STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

ALASKA STATE BOARD OF PHARMACY

MINUTES OF MEETING
September 28-29, 2006

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 September 28-29, 2006 at the Atwood Building, 550 West 7th Ave., Suite 1270, Anchorage, AK.

Call to Order/Roll Call

The meeting was called to order by Cindy Bueler, Chair, September 28, 2006 at 9:07 a.m. Those present constituting a quorum of the board, were:

Cindy Bueler, R. Ph.
Gary Givens, R. Ph.
Richard Holm, R. Ph.
Mary Mundell, R. Ph.
Leona Oberts

Michael Pauley and Bill Altland were not present at the meeting.

Present from the Division of Corporations, Business and Professional Licensing were:

Sher Zinn, Licensing Examiner
Susan Winton, Investigator

Visitors present:

Sally Clark, McKesson Corp.
Gary Cacciatore, Cardinal Health
John Schlatter, TAP
Nancy Davis, AkPha

Agenda Item 1 **Review of Agenda**

The board approved the agenda:

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

RESOLVED to approve the agenda as written.

Agenda Item 2 **Review of Minutes**

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

RESOLVED to approve the minutes of the April 27-28, 2006 meeting and the May 23, 2006 teleconference as written.

Agenda Item 3 **Ethics**

There were no ethics violations to report.

Agenda item 4 **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 **Wholesale Distributor Regulation Discussion**

Ms. Bueler started the discussion by outlining the information in the board packet. It was noted the NABP Model Rules had changed since the last board meeting including adding definitions for Chain Pharmacy Warehouse, Co-license, Drop Shipment, Exclusive Distributor and Normal Distribution Channel. Ms. Bueler explained the term pedigree. A pedigree is a paper or electronic trail that tracks the drug from the manufacturer until it reaches the pharmacy. Ms. Mundell noted that currently pharmacies do not know where a drug comes from unless it comes directly from one of the three major drug distributors. The purpose of the pedigree is to prevent the distribution of a tainted or counterfeit drug. Mr. Cacciatore, director of regulatory affairs for Cardinal Health, noted that one of the suggestions they have made to other states to clarify Drop Shipments, is to add language saying, "Drop Shipment is a sale by a manufacturer to a wholesale distributor where the wholesale distributor takes title to but not possession of the drug and the wholesaler invoices the pharmacy or other designated person or other persons authorized by law to dispense or administer prescription drugs". Mr. Cacciatore noted that Federal regulations will go into effect in December under the PDMA that will require a pedigree whenever the drug is distributed by a wholesaler who is not an Authorized Distributor of Record. He further stated, "The big wholesalers who buy direct are authorized distributors of record of all the manufacturers so we will not be passing pedigree". The pedigree will alert the pharmacy that the drug did not come directly from the manufacturer to the wholesaler. The movement is to go to electronic track and trace but a deadline cannot be set until the manufacturers standardize the system. Ms. Bueler clarified for Ms. Oberts the electronic track and trace would use the RFID (radio frequency identification) system.

The regulations drafted by Joshua Bolin from the NABP were discussed. Ms. Bueler noted the licensing regulations under 12 AAC 52.610(b) would require a surety bond and (a)(9) would require a copy of the deed of the property. She further noted many of the requirements could be waived if the board required VAWD or other board approved accreditation. Ms. Bueler stated that under the new section 12 AAC 52.675(a) it could read "The board may utilize a third party such as the National Association of Boards of Pharmacy's Verified-Accredited Wholesaler Distributors (VAWD) Program or other board approved accreditation…". Ms. Mundell noted that 12 AAC 52.610 could refer to 12 AAC 52.675 instead of listing the accreditation bodies. The board discussed whether they would consider reciprocity by other states as long as the state had

equivalent requirements, thereby waiving the licensing requirements noted under 12 AAC 52.675(3)(d). Mr. Givens noted that the board would have to review each individual state's requirements to deem it substantially equivalent to our state and would the board want to do that. He further stated that perhaps the board should require VAWD certification only. Mr. Givens suggested taking out 12 AAC 52.670(b)(1) and (2), requiring the license process to be completed through the board's requirements of 12 AAC 52.610, or accredited by VAWD. The new section 12 AAC 52.615, Minimum Qualifications for Licensure was discussed. The board decided to leave the section in the draft regulations. Ms. Bueler noted in section 12 AAC 52.620, Wholesale Drug Facilities, the draft language had only one change adding "comply with official compendium standards, such as United States Pharmacopeia-USP/NF, under (a)(2). The board discussed section 12 AAC 52.625. It was noted the section is very "wordy" but necessary. Ms. Zinn stated that once the draft is reviewed by the regulation specialist, it would be condensed to fit with department regulations. Ms. Zinn further noted in (1)(i) A set of fingerprints for the Person, under procedures specified by the Board, together with the payment of the amount equal to the costs incurred by the board for the criminal background check of the Person, would be pared down since the board would not require a separate fee for processing of the fingerprint cards. The processing of the background check is included in the application fee. Ms. Bueler noted the information in (ix), Name, address, occupation, and date and place of birth for each member of the person's immediate family. Ms. Zinn noted she was not sure if that requirement would be legal but would contact the board's attorney for an opinion on the matter. Mr. Givens stated that if the board makes the licensing requirements less stringent than the VAWD certification, most wholesalers would choose not to be accredited by VAWD. After further discussion, the question was asked whether the board should forego the draft licensing requirements and require VAWD or another board approved accreditation. Mr. Cacciatore interjected by stating that the board would then give up their licensing authority to another entity, therefore not having an appeal process for denial of VAWD. The board would need to have their own regulations to address a denial. Mr. Holm noted that if VAWD standards change the licensing requirements would not change because the board would still have their own in place. Ms. Bueler stated that this process brings it back to the time when you could be confident the drug coming off of the shelf is what it states it is. She further stated the industry had moved in recent years away from that security, and with VAWD and tightening up the regulations, would make real steps in securing product integrity. Ms. Mundell stated "if the wholesalers have already stated they will not purchase from some of the spider outside groups and everything is coming directly from the manufacturer, I am content in that". Mr. Givens said "if it's proactively fixing the system knowing that the other stuff is coming, the issue is not about the big three, but the concern is about the other 997 that are out there that need to be controlled."

Break
Off the record at 10:26 a.m.
On the record at 10:41 a.m.

Ms. Oberts noted that the board needs the option to license wholesalers outside of the VAWD accreditation. The question arose regarding who would do the inspections if the wholesaler chose to be licensed by the board's regulations. The board currently does not inspect in-state facilities but has a self-inspection report that must be submitted to the board at initial licensing and at renewal. Ms. Mundell stated the board would have to go to a third party to do the inspections. Ms. Bueler stated that the board should go with the national trend and not have the Alaska traditional self-inspection reports. The board agreed the wholesale facilities should have an on-site inspection. Mr. Givens noted that since we could not do the inspection, the board would have to go to a third party inspection process such as VAWD. Ms. Zinn asked the board if the wholesale distributor could submit an inspection report from the state in which they are located in lieu of the board doing the inspection. Mr. Givens questioned whether that would make the board's requirements less stringent than the VAWD accreditation making it more desirable to be licensed by the regulations. Ms. Mundell noted that since the board does not have an inspector and because of infrastructure, perhaps the board needs to accept the third party requirement such as VAWD for licensing. She further stated that if the board strengthens the regulations we would still have a problem with the on-site inspections. Some states do on-site inspections, some do not. The discussion turned to licensing of manufacturers if they ship directly to a pharmacy without going through a distributor. The NABP Model Rules includes "manufacturer" in the Wholesale Distributor definition. Ms. Bueler stated the board is not concerned in licensing of the manufacturer, but the distributor who is the "middle man" who may be counterfeiting.

After further discussion, the board agreed to keep the draft language and allow wholesale distributors to be licensed through the board's regulations, by VAWD or by reciprocity as long as the state in which the facility is located has equivalent qualifications for licensure, including a recent on-site inspection report. The information would be required under 12 AAC 52.610. The board decided that 12 AAC 52.675, (b) would be put back in to allow for licensure under another state that has equivalent requirements, or another accrediting body. The board also decided to add to the end of 12 AAC 52.610(d) "or licensed in another state with equivalent licensing requirements". The board further noted that if the wholesale dealer applies by reciprocity, an on-site inspection report completed within two years must be submitted. Gary Givens asked if the board investigator could do inspections for in-state wholesale distributors. Ms. Zinn stated she would contact Rick Younkins and ask if that would be viable. Ms. Zinn stated that during a legislative audit several years ago, it was determined the board needed to implement a self-inspection process instead of an on-site inspection to save the board the increased costs. Ms. Mundell noted that Idaho has two full time inspectors with less monetary resources than Alaska has. Mr. Givens stated it comes back to two processes, VAWD and our own that we could manage. If the board does VAWD, it would take a long phase in process.

Tape 2 Side B

Ms. Oberts asked if it would be reasonable to have an on-site inspection for in-state wholesalers if there were any concerns with the self-inspection report. Ms. Bueler stated if the board requires VAWD and if sometime in the future VAWD is no longer available, and there is no other third party accreditation body, the board would be left with their own licensing regulations.

Lunch Break
Off the record at 11:50 p.m.
On the record at 1:02 p.m.

The discussion continued regarding wholesale distributor licensing. Ms. Bueler asked the board what their thoughts were after the morning discussion. Mr. Givens stated that the options were either the board having its own licensing regulations or to go with the VAWD accreditation or other board approved accreditation. He further stated that if the board goes with its own licensing requirements and if they would be less stringent then VAWD, the board should leave the regulations as they are since there are many more topics that need to be discussed, such as e-prescribing. Mr. Holm noted he would be in favor of the board having its own licensing regulations. It is an issue of maintaining the board's powers and does favor a third party accreditation that meets or exceeds the boards requirements. Ms. Mundell stated the board should recognize that VAWD accreditation is acceptable. The discussion returned to the on-site inspection process. Mr. Givens asked if the out-of-state wholesale distributor would have to be VAWD accredited if the state in which the facility was located, did not require an on-site inspection, or would the board's investigator have to go to the facility to do the inspection. Mr. Holm stated that the board could contract with another inspection service in the lower 48 for the on-site inspection.

The board decided to go through the draft regulations and decide what to incorporate into the new regulations and what was not needed or could be added at a later date. The board decided to keep the new section 12 AAC 52.615, Minimum Qualifications For Licensure. Ms. Zinn noted that a statute change would be needed to obtain a criminal background check from the FBI. Ms. Zinn also noted that submission of fingerprint cards should stay under 12 AAC 52.610(6) instead of being in 12 AAC 52.625 as noted in the draft. The board decided to delete 12 AAC 52.625 (ix), requiring the name, address, occupation, and date and place of birth for each member of the person's immediate family. The board reviewed 12 AAC 52.625(d), requiring the continuing education for the designated representative.

Tape 3 Side A

Ms. Mundell left the room at 1:44 p.m. and returned at 1:50 p.m.

Mr. Cacciatore interjected and told the board that Cardinal Health had requested that provision be put into the model rules. He stated that Cardinal has in-house

training for their employees. After further discussion the board decided to come back to the continuing education requirements. The board reviewed the additions of (d) and (e) to12 AAC 52.630 and decided to keep the changes. Ms. Zinn asked the board if it wanted the written policies and procedures under 12 AAC 52.640 to be submitted with the application. The board decided that it would not be needed as part of the application but should be available to the board if the board requested it. Mr. Holm mentioned that the policies and procedures should be available during an inspection and as part of the self-inspection report. The board reviewed 12 AAC 52.645 and decided to keep all of the additions. In reviewing 12 AAC 52.650 the board decided to delete (1) and (2) until the technology is readily available. The board decided to add the Kansas proposed language mentioned by Mr. Cacciatore. The proposed language includes, "Effective at a date set by the board, pedigrees may be implemented through an approved and readily available system that electronically tracks and traces the wholesale distribution of each prescription drug starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other authorized person administering or dispensing prescription drug. This electronic tracking system will be deemed to be readily available only upon there being available a standardized system originating at the manufacturer and capable of being used on a wide scale across the entire Health Care industry which includes manufacturers, wholesale distributors, and pharmacies. Also, consideration must be given, however to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. Nevertheless, implementation should not be unnecessarily delayed." Ms. Bueler asked the board if it wanted to require a written pedigree until the technology would be available for an electronic pedigree. Mr. Cacciatore stated a paper trail should be required for distribution outside of the Normal Distribution Channel. After further discussion regarding a paper pedigree, the board decided to not keep a paper pedigree but to add the Kansas language stated earlier, making the electronic pedigree a requirement when it is available. The discussion turned to the PDMA (Prescription Drug Marketing Act) which states a distributor that is not an authorized distributor of record, shall provide a pedigree. Mr. Cacciatore noted that the wording of the PDMA would put the small wholesaler out of business because the big wholesaler would not have the pedigree to pass on to the small wholesaler. The board decided not to mention or implement a pedigree at this time. The board discussed 12 AAC 52.655, Due Diligence, and decided to keep it in the draft regulations. Ms. Zinn would obtain clarification of the lead in language from the NABP and report back to the board at its next meeting. The board would then decide if the section should stay in the regulations. The board discussed and decided to delete the new language, (d), (e) and (f) from 12 AAC 52.660. The board decided to delete the section 12 AAC 52.665 because the board would not be implementing a pedigree at this point. The board reiterated that 12 AAC 52.675 would stay as drafted with the addition at the end of (d), "or licensed in another state deemed by the board to be substantially equivalent". The board discussed 12 AAC 680, regarding inspections.

Tape 3 Side B

The board decided to word the section as the out-of-state inspection requirement is written. Prohibition under 12 AAC 52.685 would be left in. The definition section was reviewed by the board. It was decided to delete from 12 AAC 52.605, (a), (b), (d), (f), (g), and (h) and keep (c), (i) and (j). The board also decided to exempt manufacturers from licensing.

Ms. Mundell left the room at 2:40 and returned at 2:57

Break-Off the record at 2:42 p.m.
On the record at 2:57 p.m.

Agenda Item 7 **Alaska Pharmacists Association Report**

Nancy Davis joined the meeting for the report. Ms. Davis outlined the continuing education listed on the report, and noted the 2007 convention would be held March 3-4 at the Captain Cook Hotel. She also noted the association may hold two day regional meetings, possibly in the fall of each year. Other items covered in the report included:

- Biennial CE certificates would be printed November 15th.
- Legislative update regarding the Combat Methamphetamine Act of 2005, including the effective date of September 30th, log and ID requirements, and training requirements.
- The Political Action Committee would not participate in the November elections due to lack of funds.
- Pharmacy based immunization delivery training held September 22nd. Thirteen pharmacists completed the training.
- Petition for re-accreditation from the ACPE was submitted September 1. The association would be notified in January of the renewal status.
- The Department of Health and Human Services has proposed regulations for public notice, reorganizing and rewriting of the Medicaid program. Public Hearings will be held in Fairbanks and Juneau, October 17th, and in Anchorage, October 19th.

Agenda Item 6 **Regulations**

The board reviewed the request from the Institute for the Certification of Pharmacy Technicians, to accept ExCPT certification for pharmacy technician continuing education. Since the approval of the certification would need to go through the regulation process, the board decided to table the matter until its next meeting when the board addresses other regulation issues.

Tape 4 Side A

The board reviewed the regulation project that was submitted for public comment. Ms. Bueler noted that no public comment was submitted to the regulation specialist. Ms. Zinn noted two corrections that need to be made to the project. Under 12 AAC 52.135 (b)(2)(F) would need to be deleted. The NABP Final Application for License Transfer is not submitted by the NABP but by the applicant under 12 AAC 52.135 (b)(E). Also noted under 12 AAC 52.135(b)(2)(D), if the applicant is a foreign pharmacist who qualifies for licensure, they must submit a certified true copy of the original of the applicants Foreign Pharmacy Graduate Examination Committee certificate and a certified true copy of the applicant's pharmacy school diploma. Therefore, "or (D)" would have to be added after "and (b)(2)(C)".

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

> **RESOLVED to adopt the regulation project (12 AAC 52.020-.800) considering public comment and cost to the public, with the following amendments:**
>
> **Delete 12 AAC 52.135(b)(2)(F)**
> **Add (D) to 12 AAC 52.135(d) on the third line to read "An applicant who qualifies for licensure under this section but has not taken the Multistate Pharmacy Jurisprudence Examination (MPJE) referenced under 12 AAC 52.090 may qualify for that examination by submitting items required under (b)(1)(A)-(D)and (b)(2)(C) or (D) of this section and proof from NABP that the applicant has submitted an application for license transfer under this section."**

Mr. Givens started the discussion regarding e-prescribing. He noted that a physician had asked him why the board does not allow e-prescribing. The question was whether the board should amend the current regulations allowing electronic transmittal of a prescription under 12 AAC 52.490. Ms. Bueler noted that the electronic signature is not disallowed under the current regulations, but perhaps the board should address the issue and more clearly define the regulations. She noted the correspondence from the NABP regarding change of the Model Act language by taking out the word "directly" from "transmitted directly from the prescriber to the pharmacist…". Ms. Mundell stated she would like the wording "identity of the pharmacy intended to receive the transmission" to be included in the prescription information. The board decided to take out the word "directly" and "places the following information on the face of the prescription drug order before it is transmitted:" in (a) of the section, and take out (a)(1)-(4). The board also decided to take out the words "digital" and "directly" from (b) of that section. Ms. Bueler noted it would take another regulation project to implement the changes the board desired.

Susan Winton, the board investigator, joined the meeting to introduce herself to the board.

Tape 4 Side B

Ms. Winton noted the board could keep (3) in the earlier mentioned regulation by changing to "as defined in 12 AAC 52.460(1)-(8). After further discussion, the board decided to keep (3) of the regulation discussed earlier.

The board recessed at 4:18 p.m. until Friday at 9:00 a.m.

Friday September 29, 2006

Call to Order/Roll Call

The meeting was called to order by Cindy Bueler, Chair, September 29, 2006, at 9:05 a.m. Those present constituting a quorum of the board were:

Cindy Bueler, R. Ph.
Gary Givens, R. Ph.
Richard Holm, R. Ph.
Mary Mundell, R. Ph.
Leona Oberts

Michael Pauley and Bill Altland were not present.

Present from the Division of Corporations, Business and Professional Licensing were:

Sher Zinn, Licensing Examiner
Susan Winton, Investigator

Visitors present were:

Ron Miller, Safeway
Nancy Davis, AkPha

Agenda Item 8 **Review Agenda**

Mr. Givens asked if the board could revisit the e-prescribing issue. Ms. Bueler added continuation of the e-prescribing discussion to the agenda at 11:30 a.m.

Agenda Item 9 **License Application Review**

The board reviewed the pharmacy technician license application for Catherine Sanborn. Ms. Sanborn checked "yes" on one of the professional fitness questions on the application. Ms. Bueler noted that Ms. Sanborn is under a Memorandum of Agreement with the Board of Nursing.

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

> **RESOLVED in accordance with Alaska Statute 08.80.261(2), (6), (11) and (14), to deny a pharmacy technician license to Catherine Sanborn.**

The specific reasons for denial of the license were under (2), "engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities," by misappropriating the corresponding original narcotic log sheet from the facilities narcotic log book while working at Heritage Place long term care facility. Under (6), failed to comply with the Board of Nursing's MOA as noted by the Ken Weimer, investigator for the Board of Nursing. Under (11) and (14), by diverting Xanax, a controlled substance.

The board reviewed the pharmacy technician license application for Barbara Alexander. Ms. Alexander checked "yes" to one of the professional fitness questions on the application. Mr. Holm noted that Ms. Alexander is in full compliance with the Board of Nursing and had made full disclosure.

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

> **RESOLVED to approve the pharmacy technician license application for Barbara Alexander.**

The board reviewed the remainder of the license applications for pharmacists and collaborative practice agreements.

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

> **RESOLVED to approve the following applications for licensure and collaborative practice agreements as read into the record:**
>
> Pharmacists-
> Mitchell A. Garnick, pending MPJE passing score
> Janet L. Hahn, pending MPJE passing score
> Roberto Iaderosa, pending MPJE passing score, verification of employment
> Amy B. Nimmo, pending MPJE passing score, verification of licensure from IL, OH, VA, SC, GA
> William Schuman, pending MPJE passing score, verification of licensure from MT, NY, $300 license fee

Collaborative Practice Agreements-
White's Pharmacy renewal, license #167, emergency contraception, Trish White, Graham Chelius, MD
Harry Race Pharmacy, license #244, emergency contraception, Trish White, Graham Chelius, MD
Carrs Pharmacy #1811, license #322, immunization, Robert Luggie, Kimberly Anderson, ANP
Carrs Pharmacy #1812, license #323, immunization, Hyo Ju Kim, Kimberly Anderson, ANP
Safeway Pharmacy #1090, license #185, immunization, Joseph Mauer, Kimberly Anderson, ANP
Safeway Pharmacy #1832, license #401, immunization, Richard Stingley, Kimberly Anderson, ANP
Carrs Pharmacy #1805, license #316, immunization, Rex Dickson, Kimberly Anderson, ANP
Carrs Pharmacy #1805, license #316, immunization, Larry Anderson, Kimberly Anderson, ANP
Carrs Pharmacy #1805, license #316, immunization, Chantele Muffoletto, Kimberly Anderson, ANP
Carrs Pharmacy #1805, license #316, immunization, Anne Aexel, Kimberly Anderson, ANP
Carrs Pharmacy #1808, license #400, immunization, Jared Rawlings, Kimberly Anderson, ANP
Carrs Pharmacy #1808, license #400, immunization, Kimberly Nolan, Kimberly Anderson, ANP
Carrs Pharmacy #1808, license #400, immunization, Susan Easley, Kimberly Anderson, ANP

Tape 5 Side A

The board discussed the remote pharmacy application submitted for ARX Pharmacy and Safeway Pharmacy in Ketchikan. Mr. Holm said "it's precedent setting, if we allow a chain to do this, it could happen in Anchorage, it could happen in Fairbanks, it could happen everywhere. This wasn't the intent, that I see, of having a remote pharmacy. We have an existing store where they want to turn into a satellite, probably on a temporary basis." Ms. Bueler noted the 10 mile rule the board had initially intended in the regulation to make it a remote site. The board took out the ten mile rule because of public comment. Ms. Bueler said that it was a busy store, so the problem is not lack of business. Mr. Givens stated that it was not a patient safety issue because the patient could go to one of the other three pharmacies in town. Ms. Mundell's concern was if the pharmacy would advise the patients receiving the medication that no pharmacist was on staff to speak with. Ms. Mundell further stated that it could be a problem with diversion, having four technicians in a pharmacy without a pharmacist, with open bottles of CII's and narcotics. She further stated that her impression of a remote site was for giving service in a community where pharmacy services would not normally be available.

Ms. Bueler stated the intent of the board was to provide pharmacy services for underserved communities, not to have a remote pharmacy in a large community such as Ketchikan that has three other retail pharmacies. The board discussed the definition of a remote pharmacy and decided to clarify that a remote pharmacy is in "an underserved community". Mr. Givens noted that the pharmacy could hire a locum tenens pharmacist until they find a permanent one. It is costly, but ANMC does it frequently. The board decided to wait on a decision until Ron Miller speaks to the board later in the day.

Break
Off the record at 10:32 a.m.
On the record at 10:52 a.m.

Agenda Item 10 **Mandatory CE Audits**

The board reviewed the mandatory continuing education audits for Bonnie Holm, Jill Williams, Brian Janzen, Stephen Fenick and Christian Duruji.

On a motion duly made by Mr. Givens, seconded by Mr. Mundell, and approved by roll call vote (Givens-yea, Bueler-yea, Mundell-yea, Oberts-yea, Holm-abstain), it was

RESOLVED to approve the mandatory audit for Bonnie Holm, technician license #71.

On a motion duly made by Mr. Holm, seconded by Ms. Mundell, and approved by roll call vote (Givens-yea, Bueler-yea, Mundell-yea, Oberts-yea, Holm-yea), it was

RESOLVED to approve the mandatory audits for Jill Williams, technician license #254, Brian Janzen, technician license #424, Stephen Fenick, pharmacist license #1025, and Christian Duruji, pharmacist license #1112.

Tape 5 Side B

Agenda Item 11 **Division Updates**

The board reviewed the current expense report. Ms. Zinn noted the total revenue for fiscal year 2006 was $472,600 for the end of the last renewal period, which was significantly higher than the renewal period ending 2004, of $261,300. However the roll forward deficit was also significantly higher. It was noted the board would have a better understanding of the deficit by the end of fiscal year 2007. Ms. Zinn further noted the AG opinion for licensing of Native Facilities had not been completed, therefore the board had not received its final bill. The board reviewed the annual report.

Ms. Bueler noted the legislative recommendations she submitted with the report, which included a request for legislation to license of out-of-state wholesale distributors. She stated in the request that it was a public safety issue, and by licensing out-of-state wholesale distributors it would ensure the integrity of the prescription drug supply and help prevent drug counterfeiting.

The board reviewed the comments received regarding the jurisprudence questionnaire. Ms. Zinn noted the question on the pharmacist questionnaire regarding mandatory counseling was answered wrong on several forms, and one particular question on the technician form was left unanswered by several technicians. The board decided it was good to include the questionnaire in the renewal and welcomed the feedback. Many of the pharmacist's and technician's comments showed they were not aware of some of the regulations. Mr. Givens thanked Ms. Bueler for her time in writing the technician questionnaire. Ms. Zinn noted that Ron Miller mentioned the questionnaire was a good idea and wanted the board to know. Mr. Givens would mention the mandatory counseling question in the board's letter for the AkPha newsletter.

Agenda Item 6 **Regulations**

The board continued the discussion regarding the change of regulations for e-prescribing. Mr. Givens gave the board members a copy of the Washington State regulations on licensing of wholesale distributors, and electronic transmittal of prescriptions for suggested wording. Ms. Bueler mentioned that at some point the board would need to separate licensing of medical gas suppliers from wholesale distributors. The board reviewed the Washington regulations and decided to add several of the regulations to the board's current regulations, to be drafted by the regulation specialist for review by the board at its next meeting.

The following was added to 12 AAC 52.490, Prescription Drug Orders Transmitted by Facsimile or Digital Electronic Transmittal, from the Washington regulations:

- Page 2 #(6), add Electronic, or manual signature of the prescriber

Tape 6 Side A

- Page 2 #(11), identification of the electronic system readily retrievable for board of pharmacy inspection.
- Page 3 top, Consistent with state and federal laws and rules, over the counter, legend drug and controlled substance prescriptions may be transmitted electronically.
- Page 3 top, Federal and state law do not allow the electronic transfer of schedule II prescriptions.

- Page 4 #(3), Each system shall have policies and procedures on the electronic transmission of prescription information available that address the following:

  (a) Patient access. The system may not restrict the patient's access to the pharmacy of their choice.
  (b) Security. The system shall have security and system safeguard designed to prevent and detect unauthorized access, modification, or manipulation of prescription information. Accordingly, the system should include:
    (i) documented formal procedures for selecting and executing security measures;
    (ii) physical safeguards to protect computer systems and other pertinent equipment from intrusion;
    (iii) processes to protect, control and audit access to confidential patient information; and
    (iv) processes to prevent unauthorized access to the data when transmitted over communication networks or when data physically moves from one location to another using media such as magnetic tape, removable drives or CD media.
  (c) Systems that utilize intermediaries in the electronic communication or processing of prescriptions such as third party payers shall be responsible to insure that their contracts with these intermediaries require security measures that are equal to or better than those provided by this rule and prohibit the modification of any prescription record after it has been transmitted by the practitioner to the pharmacist.
  (d) Confidentiality of patient records. The system shall maintain the confidentiality of patient information in accordance with the requirements of any applicable state and federal laws.
  (e) Authentication. To be valid prescriptions transmitted by an authorized prescriber from computer to fax machine or from computer to computer must use an electronic signature.
- Page 4 #(5), The system must authenticate the sender's authority and credentials to transmit a prescription.
  (a)The system shall provide an audit trail of all prescriptions electronically transmitted that documents for retrieval all actions and persons who have acted on a prescription, including authorized delegation of transmission;
  (b) The right of the board to access electronically submitted prescriptions for purposes of investigations in disciplinary proceedings.
- Page 4 #(6), If a hard copy prescription, generated from the electronic prescription system, is printed on security paper that insures it is not subject to copying or alteration, an electronic signature may be substituted for a manual signature.

- Page 5, top, Each pharmacy must have policies and procedures that ensure the integrity and confidentiality of patient information transmitted electronically as required by this chapter and federal law. All pharmacy employees and agents of the pharmacy are required to read, sign and comply with the policy and procedures.

The following was added to 12 AAC 52.995, definitions:

- Page1 #(1), "Electronic transmission of prescription information" means the communication from an authorized prescriber to a pharmacy or from one pharmacy to another pharmacy, by computer, by the transmission of an exact visual image of a prescription by facsimile, or by other electronic means other than electronic voice communication, of original prescription information or prescription refill information for a legend drug or controlled substance consistent with state and federal law.
- Page 1 #(4), "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by an authorized person with the intent to sign the prescription.
- Page 1 #(5), "Security" means a system to maintain the confidentiality and integrity of patient records including:
  (a) Documented formal procedures for selecting and executing security measures;
  (b) Physical safeguards to protect computer systems and other pertinent equipment from intrusion;
  (c) Processes to protect, control and audit access to confidential patient information; and
  (d) Processes to prevent unauthorized access to the data when transmitted over communication networks or when data physically moves from one location to another using media such as magnetic tape, removable drives or CD media.

Lunch Break
Off the record at 12:05 p.m.
On the record at 1:04 p.m.

Ms. Oberts returned to the meeting at 1:10 p.m.

Agenda item 13 **New Business**

Mr. Givens spoke regarding pharmacy remote review, where a pharmacy outside the state of Alaska would review the orders after the pharmacy in Alaska is closed. Ms. Bueler stated that she thought of it as an institutional issue when the hospital pharmacy is closed at night and the hospital contracts with another pharmacy to review order entry on new orders, so that a nurse may dispense the drug. Ms. Bueler noted two letters in the correspondence section from retail pharmacies that want to utilize the same type of system to spread the workload more evenly. Ms. Bueler stated that it would not be able to be done unless the pharmacy and the remote pharmacy are both located in the state. Under the present telepharmacy regulations, neither case fits the model that was intended by the board. The board would need to write regulations to address the situation. Ron Miller joined the discussion since it was the same issue he wanted to speak to the board about. Mr. Miller noted that he had met with the North Dakota board about telepharmacy regulations and spoke with the DEA regarding 12 AAC 52.425 (e), which states "Drugs may be shipped to a remote pharmacy only from the central pharmacy". The DEA states that they do not have a problem with the non-controlled substances, but they take exception to controlled substances because the drugs need to go to the DEA registrant. Mr. Miller stated that the DEA would require both the central pharmacy and the remote pharmacy to have separate DEA numbers, with the central pharmacist as the registrant for the remote pharmacist. The drugs would be shipped directly to the remote pharmacy with the pharmacist located at the central pharmacy, watching by video link the inventory of the drugs by the staff at the remote pharmacy. The DEA would consider the central pharmacy a distributor if the drugs went to the central pharmacy before being sent to the remote pharmacy. If the board wanted the drugs to go from the central pharmacy to the remote pharmacy, the central pharmacy would have to obtain a wholesale distributor license.

Mr. Holm left the room at 1:22 p.m. and returned at 1:23 p.m.

Ms. Bueler asked Mr. Miller to tell the board about the remote pharmacy application that was discussed by the board earlier in the day. Mr. Miller stated the problem was strictly a staffing issue. He stated that they had two options, to get a telepharmacy license or close the pharmacy. He said that he had already spent $300,000 staffing the pharmacy in Ketchikan. Ms. Bueler asked what recruitment efforts he had made to obtain appropriate staff. Mr. Miller stated he had contacted 40 to 50 people. They are paying $10 or more per hour than Anchorage with $60,000 sign on bonuses, but having no luck. He did state that they are using locum tenens pharmacists but it is very expensive. The ideal solution is to have a pharmacist there.

Tape 6 Side B

Mr. Miller stated they are open on Sundays, and none of the other retail pharmacies are. They have looked at closing on weekends but decided it was not good for the community. Ms. Bueler stated that the intent of the telepharmacy regulation was to serve underserved communities, not address staffing issues. Mr. Miller stated that they were also looking into telepharmacy licenses for other Safeway stores in Girdwood and Valdez that currently do not have a pharmacy. The pharmacy would have a full time pharmacist during weekdays and would utilize the telepharmacy on weekends only. It is a financial choice between a telepharmacy and closing. Ms. Bueler stated the board reviewed the application earlier in the day and did not feel comfortable about approving it. The board would like to table the application and give it further consideration. Ms. Bueler reiterated the board's intention of the telepharmacy regulations, to allow provision of pharmacy services in underserved areas that could not support a pharmacy. The board would also consider remote order entry and the definition of remote pharmacy at a later date. Mr. Miller stated the remote pharmacy would only be on weekends, filling approximately 70 to 80 prescriptions per day. The central pharmacy would be in Anchorage and would only process the prescriptions for the remote pharmacy. It currently processes refills only.

Ms. Bueler asked Mr. Miller if Safeway had been getting e-prescriptions from physicians. Mr. Miller stated that currently the e-prescriptions are being sent to the fax machine, but they would be able to get them through the computer by the end of October. He noted that there are probably several hundred physicians set up for e-prescribing. Ms. Mundell asked Mr. Miller if a technician would have access to a pharmacy without the pharmacist being on site. Mr. Miller stated that the technician does not have access to the pharmacy, but for a remote site, they are looking into a lock that can only be opened remotely from the central pharmacy by the pharmacist. The cost is approximately $20,000. The technician would not be able to open the pharmacy unless the pharmacist unlocks it from their location. Cameras in the remote pharmacy would have a 360 degree view with zoom and can be moved remotely by the pharmacist. Pharmacist would have a picture of the filled prescription as verification. He further stated the counseling would be done via video, and the patient would be told the pharmacist is not on-site.

Ms. Bueler noted the letter from Wal-Mart regarding kiosks. The pharmacy would have a will-call bin that dispenses pre-packed drugs specifically for a patient after hours. Mr. Miller noted that he knows they are out there, but in Alaska they are not used. He noted that California allows the dispensing through kiosks. He stated Wal-Mart and Longs also uses them, and also some Safeway stores. The kiosks are allowed in Utah and California. He also noted that processing can also be done very cheaply in countries such as India.

Mr. Givens left the room at 1:56 p.m.

Ms. Bueler thanked Mr. Miller for coming to the meeting and clarifying the DEA issue in the telepharmacy regulations and stated the board would make a decision on the remote pharmacy application at a later date.

Ms. Bueler addressed the letter from Vickie Kroll, HME Interim Director of Fairbanks Memorial Hospital. The letter asked the board what kind of license they must obtain to transfill liquid oxygen to compressed gas. The compressed gas would be sold and distributed to Home Medical Equipment's home oxygen patients, medical offices, Fairbanks Memorial and Denali Center. After discussion the board ruled they would need to have a wholesale distributor license, since they repackage and sell the oxygen to medical offices, Fairbanks Memorial and Denali Center. The board also stated that in the future they would look into making a separate category for medical gasses.

Tape 7 Side A

Agenda Item 12 **Correspondence**

The board reviewed the following correspondence:

NABP-September 12, 2006-Wholesale distributor Requirements Applicable to Manufacturers-For information only, no action required.

NABP-September 5, 2006-January 2007 MPJE State-Specific Review Meeting-Ms. Zinn will fax the completed form and send to NABP. Three board members may be available to attend.

NABP-July 18, 2006-Revision of the Report of the 2005-2006 Committee on Law Enforcement/Legislation-For information only, no action required.

NABP-June 30, 2006-NABP Launches Pharmacy Authenticated Licensure Service Program-For information only, no action required.

NABP-June 20, 2006-FDA Final Rule on PDMA Pedigree Requirements-For information only, no action required.

NABP-May 8, 2006-Nevada State Board of Pharmacy-For information only, no action required.

Providence Alaska Medical Center-September 11, 2006-Report of Theft or Loss of Controlled Substances-For information only, no action required.

SEARHC Medical Center Pharmacy-August 10, 2006-Report of Theft or Loss of Controlled Substances-For information only, no action required.

Fred Meyer Stores-May, 10, 2006-Report of Theft or Loss of Controlled Substances-For information only, no action required.

CCGP-September 5, 2006-Request for CE Approval of the CCGP Certification-Ms. Zinn will respond. The certification, by regulation, must be ACPE approved to be allowed as continuing education.

Kroger-June 14, 2006-New Pharmacy Management System-Ms. Zinn will respond, there are no regulations allowing the pharmacy management system at this time. The board will address the issue at a future meeting.

Mr. Givens returned at 2:20 p.m.

Wyoming Board of Pharmacy-June 23, 2006-USP 797-For information only, no action required.

Board of Nursing-June 12, 2006-Controlled Substances for Treatment of Pain by a Nurse Practitioner-Ms. Bueler will write a letter of acknowledgement.

UPS-September 13, 2006-Licensing and Pedigree of Prescription Drugs-Ms. Zinn will respond. No pedigree requirement at this time.

NABP-September 15, 2006-Disaster Plans-For information only, no action required.

NABP-September 15, 2006-Unauthorized Use of the VIPPS Seal Internet Pharmacy Sites-For information only, no action required.

Wal-Mart Pharmacy-August 25, 2006-Utilization of secured will-call bin technology. Ms. Zinn will respond after the board reviews favorable information from Utah and California.

Wal-Mart Pharmacy-September 12, 2006-Utilization of Central Processing Technology. Ms. Zinn will respond. The board would give it further consideration and not make a determination at this point.

IACP-September 20, 2006-Pharmacy Compounding-For information only, no action required.

Agenda Item 14 **Investigative Report**

Susan Winton, investigator, joined the meeting to discuss the investigative report. Ms. Winton requested the board go into executive session for comments about the discussion.

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

> **RESOLVED in accordance with the provision of AS 44.62.310(c)(2), to go into executive session for the purpose of discussing the investigative report.**

Off the record at 2:42 p.m.

Board members and staff present during executive session.

On the record at 3:10 p.m.

Break
Off the record at 3:10 p.m.
On the record at 3:20 p.m.

Ms. Winton noted the technician license application for Terra Abbott had been forwarded to the investigator for review and the investigation was complete.

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

> **RESOLVED in accordance with the provision of AS 44.62.310(c)(2), to go into executive session for the purpose of discussing the pharmacy technician license application for Terra Abbott.**

Off the record at 3:28 p.m.

Board members and staff present during executive session.

On the record at 3:40 p.m.

Ms. Oberts left the room at 3:40 p.m.

On a motion duly made by Mr. Givens, seconded by Mr. Holm, and approved by roll call vote (Givens-yea, Mundell-yea, Bueler-yea, Holm-yea) it was

> **RESOLVED in accordance with 08.80.261(7)(c), to deny the pharmacy technician license application for Terra Abbott.**

Mr. Givens noted the reason for denial of the license was for addiction or severe dependency on alcohol or a drug that impairs the applicants; or licensee's ability to practice safely.

Ms. Oberts returned at 3:45 p.m.

Agenda Item 11 **<u>Correspondence</u>**

The board continued the review of the correspondence. Ms. Bueler returned to the Wal-Mart letter regarding central processing of prescriptions. Ms. Bueler stated the pharmacy and the central processing sites must both be located in the State of Alaska, and may not be in a person's home. It was noted that both sites must have pharmacists on-site. The dispensing pharmacist must complete the mandatory counseling. It would be considered central fill, not a remote pharmacy.

Mr. Givens noted that the intention was to spread the workload, where the high volume pharmacy would utilize the low volume pharmacy to process the prescription.

Tape 7 Side B

Mr. Givens said the board should not make a decision at this time, but review it further. Ms. Mundell stated she would like the board to look at all three technology issues at the same time and would prefer to make a determination at a later date. Ms. Bueler stated that the response should be the board would give it further consideration and would not make a determination at this point. Mr. Givens noted he would put the issue in the board newsletter and the board would welcome any input from the public.

Mr. Holm left the room at 4:04 p.m. and returned at 4:06 p.m.

The board reviewed the letter and information from Cathy Geissel, Chair of the Board of Nursing, regarding the Board of Nursing's Advisory Opinion on "The Use of Controlled Substances for the Treatment of Pain by Advanced Nurse Practitioners". Ms. Bueler will respond with a letter of acknowledgement.

Mr. Givens left the room at 4:21 p.m. and returned at 4:28 p.m.

The board once again discussed the remote pharmacy application and determined to table the matter until the next meeting.

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

RESOLVED to table the remote pharmacy application for ARX Pharmacy and Safeway Pharmacy #1818.

Ms. Bueler stated that the board would look into remote order review, telepharmacy regulations clearly defining "remote site" and "underserved area", automated systems, central fill, and would discuss during a teleconference to be determined at a later date. Mr. Givens would look at other states regulations regarding remote review. Ms. Mundell would look into central processing. Ms. Bueler would look into wording regarding charges or a conviction of a felony for adding to the disciplinary guidelines.

Tape 8 Side A

Ms. Bueler signed the regulation project adoption order.

Agenda Item 16 **<u>Office Business</u>**

Election of officers.

Mr. Givens was elected as the board chair. Ms. Mundell was elected as the vice chair, Ms. Bueler was elected as secretary.

The tentative meeting dates for 2007 are:

March 1-2, 2007 in Anchorage
May 17-18, 2007 in Anchorage
September 27-28, 2007 in Anchorage

Ms. Bueler signed the minutes for the April 27-28, 2006 meeting and the May 23, 2006 teleconference. The wall certificates and TA's were signed.

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

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

The meeting adjourned at 4:52 p.m.

Respectfully Submitted:

_____
Sher Zinn, Licensing Examiner

Approved:

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

Date: _____