STATE OF ALASKA DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION OF OCCUPATIONAL LICENSING

ALASKA STATE BOARD OF PHARMACY

MINUTES OF MEETING April 28-29, 2005

By authority of AS 08.01.070(2) and in compliance with the provision of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held on April 28-29, 2005 at the Atwood Building, 550 West 7th Ave., Suite 1860, Anchorage, AK.

Call to Order/Roll Call

The meeting was called to order by Cindy Bueler, Chair, April 28, 2005 at 1:00 p.m. Those present, constituting a quorum of the board, were:

Cindy Bueler, R. Ph. Bill Altland, R. Ph. Gary Givens, R. Ph. Mary Mundell, R. Ph. Leona Oberts Margaret Soden, R. Ph.

Michael Pauley was not present at the meeting.

Present from the Division of Occupational Licensing were:

Sher Zinn, Licensing Examiner Rick Younkins, Investigator (Agenda Item 6)

Visitors present:

Sharon Hamrick, Alaska Pharmacists Association Nancy Davis, Alaska Pharmacists Association

Agenda Item 1 <u>Review of Agenda</u>

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

RESOLVED to approve the agenda with the following amendments:

Add new board member orientation after agenda item 2.

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Agenda Item 2 Review of Minutes

The board reviewed the minutes from the meeting of January 27-28, 2005. The following corrections were noted by Ms. Soden and Ms. Bueler;

- Page 14-line 7, add fee after processing
- Page 15-line 8 under NABP Update, change any to many

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

RESOLVED to approve the minutes of the January 27-28, 2005 meeting with the corrections noted.

Ms. Bueler welcomed the new members to the Board of Pharmacy, Leona Oberts and Mary Mundell, R. Ph.. Ms. Bueler read the new board member orientation information. The information included the differences between the Alaska Pharmacists Association and the State Board of Pharmacy; ethics disclosure; the boards role in the regulation process; investigative process.

Each of the board members introduced themselves.

Agenda Item 3 <u>Ethics Disclosure</u>

No ethics violations were reported.

Agenda Item 4 Goals and Objectives

The board read and reviewed the goals and objectives. No changes were made to the 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 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, remote sites, sterile products, 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 assess and evaluate the growing public concern regarding abuse of prescription drugs.

Agenda Item 5 Continuing Education Audit

The board reviewed the CE audit for pharmacists as noted in the board packet. Sher Zinn explained the continuing education for Glen Wyndham. Mr. Wyndham submitted 2.5 hours from the previous licensing period and subsequently completed the deficiency in the CE's in September of 2004. The board agreed they would accept the hours completed in September 2004 as part of the required CE's because Mr. Wyndham had disclosed the reason for the discrepancy in the letter to the board.

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

RESOLVED to accept the continuing education audit for pharmacists as presented to the board.

The board reviewed the pharmacy technician audit. Ms. Zinn explained the circumstances for completing continuing education hours outside of the required time period. The board accepted the explanations for the following technicians and allowed them to be used for the current renewal period:

Bonnie Holm, license #71 Keith Graham, license #870 Melissa Whipple, license #828 Mr. Altland asked about the University of Alaska Southeast course that Ann Damassiotis submitted for the continuing education audit. Ms. Zinn explained that pharmacy technicians may use an approved college course for renewing of their Pharmacy Technician Certification Board (PTCB) certification. The regulations state that a technician may complete continuing education that is approved by the PTCB.

On a motion duly made by Ms. Soden, seconded by Ms. Mundell and approved unanimously, it was

RESOLVED to approve the continuing education audit for technicians as presented to the board.

The board noted that a letter should be written to the licensees who completed continuing education hours outside of the correct renewal period. The letter should note that the hours may not be used for the next renewal period, 2006-2008.

Ms. Soden noted that in Oregon there was an impressive number of pharmacists who were discovered through the CE audit process to be out of compliance. Disciplinary action for failure to meet the requirements and indicating on the renewal that they had met the requirements when they had not, included taking the Multistate Pharmacy Jurisprudence Exam at the licensees expense. Ms. Soden noted that Alaska had done much better this renewal than in previous licensing periods.

<u>Tape 1 Side B</u>

Ms. Zinn brought to the board for review, the renewal and CE documentation for pharmacist Mary Martha Hall, license #1188. Ms. Hall had not been part of the audit, however she had submitted the CE documentation with the renewal. When reviewing the documentation Ms. Zinn determined the CE's completed for the Oregon State Pharmacy Association were not ACPE approved as required by regulation. Ms. Hall had petitioned the board to allow her to make up the remainder of the required hours totaling 8.5, during the current licensing renewal period. This would mean that she would submit 38.5 hours of continuing education at the next renewal instead of the required 30 hours. Ms. Hall had stated she was not aware that the Oregon State Pharmacy Association continuing education hours were not ACPE approved, and that the association had not responded to her inquiry regarding the matter.

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

RESOLVED to accept the ACPE hours submitted by Mary Hall and allow her to complete the remainder 8.5 hours during the current renewal period. The board noted that Ms. Hall would need to complete 38.5 hours during the current licensing period to be in compliance with the continuing education requirements.

Agenda Item 15 Correspondence

The board reviewed the NABP correspondence.

<u>NABP</u>-January 28, 2005-CMS Releases Final Medicare Prescription Drug Benefit Regulations. For information only, no action required.

<u>NABP</u>-January 31, 2005-Results of NABP Investigation on Purchasing Steroids via eBay. For information only, no action required.

<u>NABP</u>-February 4, 2005-CMS Releases Electronic Prescribing Proposed Rule. For information only, no action required.

<u>NABP</u>-February 11, 2005-NABP Testimony on Electronic Prescribing of Controlled Substances. For information only, no action required.

<u>NABP</u>-Foreign Pharmacy Graduate Examination Committee. For information only, no action required.

<u>NABP</u>-February 18, 2005 e-mail-FPGEC Waiver Memo. For information only, no action required.

<u>NABP</u>-March 18, 2005-NCVHS Submits Second Set of Electronic Prescribing Recommendations to the Secretary of the USDHHS. For information only, no action required.

<u>NABP</u>-March 25, 2005-State Board of Pharmacy Multi Survey Results. For information only, no action required.

<u>NABP</u>-April 1, 2005-Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities. For information only, no action required.

Break Off the record at 2:12 p.m. On the record at 2:32 p.m.

Mr. Givens returned to the meeting at 2:34 p.m.

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Agenda Item 6 Investigative Report

Rick Younkins, Acting Chief Investigator, joined the meeting for the investigative report. Mr. Younkins noted he added case #2606-05-001 to the open case report since it was submitted to the board. The case involved a technician with a lapsed license. The technician was apprehended trying to pass a forged prescription. Mr. Younkins proposal to the board would be to offer a voluntary surrender of the license. Mr. Younkins noted since her license is lapsed that she could apply to renew her license within five years. He suggested that the licensing examiner would be notified to flag the file. Ms. Soden asked if the national database would be notified of the surrender. Mr. Younkins confirmed that the NABP would be notified. Ms. Mundell asked if once a licensee voluntarily surrendered a license, would they be able to have the license reinstated. Mr. Younkins stated the licensee would have to reapply to the board for reinstatement of a surrendered license. The licensee would need to prove to the board they were capable of assuming their duties, and they would have to provide proof they had successfully completed rehabilitation or were continuing in recovery. The board agreed that Mr. Younkins should offer the licensee a voluntary surrender.

Mr. Younkins discussed with the board the closed and open cases from his report.

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

RESOLVED in accordance with the provisions of AS 44.62.310(c)(2), to go into executive session for the purpose of discussing case #2600-02-017, #2600-03-002, in the matter of Donald Schultz, case #2602-03-002, in the matter of Tammie Stenseth, case #2602-04-001, in the matter of Douglas Bartko, and case #2650-04-001, in the matter of Sarah Martin.

Off the record at 2:46 p.m. On the record at 3:21 p.m.

Board members and staff, Rick Younkins and Sher Zinn, were present during executive session.

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

RESOLVED to adopt the Judgment By Default to permanently revoke the pharmacist license of Donald F. Schultz, license #1186, case #2600-02-017 and #2600-03-002. On a motion duly made by Mr. Givens, seconded by Ms. Soden and approved unanimously, it was

RESOLVED to adopt the Voluntary Surrender of pharmacy technician license of Tammie M. Stenseth, license #1030, case #2606-03-002.

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

RESOLVED to adopt the Memorandum of Agreement and Proposed Decision and Order for Sarah Martin, pharmacist license #1135, case #2650-04-001, as amended.

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

RESOLVED to accept the license surrender of TKO Pharmacy, pharmacy license #209, case #2602-04-001.

Tape 2 Side A

Agenda Item 7 Report by the Alaska Pharmacists Association

Nancy Davis, Association Executive Director, presented the report from the Alaska Pharmacists Association.

- Continuing Education report-

"RxPatrol: Pharmacy Safety and Security"

"Generics: Keeping Prescription Drugs Within your Patient's Reach" "Antimicrobial Resistance: Trends and Impact on Clinical and Public Health Practice in Alaska"

"Alaska Palliative Care Symposium: Joining together to Share Palliative Care Knowledge & Resources"

Providence Alaska Medical Center, co-sponsored presentations for 2005

- Biannual CE certificates will be printed May 15th and members should receive the CE certificates by May 30th. There are a total of 18 hours of convention CE's.
- Legislative Update provided by Caren Robinson AkPhA lobbyist and Barry Christensen, AkPhA legislative chair.
 - Pharmacists as Healthcare Provider: the association helped draft an amendment to HB 123 that would recognize pharmacists as healthcare providers. The bill was heard and held in House Finance on April 8th without the association sponsored amendment included. The association will continue to push for the amendment or separate legislation for provider status. If passed, HB 123 will extend the Board of Pharmacy until 2010.

- 2) HB 185 Prescribed Medications for Students. The association was able to amend this legislation to include pharmacists as Healthcare Providers capable of documenting the instruction of Metered Dose Inhalers and epinephrine injectors for student use in schools. HB 185 passed the house and is making good progress in the Senate.
- Psuedoephredrine limits/tracking legislation. The association has been monitoring three bills on Psuedoephrine sales. Most notably the association has met with Senator Guess on SB 106 and has offered testimony in committee on limits of sales and tracking.
- Uniform Prescription Drug Card Regulation: AkPhA continues to monitor the movement and status of the proposed regulations.
- The committee is monitoring proposed legislation on a Narcotic Tracking Program (PMP) and Workers compensation Statute changes.
- Legislative Dinner: AkPhA sponsored a legislative day/dinner in Juneau on March 16th. Ten AkPhA members, along with Nancy Davis and Lis Houchen (NACDS), participated in events and discussions with legislators.
- ACPE Changes: June 30-Co-sponsored CE w/PhRMA disallowed per OIG.
- Board of Medicine Proposed Regulation "Cooperative Practice Agreements with Pharmacists"-On 4/20/05 Sharon Hamrick, AkPhA President, drafted a letter to the Board of Medicine echoing concerns expressed by the Board of Pharmacy.
- AkPhA BOD Retreat: May 7 & 8-Captain Cook Hotel

Agenda Item 8 <u>Public Comment</u>

There was no public comment.

Ms. Bueler noted an item of interest in the NABP February newsletter article titled "Iowa Board Investigates Internet Pharmacies". The article outlined investigations by the Iowa board where Iowa licensed pharmacies had been contacted by a company in Moldava for filling internet prescriptions. Ms. Bueler noted that perhaps someday Alaska may need to address the issue.

Agenda Item 17 <u>New Business</u>

The board discussed the NABP question writing workshop for the MPJE. The board is required to write 30 questions for the Alaska MPJE exam. It was determined that none of the board members would be able to attend the question writing meeting in Chicago in June.

Tape 2 Side B

After discussion, the board agreed that Ms. Bueler, Mr. Givens and Ms. Mundell would write the questions and send them to the NABP.

On a motion duly made by Ms. Soden, seconded by Ms. Mundell and approved unanimously, it was

RESOLVED to recess and return at 9:00 a.m., April 29, 2005.

The board recessed at 4:15 p.m.

Tape 3 Side A

Call to Order/Roll Call

The meeting was called to order by Cindy Bueler, Chair, April 29, 2005, at 9:05 a.m. Those present, constituting a quorum of the board were:

William Altland, R. Ph. Cindy Bueler, R. Ph. Gary Givens, R. Ph. Mary Mundell, R. Ph. Leona Oberts Margaret Soden, R. Ph.

Michael Pauley was not present at the meeting.

Present from the Division of Occupational Licensing were:

Sher Zinn, Licensing Examiner Jun Maiquis, Regulations Specialist (Agenda Item 11)-telephonically

Present telephonically from the Department of Law:

Gayle Horestski, Assistant Attorney General (Agenda Item 11)

Visitors present were:

Mark Bohrer, agenda item 11 Louise Kressley, agenda item 11 Alaska State Board of Pharmacy Minutes of Meeting April 28-29, 2005 Page 10 of 21

Agenda Item 9 Review of Agenda

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

RESOLVED to approve the agenda as written.

Agenda Item 10 Review of License Applications

Margaret Soden left the meeting at 9:45 a.m. and returned at 9:50 a.m.

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

RESOLVED to approve the following applications for licensure as read into the record:

Providence Valdez Medical Center, Drug Room name change Three Bears Pharmacy #60, Retail Pharmacy Pacific Pulmonary Services, Out-of-State Pharmacy Peacehealth Medical Group Pharmacy, Out-of-State Pharmacy Douglas R. McManus Pharmacist Randal Brown, Pharmacist, pending MPJE passing score and verification of employment

Collaborative Practice Protocol applications:

Anchorage Neighborhood Health Center, License #311 Safeway #405, License #383 Safeway #3410, License #357 Safeway #548, License #396 Safeway #1090, License #185 Carrs Pharmacy #520, License #362, pending additional information Carrs Pharmacy #1805, License #316, pending additional information

Agenda Item 11 Regulations

Mark Bohrer joined the discussion. Mr. Bohrer was one of the original board members who was involved with the project from its inception. Ms. Bueler asked that Mr. Bohrer be a part of the discussion.

Tape 3 Side B

Mark Bohrer was asked to explain what telepharmacy is for Ms. Oberts, the new public board member. He stated it is a remote pharmacy in a rural area that is locked and secured, staffed by a licensed pharmacy technician. The remote pharmacy is linked to the central pharmacy via video, audio and computer link, allowing the pharmacist to be in control of what was going on in the remote pharmacy. A prescription would be faxed to the central pharmacy, then the prescription would be entered into the computer system by the pharmacist. The medication would then be prepared and distributed at the remote site by complete automation or by the licensed technician. The pharmacist would be able to view the distribution and provide patient counseling through the audio-video link.

Mr. Givens stated he reviewed the public comments regarding the proposed regulations. Mr. Givens noted a physician who commented that even in Anchorage, where pharmacy services were not provided after hours, this may be an application to provide more pharmacy care in Anchorage. Mr. Givens noted that potentially 24 hour hospitals could provide retail services through telepharmacy. In relation to the ten mile rule, he stated SEARHC said it would not be in the best interest of public health and safety, ACPA said it could be reviewed as a restraint in trade.

Ms. Bueler noted the letter from Barry Christensen and his concerns about the idea of using it for retail pharmacies in urban areas for after hours. Mr. Bohrer noted that when the proposals were first written, the board debated whether the remote pharmacy mile rule should be 0, 10, 25 or 50. He noted that in response to public testimony implicating Mr. Altland as being responsible for the mileage limit for proximity of remote pharmacy sites to other pharmacies, it was not Mr. Altland but the board prior to Mr. Altand's position on the board, that made the decision and further stated that the ten mile rule was modeled after Texas.

In response to the statements made in the public comment regarding the board member who has a retail pharmacy in Craig, Ms. Soden stated that she had been on the board in the 1980's and recently since 1998. This is the first time she had heard any "snarky" comments in public testimony. Ms. Soden further stated that board members are volunteers, work very hard and don't have a lot of lawyers helping draft regulations. The board uses regulations from other states and model regulations from NABP and tailors them to Alaska. The ten mile rule came from Texas and the board thought that it might be a problem but the board left it in. Ms. Soden further noted the very positive points made in several letters, particularly Alaska Primary Care Association, Robert Young, pharmacist from Sitka, and Anchorage Neighborhood Health Center.

The board further discussed the ten mile rule. The board noted that they knew it might be a problem in Alaska when they first discussed this in 2002. At that time the board went ahead with Texas' model and knew there would be further discussion regarding this when the public had a chance to submit comments.

Gayle Horetski, Assistant Attorney General and Jun Maiquis, Regulations Specialist, joined the meeting via telephone to discuss the telepharmacy regulation project. Ms. Bueler stated that the board would like to clear the potential ethics confusion mentioned in the letters submitted for public comment, and asked Ms. Horetski how that might be achieved. Ms. Horetski stated that they would need to make it clear on the record where the ten mile idea came from. Ms. Horetski noted that in a couple of the letters, people expressed concern of a possible conflict of the executive branch ethics act. The suggestion in the letters of a possible conflict may not make it appropriate for a board member to vote on a provision in the regulations that would personally benefit him or her.

The important point that the concept of the ten mile limit came from somewhere else, not from that particular board member, is good to know but not dispositive of any of the issues raised in the letters. That is essentially irrelevant to the analysis of whether a public official would be engaged in official action on an issue that would personally benefit the board member or an immediate family member. The benefit could be directly financial, or could be other benefits of value. The analysis should be that all of the board members should examine at that point whether there are provisions in the

proposed regulations that could have a direct financial benefit or a financial interest. If that is true then that board member should not participate.

Mr. Altland said the letter from Sonosky, Chambers, Sachse, Miller & Munson, stated that he was the board member that proposed the ten mile limit, and he would like to make it clear that it did not come from him. He is willing to recuse himself from the vote and the discussion of the ten mile rule. Mr. Altland stated that he learned that his business is in direct competition to the Native clinic down the road. He noted that he learned that the tribal clinic pharmacy seven miles down the road from his pharmacy, is considering telepharmacy for that site.

Ms. Horetski stated that the comment she saw in the letter was if at some future time, that particular clinic on Prince of Whales Island wished to begin a telepharmacy based on these regulations, then this might raise the issue of being exclusive territory. She did not read the letter as indicating a plan or intent to do so.

Ms. Bueler noted the public comment regarding dispensing by other practitioners. Mr. Givens stated that the way the board had written the regulations, the board had excluded other providers from acting within their scope of practice. The regulations say that a pharmacy technician has to be at the remote pharmacy to do the dispensing. The board's intent was not to say a physician, nurse practitioner or pharmacist could not dispense. Mr. Bohrer stated that it excludes them from dispensing out of the stock located within the remote pharmacy. If they were to create their own emergency supply or however they normally handle it, it wouldn't exclude them because as a board of pharmacy, we do not have the right to regulate other boards. Mr. Givens noted that would make them have to have two separate inventories.

Their point is, if they do not have to have dual inventories now, why would we force them to do that. They have a whole cabinet full of drugs they have paid for and secured, this regulation would require another area of drugs which would need to be secured. Ms. Bueler stated that the board should clarify that this does not affect dispensing from the office of a practitioner.

Ms. Horetski cited Alaska Statute 08.80.157 (j) and 08.80.400 where it states "this chapter does not affect the practice of medicine by a licensed medical doctor, and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced nurse practitioner, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license".

Ms. Soden noted the letter from the Board of Nursing which states "An ANP who is a provider in a rural setting, affiliated with telepharmacy services, would be

prohibited from accessing the pharmacy and dispensing needed medications during time periods when the pharmacist or pharmacy technician is not available". Ms. Horetski stated that they don't have access now to pharmacies and said that if the board wanted them to have access, they could put it into the regulations. Mr. Givens asked if that's what the board wanted to do. Mr. Altland stated that with his experience in remote areas, that would be a problem. As a pharmacist in charge, you would lose control over entry. Mr. Givens stated that perhaps the board would consider splitting off into two distinct models. One with a drug cabinet and one where the pharmacist would view the work being done. Mr. Altland stated he did not believe that would work in places like Talkeetna. Haines. Seward or Glennallen because of the volume. He stated it would need to be more inline with North Dakota's model. Mr. Givens noted that in both cases, you would have to communicate with the pharmacist in the central pharmacy, so that person would have to review the order. Mr. Givens didn't believe there would be much difference in time and would like to see which one worked best.

<u>Tape 4 Side B</u>

On a motion duly made by Ms. Soden, seconded by Mr. Givens and approved by roll call vote, 5 yeas (Bueler, Givens, Mundell, Oberts, Soden), and 1 abstention (Altland), it was

RESOLVED to delete E and F in Appendix D, from the proposed telepharmacy regulations.

For clarification purposes, it was noted that E and F in Appendix D related to the ten mile limitation of a remote pharmacy.

Mr. Givens brought up the idea of having telepharmacy include out-of-state pharmacies. He noted that companies are sprouting up all over the country where a hospital could send a scanned order electronically to the out-of-state pharmacy to communicate back to the Pyxus drug cabinet. The joint commission proposed regulations may make that necessary. If the regulations stated that it had to be an in-state pharmacy, it would prohibit that.

Mr. Altland asked how the regulation regarding mandatory verbal counseling would work at a remote site. Ms. Bueler noted that is why the telepharmacy regulations require real time communication between the central pharmacy and the remote pharmacy. Mr. Givens commented that out-of-state pharmacies have the 800 numbers for that purpose.

The board discussed the pros and cons of allowing an out-of-state licensed pharmacy as a central pharmacy. Mr. Altland stated he thought it would be best for the patient in out-patient situations to have the pharmacist in Alaska. Ms. Soden noted proposed regulations in Oregon that would allow remote dispensing by adopting a rule that would allow the pharmacies the option to install their systems to remotely dispense. "The primary reason for this rule is to expand pharmacy options in rural areas, this rule does not affect automated systems such as Pyxis, that are used primarily in hospitals or long term care. A responsible pharmacy located outside of Oregon that operates a remote dispensing device in Oregon must be currently licensed and in good standing in Oregon. The pharmacist in-charge must also be currently licensed and in good standing in both Oregon and in the state in which the responsible pharmacy is located". Ms. Mundell stated she believed it would be essential to have the central pharmacy located and licensed in Alaska. Ms. Bueler noted she liked the pharmacist in-charge to be licensed in Alaska. That would give personal responsibility.

On a motion duly made by Mr. Givens, seconded by Ms. Soden and by roll call vote, 3 yeas (Bueler, Givens, Oberts), 3 nays (Altland, Mundell, Soden) it was

RESOLVED to change the proposed telepharmacy regulations in Appendix D, item (a), to "Only a central pharmacy licensed or registered in this state may provide pharmacy services through a telepharmacy system to a remote pharmacy".

The motion failed.

Mr. Givens left at 11:09 a.m. and returned at 11:26.

Ms. Horetski asked for clarification of a pharmacy located outside of the state and a remote pharmacy. Are they a subset of pharmacy or are they different? If they are a subset of the pharmacy then you have general requirements that would apply to all of them. Ms. Bueler noted that the board would need to determine that, if it is a subset under pharmacy, then the minimal requirements for pharmacy would apply.

If it is separate then the minimal requirements would not apply. Ms. Soden stated she thought it would be a subset under a pharmacy. Ms. Horetski noted AS 08.80.480(24-25), definitions for pharmacy and a pharmacy located outside of the state. The pharmacy definition could include a remote pharmacy.

The board should add a definition of pharmacy under the proposed regulations that says "pharmacy as used in AS 08.80.480 (24) includes a remote pharmacy and a telepharmacy", if that is the board's intent. Ms. Bueler stated that would sound reasonable.

Ms. Horetski noted that the board should instruct the regulation specialist during the next division fee change, to propose an amendment to 12 AAC 02.310(a), in the lead in language, that would include an out-of-state pharmacy for the application fee. Other changes Mr. Horetski suggested are, paragraph 2 on page 3 of the proposed regulations under 12 AAC 52.130(b)(2) should be changed to, "any applicable application fee and out of state registration fee". Page 4, 12 AAC 52.200(a), leave the language that is there now and add a new sentence that would say, "the pharmacist in-charge must either practice in that pharmacy location or for remote pharmacies insure that all practice in that location is under the direct supervision of a licensed pharmacist". Make it one additional sentence instead of 1 and 2. Page 5, 12 AAC 52.420(f) should have brackets around "the removal is". It would then read, "prescriptions shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent". Page 6, 12 AAC 52.425 change the wording "engages in" to "operates a". Page 7, 12 AAC 52.995(13), change "either by physical proximity or by a telepharmacy system" to "either by personal supervision or through a telepharmacy system".

Tape 4 Side B

Page 8 paragraph 26, take out A and add "computer link and video link with sound, which could include one of the following; still image capture; real time link; store and forward". The appendix should be changed and added as a new section 52.427, under Article 4, Guidelines For Pharmacies And Pharmacists. The board decided under the advice of Ms. Horetski, to change the current proposed format by adding a separate section for the requirements for licensing of a remote facility. Ms. Horetski and Mr. Maiquis would redraft the regulations and bring back to the board for review.

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The board decided to hold a teleconference once the regulations are re-drafted since the next board meeting would not be held until September.

Break Recess for lunch, off the record at 12:10 p.m.

On the record at 1:00 p.m.

<u>Tape 5 Side A</u>

The board discussed the public comments submitted regarding the telepharmacy regulation project. Ms. Bueler asked Mr. Givens what the drawbacks of telepharmacy would be to native villages serviced by native hospitals. Mr. Givens stated that currently the regulations would require a technician to staff the remote pharmacy. The qualifications to obtain a technician license are a high school diploma or GED, no felony convictions, and the licensing fees. In smaller remote areas serviced by native facilities or the federal government, most health care providers are health aides. The health aides would need to obtain a technician license to staff the remote pharmacy. This would place a hardship on the community because many health aides do not have a high school diploma or GED, and may not be able to afford the cost of the license. Mr. Givens stated that health aides are gualified to staff a remote pharmacy based on the four to eight months of training which is required to become a health aide. Mr. Altland commented that telepharmacy remote site would not be appropriate for the smaller end of the range of population. A health aide is overseen by a practitioner, and in the smaller communities, the health aide should continue to operate as the delegated dispensing agent for that practitioner.

The board discussed the difference between a drug cabinet and a pharmacy. If it is a drug cabinet, a practitioner or health aide would have access without having to be licensed by the board of pharmacy. The telepharmacy regulations would not pertain to that type of situation. Ms. Mundell noted the board may need to define the two.

Mr. Altland stated that a pamphlet from the Sunshine Community Health Center he brought to the meeting, noted they have a pharmacy, however they do not have a pharmacy license. The board determined that under Alaska Statutes, to be called a pharmacy or practice as a pharmacy, it would have to be licensed as a pharmacy. It was noted that a practitioner may dispense from a drug cabinet 24 hours a day. A technician would not be required if the practitioner used a drug cabinet. It was further noted that if a clinic wanted a small telepharmacy, and a technician managed the stock, the practitioner would not be able to dispense directly from the telepharmacy after hours, but would have to have a separate area or drug cabinet in which they could dispense medication.

<u>Tape 5 Side B</u>

The board discussed the comment from Barry Christensen. Mr. Christensen asked if the proposed regulations would allow two licensed retail pharmacies to utilize a telepharmacy system. The board determined that the regulations as currently written, already address that a telepharmacy system is between a central pharmacy and a remote pharmacy.

Ms. Bueler asked the board if there should be a disclaimer stating that the telepharmacy regulations do not include institutions. Mr. Altland noted that the Ketchikan hospital has after hours drug orders reviewed from the state of Washington. Ms. Soden stated that is not telepharmacy but telereview of orders. Ms. Zinn noted the letter in the correspondence section that outlined the same scenario. The letter asked the board if it felt there was a need in Alaska for this type of service. Mr. Givens noted that the pharmacist in the other state would review the order then dispense the order through a Pyxis system. Ms. Bueler stated that would be telepharmacy. Ms. Mundell noted that in an institutional setting, the pharmacist does not have to do numerous things that a pharmacist would have to do in an out-patient setting. The board may have to segregate the two. Ms. Bueler stated the definition of the telepharmacy system is aimed at dispensing to patients. If the board called the other scenario telepharmacy, the definition would be different. You would not need a visual computer link. Ms. Mundell stated she did not believe that would be telepharmacy but review of orders. Ms. Bueler stated that perhaps the board should have a disclaimer stating that telepharmacy does not address institution to institution order review.

Ms. Oberts brought up the letter from Mr. Hurley regarding frequency of physical inspections. Mr. Hurley commented that it would be difficult for their staff because of cost and weather issues to visit 24 sites in one year. Mr. Givens noted that the board started with required visits once a quarter then ended up with visits just once a year.

On a motion duly made by Ms. Soden, seconded by Ms. Mundell, and approved unanimously, it was

RESOLVED, after consideration of public comment, to table the telepharmacy regulation project until the revisions are made by the Attorney Generals office and the regulation specialist.

Break Off the record at 2:20 p.m. On the record at 2:33 p.m. The board discussed the proposed pharmacy technician exam and other regulation changes. Ms. Zinn, by a request of the board from the January meeting, queried other state boards regarding the requirement of a technician law exam. Ms. Zinn stated that 39 states and territories license, register or certify technicians. Of the 39 states, 12 require an exam, and Utah is the only state that requires a law exam. Other states require PTCB certification or a state competency exam. Ms. Zinn further stated that the regulations for interns, pharmacists and pharmacies should be clarified for the purpose of licensing requirements and qualifications. Currently the statutes have qualifications for licensing of pharmacists, however the regulations are not clear on what documentation is required for licensure.

<u>Tape 6 Side A</u>

After discussion, the board requested Ms. Zinn to draft regulations for the boards review at the next meeting, including licensing requirements for interns, technicians, pharmacists, drug rooms, wholesale distributors. Other regulations which should be addressed are the renewal requirements for technicians including allowing PTCB re-certification, definition of certificate of completion to include NPTA and PTCB approved courses.

Agenda Item 13 <u>NABP Update</u>

Ms. Bueler stated she would review the NABP's updated Model Rules for Wholesale Distributors.

Agenda Item 12 Legislative Update

The board reviewed the updates for the Pseudoephedrine bills and the sunset bill during the Alaska Pharmacists Association report.

Agenda Item 14 Division Updates

The board reviewed the budget and the licensing examiner's report.

Agenda Item 15 <u>Correspondence</u>

The board reviewed the remainder of the correspondence.

<u>National Consumers League</u>-March 2, 2005-Senate Bill 103/House Bill 314, the Combat Meth Act of 2005. For information only, no action required.

<u>DEA</u>-March 18, 2005-Accumulation of Surplus Controlled Substances in Long Term Care Facilities. For information only, no action required.

Medistar- April 5, 2005-Pharmacists Helping Pharmacists. Ms. Zinn will respond.

<u>Vivian Knop</u>-April 11, 2005-Drug room question. Ms. Bueler will respond. Drug rooms do not have technicians therefore, the consultant pharmacist does not need to meet the requirements of a technician supervisor.

<u>DEA</u>-April 18, 2005-Final Rule on Digital Signatures for Schedules I & II Controlled Substances. For information only, no action required.

<u>NABP</u>-April 26, 2005-DEA Issues Final Rules for Electronic Orders for Controlled Substances. For information only, no action required.

<u>NABP</u>-April 15, 2005-NABP Letter to New York State Attorney General Eliot Spitzer. For information only, no action required.

<u>NABP</u>-April 12, 2005-NABP Letter to CMS Addressing the Electronic Prescribing Proposal Rule. For information only, no action required.

<u>NABP</u>-April 8, 2005-Committee Volunteers. For information only, no action required.

Agenda Item 16 Old Business

The board discussed the issue regarding the North Star Behavioral Health System Residential Treatment Center. The board previously discussed the issue at the

September and January board meetings and determined that Ms. Bueler and Mr. Givens would visit Vivian Foote at the facility to get a better understanding of the situation. Ms. Bueler visited Ms. Foote and found that North Star Behavioral Health System has two treatment centers, in Palmer and Anchorage. North Star plans to add a new building that would contain six new treatment centers, two treatment centers to a floor. Each unit would be locked. If each treatment center need a drug room license.

<u>Tape 6 Side B</u>

Mr. Givens suggested that each treatment center have a Pyxis machine. Ms. Mundell stated that since the units are on the same campus, they would not need a separate drug room license for each unit. It would be treated like a satellite pharmacy at a hospital. Ms. Bueler noted that Ms. Foote also wanted to know who would rule on whether mental health specialists could administer medication. Ms. Bueler stated that Ms. Foote should contact the Medical Board on questions regarding delegation of administration of medication. Ms. Bueler would respond to Ms. Foote's inquiry. The board discussed the Medical Board's proposed regulations in regards to cooperative practice with pharmacists. Ms. Bueler will write a letter in response to the proposed regulations when the regulations go out for public comment. The letter would reiterate the previous letter to the Medical Board sent in April.

Ms. Zinn gave the board a letter of inquiry from a company in California that supplies a chemical reagent that is incorporated into disposable strips that are inserted into medical devices mixing with blood that is collected and analyzed. The company, Tapestry Medical, wanted to know if they needed a pharmacy license to distribute the strips to patients in Alaska. The board determined that a pharmacy license would not be required.

Agenda Item 17 <u>New Business</u>

Ms. Bueler, Mr. Givens, and Ms. Mundell discussed a time to meet to write questions for the MPJE exam workshop.

Mr. Altland brought up licensing of technicians once again. After discussion, it was decided Mr. Givens would talk with two members from the technician committee who work at ANMC, and advise them that the board would be interested in their input of licensing requirements of technicians. The board would like to have the committee come to the September board meeting and discuss the issue.

The board chair signed the approved minutes from the January 27-28, 2005 meeting.

The board chair and secretary signed the wall certificates.

On a motion duly made by Ms. Soden, seconded by Ms. Mundell and approved unanimously, it was

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

The meeting adjourned at 4:10 p.m.

Respectfully Submitted:

Sher Zinn, Licensing Examiner

Approved:

Cindy Bueler, R.Ph., Chair	
Alaska Board of Pharmacy	

Date _____