The board discussed whether the label should have the remote (distributing) pharmacy or the central (dispensing) pharmacy on the label. Mr. Altland and Ms. Soden will check federal regulations regarding label requirements.

Add to new Appendix "D" or under new section 12 AAC 52.425  
GUIDELINES RELATING TO REMOTE PHARMACIES:

1. Only a central pharmacy located in this state may provide pharmacy services through a telepharmacy system to a remote pharmacy.

The board noted that telepharmacy regulations could only apply to central and remote pharmacies located within the state. The board has no jurisdiction over facilities licensed in another state and pharmacists from out of state would not necessarily be licensed in Alaska.

2. A telepharmacy system is required to be under the personal supervision of a pharmacist

The board emphasized that personal supervision of a "telepharmacy system" needs to be monitored in "real time." Ms. Bueler and Mr. Bohrer will consult with technical experts for a definition of "real time."

3. A remote pharmacy is required to be under the direct supervision of a pharmacist through a telepharmacy system.
4. A remote pharmacy must be staffed by a pharmacy technician, pharmacist or other person that has received board approval.

The board discussed the licensing of "other person(s)" and noted that it had no statutory authority to regulate or license "other person(s)" The board currently licenses pharmacists, interns and pharmacy technicians.

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

**RESOLVED to revise #4 to read: “A remote pharmacy must be staffed by a pharmacy technician, pharmacist or pharmacist intern.”**

5. A remote pharmacy may not be located closer than 10 miles to a licensed pharmacy that dispenses prescription drug orders to outpatients.

6. A remote pharmacy in operation at the time a new pharmacy is established may continue to operate. There is no limitation to the distance between remote pharmacies.

7. Before providing remote pharmacy services, the telepharmacy system in place between the central pharmacy and remote pharmacy must be tested by the central pharmacy and found to operate properly. The central pharmacy shall make the results of such testing available to the board upon request

8. The remote pharmacy must be inspected by a pharmacist annually.

The board discussed frequency of inspections for remote pharmacies and decided to change #8 to read: “ The remote pharmacy must be inspected by a pharmacist quarterly.”

9. The pharmacist-in-charge is responsible for ensuring the remote pharmacy is in compliance with all board regulations.

10. The remote pharmacy shall be secured to prevent unauthorized access when a pharmacist is unavailable to provide direct supervision

11. Drug Procurement

A. Drugs may only be shipped to the remote pharmacy from the central pharmacy.

B. Drugs must be shipped in a sealed container with an itemized list of products contained. This list must be kept on file at both the remote pharmacy and central pharmacy.

C. Records of drugs received at the remote pharmacy must be kept for 2 years.

D. Records of drugs shipped/received must be verified by an employee at both the remote pharmacy and central pharmacy.

12. Prescription dispensing/distribution

A. Prescriptions filled at the remote pharmacy must be from those filled at the central pharmacy.

B. Prescription records must be maintained at the central pharmacy.

C. All prescription labels must meet the requirements of 12 AAC 52.480.

D. Prescriptions may not be distributed until a pharmacist at the central pharmacy utilizing telepharmacy systems has verified the finished prescription product.

E. Dispensing is considered to be done at the central pharmacy. Distribution is considered to be done at the remote site.

13. Records

A. A central pharmacy shall keep a record of all drugs sent to and returned from a remote site separate from the records of the central pharmacy and from any other remote pharmacy's records.

B. A central pharmacy shall conduct an inventory at each remote site at least annually.

(1) This record of inventory shall be kept at both the central pharmacy and remote pharmacy.

(2) This inventory shall be separate from the drugs of other remote pharmacies and the central pharmacy.

12 AAC 52.995 Definitions is amended to read:

(13) "Direct supervision" means [VISUAL OR PHYSICAL PROXIMITY] **supervision** that insures adequate safety controls **either by physical proximity or by a telepharmacy system.**

The following definitions should be added under 12 AAC 52.995  
DEFINITIONS:

“Remote pharmacy” means a facility that provides pharmacy services, including the storage and dispensing of prescription drugs, drug regimen review and patient counseling through a telepharmacy system.

“Telepharmacy system” means a system under the personal supervision of a licensed pharmacist that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services through all of the following types of technology:

1. Audio link
2. Video link
  - A. Still image capture
  - B. Save and forward
  - C. Computer link

“Personal supervision” means visual or physical proximity that ensures adequate safety controls.

“Central pharmacy” means the pharmacy providing remote pharmacy services through telepharmacy systems.

“Still image capture” means a specific image captured electronically from a video or other image capture device.

“Store and forward” means a video or still image record that is saved electronically for future review.

A few loose ends remain to be decided by the board, including the following:

1. Should there be a maximum number of remote sites that could be under the supervision of one pharmacist?
2. Should additional training be required for remote site pharmacy technicians?
3. Should there be multiple levels of technician licensing? The board recommended that regulations requiring pharmacy technicians at remote sites be pursued now, and that they would address adding levels of technician licensing at a later date.
4. Should an exam, similar to the Intern Jurisprudence Exam be required for technician licensing? Ms. Bueler

and Ms. Soden will work on writing a technician exam for the board's review at the next meeting.

Ms. Soden thanked the telepharmacy ad hoc committee for their efforts in sorting through many difficult issues and their success in getting a draft of the regulations down on paper. The board agreed to work through the loose ends and to call a teleconference to discuss the regulations. Draft regulations could be finalized in the teleconference and then adopted at the September 2004 meeting.

**Break**

Off record: 3:40 PM

Back on record: 3:45 PM

**Agenda Item 20**

**Office Business**

- The board set the 2004 meeting schedule as follows:  
September 16-17, Anchorage at Atwood Building.  
July 22-23, 2004, meeting canceled.  
October 21-22, 2004, meeting canceled.
- The Chair signed the approved minutes from the February 5-6, 2004 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 4:55 PM.

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Respectfully submitted:

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Barbara Roche, Licensing Examiner

Approved:

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

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