

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
February 14-15, 2008**

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 February 14, 2008, at the Atwood Building, 550 West 7th Ave., Suite 1270, and February 15, 2008, at the Anchorage Marriott Hotel at 820 West 7th Ave., Juneau/Haines room.

Call to Order/Roll Call

The meeting was called to order by Mary Mundell, Chair at 9:01 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.
Dirk White, R. Ph.

Leona Oberts was not present at the meeting.

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

Sher Zinn, Licensing Examiner
Susan Winton, Investigator
Jun Maiquis, Regulation Specialist-via telephone

Visitors present:

Terry Thurbon, Administrative Law Judge, Dept. of Administration
Robert Young, Pharm D., SEARHC
Lis Houchen, NACDS

Review of Agenda

The board reviewed the agenda, no changes were made.

Agenda Item 1 Review Minutes

The board reviewed the minutes from the September 20-21, 2007 meeting. The only change made was on page 19 under Agenda Item 11. The time for Mr. White and Ms. Oberts returning to the room was incorrect.

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

RESOLVED to approve the minutes of the September 20-21, 2007 meeting with the correction as noted.

Agenda Item 2 Ethics Disclosure/Goals and Objectives

There were no ethics violations to report.

The board noted the changes that were made to the Goals and Objectives from the last meeting. It was further noted number 11 should be changed to 10.

1. The board will continue to educate licensees regarding the Pharmacy Practice Act and pharmacy regulations.
2. The board will continue to provide input and comment on any proposed legislation/regulations involving medications or pharmaceutical care.
3. The board will continue to promote effective patient counseling by licensees.
4. The board will continue to assess and evaluate the Multi-state Pharmacy Jurisprudence Examination (MPJE).
5. The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.
6. The board will continue to assess and evaluate the licensing of pharmacy technicians.
7. The board will continue its affiliation with NABP and send one board member to the District Seven NABP meeting and two members to the annual NABP meeting. The Division's budget currently allows only one out-of-state travel per fiscal year; this is generally used for attendance at the District Seven NABP meeting.

8. The board will continue to evaluate the impact of current regulations and the need for new regulations.
9. The board will continue to evaluate regulations regarding collaborative practice, and to establish procedures for reviewing/approving appropriate protocols for collaborative practice.
10. The board will assess and evaluate the growing public concern regarding abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs, and development of a prescription monitoring program.

Agenda Item 3

Terry Thurbon, Administrative Law Judge

Terry Thurbon from the Office of Administrative Hearings attended for the purpose of training the board on the hearing process for an appeal. Ms. Thurbon stated the role of the Administrative Law Judge was to be the legal advisor for the board for a particular case, not the legal advisor for general issues. The board is the final decision maker in all cases. The board essentially wears two hats. One hat is worn as the regulatory body for the profession and another when the board hears a case. The board then wears a part jury and judge hat in that the board will make the final decision. They may hear from the parties before the board deliberates on a case only for answering questions or making an argument, but may not hear evidence. The board may request the Office of Administrative Hearings to take more evidence if the board felt that everything had not been covered in the hearing. The board had five options for a decision once it gets to the board after the hearing: to adopt the administrative law judge's decision; to return the decision back to the office of administrative hearings for a follow up such as additional evidence taking or additional fact finding or other proceedings, which would allow the administrative law judge to rewrite some aspect of the decision; adopt the decision and conclusions of law but change the outcome such as a disciplinary sanction; change a finding or a legal interpretation that was put in the proposed decision. The last two options would be more difficult to explain the why and where in the law would be the support to the change of the findings or legal interpretation. When the board is wearing the judge and jury hat, they may go into executive decision to deliberate the case off the record so they may have a frank discussion of the issues. However, the only other parties which may be allowed during the executive decision would be the administrative law judge who heard the case, or a legal advisor from the department of law. Essentially the board is sequestered while deliberating the decision as a jury would be. The board would then come back on the record to record the vote and give any direction. Once the decision has been filed, either party may then petition for reconsideration within 15 days of the filing. The Final Administrative order may then be appealed to the superior court within 30 days after the decision of the reconsideration has been filed. An assistant attorney general would then be the division's legal council in court. Less than one percent of boards and commissions licensing cases are appealed to the court. Ms. Thurbon noted the Executive Branch Ethics Act. The statute states a public officer, including the licensing examiner or investigator, may not have ex parte communication with a board member regarding the case with the purpose

to influence the outcome of the case. There may however be other executive branch members who are not aware of the statute who may attempt to contact a board member in dealing with a complaint from a constituent or a citizen about an issue. They may talk to a board member to discuss the issue generally and it may come up without them realizing that it may be in the context of a case that would come before the board. At that point, the board member must stop the conversation and remind them that they are not just a regulatory board but have an appropriate role in addressing a citizen complaint through a decision making process in licensing and disciplinary cases and cannot talk to them about the issue. The same rule applies to the other parties but they are not subject to the Executive Branch Ethics Act. It is still considered ex parte communication.

There are two types of cases the board may make a decision on. One is the license application denial in which the board would have all the information contained in the application file to make their determination. If the board denies a license, the applicant could then appeal. The appeal would give both parties the opportunity to gather more information which the board may not have seen in the application file. Fact questions may come into play in that the application may have been incomplete and the board did not see the whole picture. The other would be a disciplinary action in which they may start from scratch. It would be more like a prosecution of an alleged offense. The division may start an investigation, prepare an accusation and the division would have the burden to bring in the evidence. The case is shaped almost entirely through the hearing process. The board would not have an opportunity for decision making until the case is complete and presented to the board. Mr. White asked Ms. Thurbon if the board paid for the hearings. Ms. Thurbon stated yes, through licensing fees.

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

RESOLVED to go into executive session in accordance with AS 44.62.310(c)(2), to discuss case #2650-06-001, in the matter of Mahdi Cezar.

Board members and Ms. Thurbon only remained in the room.

Off the record at 9:39 a.m.
On the record at 10:15 a.m.

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

RESOLVED to table the Mahdi Cezar decision until Ms. Thurbon rewrites the decision and brings it back to board for consideration.

It was noted Ms. Thurbon would return at 1:30 p.m. with the new decision for the board's consideration.

Break-
Off the record at 10:15 a.m.
On the record at 10:25 a.m.

Agenda Item 5 Investigative Report

Susan Winton, investigator, joined the meeting to give the investigative report. Ms. Winton outlined the open and closed cases, including investigations and complaints. There were 13 open investigations, 23 open complaints, two probation monitoring cases and nine closed cases. Ms. Winton noted that since the report of February 5th, three investigations have been completed. Three would be closed with no violation, one remains requiring a review and one would be brought to the board for review later in the meeting.

Agenda Item 6 Ruth Parent Reinstatement Application

The board considered the application reinstatement for Ruth Parent, R. Ph.

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

RESOLVED to approve the pharmacist license reinstatement application for Ruth Parent.

Agenda Item 7 License Application Review

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

RESOLVED in accordance with AS 44.62.310(c)(2), to go into executive session to discuss the license applications for case #C2650-07-007, #C2650-08-002, #C2612-07-004

Board staff to remain in the room during executive session.

Off the record at 11:00 a.m.
On the record at 12:01 p.m.

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

RESOLVED to table the license application for Thomas Vickers, case #C2650-07-007 until the next meeting.

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

RESOLVED to approve the license application for Ghazi Sinada, case #C2650-08-001 pending receipt of passing MPJE exam score and Certified True Copy of the original diploma showing a pharmacy degree.

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

RESOLVED to table the intern license application for Jennifer Ragan, case #2612-07-004 until the next meeting.

Lunch Break

Off the record at 12:05 p.m.

On the record at 12:57 p.m.

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

RESOLVED in accordance with AS 44.62.310(c)(2), to go into executive session to discuss the license applications for case #C2656-07-006, #C2652-08-001, #C2659-07-002.

Board staff to remain in room during executive session.

Off the record at 1:02 p.m.

On the record at 1:32 p.m.

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

RESOLVED to approve the intern license application for Adam Hurley, case #C2652-08-001.

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

RESOLVED to approve the technician license application for Tesa Heisa, case #C2656-07-006.

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

RESOLVED to deny the out-of-state pharmacy license application for Bellevue Pharmacy Solutions based on AS 08.80.157(h)(2).

Ms. Thurbon from the Office of Administrative Hearings rejoined the meeting with the revised decision in the case of Mahdi Cezar which was discussed earlier in the meeting.

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

RESOLVED in accordance with AS 44.62.310(c)(2), to go into executive session to discuss case #2650-06-001.

Board members and Ms. Thurbon only remained in the room.

Off the record at 1:37 p.m.

On the record at 1:42 p.m.

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

RESOLVED to deny the license application for case #2650-06-001, based on the decision by the board of February 14, 2008, reaffirming the board's prior decision.

Ms. Mundell signed the original document. For the record, the license application denial was for Mahdi Cezar, R. Ph.

Agenda Item 7 License Application Review

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

RESOLVED in accordance with AS 44.62.310(c)(2), to go into executive session to discuss the pharmacy technician license application for Jason Fitchett.

Board staff to remain during executive session.

Off the record at 1:46 p.m.

On the record at 1:51 p.m.

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

RESOLVED to deny the pharmacy technician license application for Jason Fitchett.

The board cited AS 08.80.261(a) for the reason for denial which states: The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable, (4)has been convicted of a felony or has been convicted of another crime that affects the applicant's or licensee's ability to practice competently and safely. The board also noted 12 AAC 52.140(b)(2) in the pharmacy technician license regulations which states the application includes a certification that the applicant

has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently. The board noted repeated Driving Under the Influence offenses which included one felony conviction, as well as a person under 21 on a licensed alcohol premise.

The board reviewed the license applications for pharmacists, pharmacies, and wholesale distributors. The board also reviewed collaborative practice agreement applications.

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

RESOLVED to approve the license applications as read into the record.

Wholesale Distributor-

T & S Welding- pending Department of Public Safety Fingerprint report

Pharmacies-

North Star Behavioral Health, Bragaw Campus

Pharmacists-

Suzanne Alexander- pending MPJE passing score, completed application, one affidavit of moral character

Thomas Ewers- pending verification of one year of practice, MPJE passing score, verification of licensure from Iowa

Michelle Miranda- pending MPJE passing score

Deborah Padilla- pending MPJE passing score

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

RESOLVED to approve the collaborative practice agreement applications as read into the record.

Collaborative Practice Agreements-

Carrs Pharmacy #1812, license #323, pharmacist Shannon Hanson, Kimberly Anderson, ANP, for emergency contraception

Carrs Pharmacy #0520, license #362, pharmacist Catherine Vanderpol, Kimberly Anderson, ANP, for emergency contraception

Mr. White and Mr. Holm left the room at 2:01 p.m. and returned at 2:04 p.m.

Agenda Item 8 Intern Jurisprudence Questionnaire

The board reviewed the current jurisprudence questionnaire to determine if any of the questions were outdated or should be changed to reflect updated or new regulations. The board decided to change question #23 to “the pharmacist shall verbally provide counseling” and take out “and refill”. The word “tubex” was deleted from #38.

Agenda Item 9 Regulations

Jun Maiquis, regulation specialist, joined the meeting via telephone to discuss changes to the pamphlets referenced in 12 AAC 52.400, 12 AAC 52.430, and 12 AAC 52.440, also known as Appendix A, B and C at the end of the regulation booklet. At a previous meeting the board decided to change Appendix B, Facility Standards for Pharmacies. Mr. Maiquis noted that while reviewing and drafting the changes the board requested, several discrepancies appeared between the pamphlets and the appendices originally adopted by the board. Since the pamphlets were noted in the regulations by reference, the pamphlets would be the correct reference, not the appendices. Therefore the date on the pamphlet must be updated to reflect the date the board changed the pamphlet. After review by the board, they made the following changes to the draft:

- change “physicians” back to “prescribing practitioners” in all places where noted in all three pamphlets;
- change “Micromedix” to “Micromedex” in Facility Standards for Pharmacies under the Library reference section;
- keep “Good” in title of “Good Compounding Practices”;
- in the Sterile Pharmaceuticals pamphlet under Drug Distribution and Control take out (e) which states “Intravenous Access. When continued intravenous access is required by a home care patient, the pharmacy may supply the licensed nurse with sodium chloride 0.9 percent for injection or heparin for injection in concentrations up to 100 units per cc to be used to maintain the intravenous access subsequent to authorization by the prescribing practitioner”, and leave out “dispensing” from subsection (d);
- in the Facility Standards for Pharmacies under General Requirements, leave in paragraph (b), “There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.”;
- add the same statement under (b) of the General Requirements in the Facility Standards for Pharmacies pamphlet to the Good Compounding Practices pamphlet at the end of (a) under Compounding Facilities.

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

RESOLVED to make the changes to the pamphlets referenced in 12 AAC 52.400, 12 AAC 52.430 and 12 AAC 52.440 and send out for public comment.

Break-
Off the record at 2:49 p.m.
On the record at 3:06 p.m.

Shared Pharmacy Services

The board discussed the Shared Pharmacy Services proposed regulations which were tabled from the September 2007 meeting. The board discussed what Shared Pharmacy Services would include. Ms. Bueler suggested that Shared Services would include workload balancing, for example between retail pharmacies within a chain. The pharmacist in another store for the same chain could review the prescription drug order for the busy store. A pharmacist on duty at one hospital could review orders from another hospital when a pharmacist was not on duty. For example the pharmacist at Providence in Anchorage could process the drug order electronically for Providence in Seward when there was no pharmacist available at the Seward site. It would also include remote order entry and remote order review for insurance purposes. The board discussed whether the shared pharmacy services should be restricted to pharmacies located inside the state. It was noted the board had discussed drafting a definition for shared pharmacy services at the previous meeting. Ms. Mundell asked if the board should specify differences between retail and hospital settings in the definition. Mr. White noted that something in the regulations that would allow insurance adjudication would be helpful. He further stated that insurance adjudication could take 20 minutes, taking the pharmacist away from filling prescriptions. Mr. Givens stated the shared pharmacy services would not include insurance adjudication since it would be between two pharmacies. Ms. Mundell stated that the board needed to define shared pharmacy services and keep it within the state. Ms. Bueler stated she would find the definition from information contained in a previous board packet that had a definition and bring to the meeting on Friday for further discussion.

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

RESOLVED to table the Shared Pharmacy Services regulation discussion until Friday.

Agenda Item 10 Expense Report

Ms. Zinn reviewed the expense report for the board and noted that there would not be a fee increase for renewals this year.

Ms. Zinn asked the board if they had reviewed the e-mail she had sent the board regarding the State Specific MPJE review from the National Association of Boards of Pharmacy. The NABP specifically asked for board members to review questions that may be implemented in the MPJE exam for Alaska since no one was available to attend the meeting in January. The board discussed the issue

and decided that no one would be available to do the review on such short notice. Two board members would be off of the board as of March 1st, one would be out of town, and two members could not take time off of work. The board instructed Ms. Zinn to contact the NABP and notify them no one would be available.

Agenda Item 15 Correspondence

The board reviewed the correspondence.

NABP Correspondence-

NABP-January 2008-State News Roundup-No action required.
NABP-January 11, 2008-DEA letter-No action required.
NABP-January 16, 2008-APhA Survey-No action required.
NABP-January 4, 2008-ASAP Technical Standard for Electronic Tracking of PSE Purchases-No action required.
NABP-December 13, 2007-NABP's 104th Annual Meeting Information-No action required.
NABP-November 15, 2007-E-news-No action required.
NABP-November 1, 2007-Petition for Associate Membership-No action required.
NABP-November 1, 2007-Resource on Pharmacy Compounding Laws and Regulations and CE Renewal Requirements-No action required.
NABP-October 17, 2007-E-news-No action required.
NABP-February 7, 2008-E-news-No action required.

General Correspondence

ICPT-November 27, 2007-Acceptance of ICPT Certification for Technicians-Ms. Zinn would reply by stating the board may review the pharmacy technician regulations at a future date to change to "any nationally recognized certification program."
Nancy Sanders, Board of Nursing-January 4, 2007-Pharmacist Collaborative Plan for Yellow Fever-No action required.
Amy Tull-January 17, 2008-Automated Compounding Device-Ms. Zinn would respond by stating the Board of Pharmacy does not endorse any automated systems for dispensing or distribution. The Pharmacist in charge must make sure the system is in compliance with all state and federal laws and regulations.
Lauren Fوسفeld-January 8, 2008-Distribution of Prescription Drugs in Pre-packaged Kits-Ms. Zinn would respond.
Deborah Wells-December 20, 2007-Prescription Drug Refills-Ms. Zinn would contact and notify them it is an acceptable practice.
Samantha DeLoache-December 18, 2007-Chantix Prescription Stamps-Ms. Zinn would respond and notify them it is an acceptable practice.
Diane Skaggs-December 18, 2007-Report of Theft or Loss-No action required.
Anonymous-December 4, 2007-Concerns About Patient Safety-No action required.

IACP-November 5, 2007-Letter of Response to FDA Regarding Compounding-No action required.

Pattie Strickland-University of Georgia-October 22, 2007-University of Georgia College of Pharmacy Statement-No action required.

Norton Sound Health Corp-October 22, 2007-Report of Theft or Loss-No action required.

Dan Caufield, H & SS-October 1, 2007-Generating of Oxygen-Who is Responsible-No action required.

Norton Sound Regional Hospital-September 24, 2007-Report of Theft or Loss-No action required.

Kroger-January 9, 2008-Pharmacy Management System-Ms. Zinn would respond with a statement the board does not approve individual proprietary systems or services. They must comply with all state and federal laws.

Cindy Bueler E-mail-February 8, 2008-E-mail regarding new P and T designations on Continuing Education Certificates-No action required. Board will wait one renewal cycle until recognizing the P and T on certificates.

The board recessed until Friday, February 15th at 9:00 a.m.

Off the record at 4:41 p.m.

Friday February 15, 2008

Call to Order/Roll Call

The meeting was called to order by Ms. Mundell, Chair, February 15, 2008, at 9:10 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.
Dirk White, R. Ph.

Leona Oberts was not present at the meeting.

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

Sher Zinn, Licensing Examiner
Jun Maiquis, Regulation Specialist-via telephone
Gayle Horetski, Assistant Attorney General-via telephone

Visitors present:

Robert Gruszyski, Dakota Med Temps
Robert Young, Pharm D., SEARHC
Ron Miller, Safeway
Jo Ann Nelson
Sarah Altland, Whale Tail Pharmacy
Catherine Kawalski, Petersburg Rexall
Barry Christensen, AkPhA
Jennifer James, Outcomes
Fred Eckel, NCAP
Dan Nelson
Don Boyd, Wal-Mart
Lis Houchen, NACDS
Nancy Davis, AkPhA
John Wanek, AkPhA
Caren Robinson, AkPhA
Shirley Evans

After review of the agenda from the previous day, it was noted the Shared Pharmacy Services discussion would be added to the agenda.

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

RESOLVED to approve the agenda as noted.

Agenda Item 12 Public Comment

Barry Christensen spoke representing the Alaska Pharmacist Association in regards to legislative bills being considered by the legislature. Mr. Christensen noted concerns the association had with SB 196, and companion bill HB 316, the legislation regarding a Prescription Drug Monitoring Program. He stated the concerns were addressed with Senator Green's office and changes had been made to SB 196 because of those concerns. Noted was the requirement for the information from the party picking up the prescription, noting that most current pharmacy systems do not have the ability to track that information. The other concern was the ongoing funding for the program after Federal funds are no longer available. He noted the letter of intent attached to the bill which stated it was not the intent of the legislature to put the burden of the ongoing costs of the program on the professional users of the program. The last concern was that pharmacists not licensed by the board would not be required to submit the information for the database. He said the legislation had been changed to allow the Board to enter into an agreement with military and native healthcare facilities to submit and access the information. Ms. Bueler asked Mr. Christensen if the legislation was patterned after other states legislation in that the information

would only be able to be accessed by limited groups of people. Mr. Christensen stated he believed the legislation was intended to keep access of the information limited to prescribers, pharmacists and the law community when warranted. Ms. Mundell stated she had been to a meeting with prescribers who were concerned that they would be targeted for inappropriate prescribing. She noted they felt it looked punitive to them and that they believed that was not the intent of the bill. She further noted the board would deal with those problems when the regulations for the program were to be drafted by the board. Ron Miller spoke and noted there were concerns the database would not be secure enough. That a prescriber or pharmacist could access the database by using an ID and password however it would not be for a specific computer, therefore anyone who had obtained the ID and password could access the information. Mr. Christensen stated he thought access of the database would be tracked. Ms. Mundell noted that many states have already implemented a tracking system and would be more than willing to help in setting up the program. Mr. Christensen noted SB 107, the bill that would allow naturopaths to prescribe. He stated the lobbyist for the association said it did not look like the bill would pass this year. The concern in the last committee hearing was that the advisory committee did not give a final review of the committee's findings, only a draft. The last bill noted was HB 304 for the Cancer Drug Repository. He noted the drive of the bill was probably the extensive cost of cancer treatment drugs. The bill would allow a drug repository and redistribution program for Medicaid patients.

Robert Young, Pharm D., spoke representing SEARHC regarding the 10 mile rule regulation the board would discuss later in the meeting. Dr. Young noted he had received from Ms. Zinn the information regarding other states statutes and regulations which was included in the board packet. He noted that Wyoming was the only state that had a statute regarding a mileage rule, while the others only had a regulation. He noted that he personally did not believe the board could impose a 10 mile rule because it would restrict the pharmacy trade. He further noted he believed telepharmacy provided a valid service and the market should be the judge.

Agenda Item 13 Legislative Update

Ms. Mundell noted SB 196 was covered during the public comment period. Ms. Mundell noted SB 107 and asked the board if they should write a letter to the legislature regarding the bill and prescriptive authority for Naturopaths. Mr. Holm noted that the committee which he was on for two years, submitted a draft of the committee's findings to the legislature, but a final version was never submitted. Ms. Bueler asked what naturopaths wanted the prescriptive authority for. Mr. Holm stated they wanted to prescribe thyroid medication, pain medication and hormones. He noted one of the concerns of the committee was how would anyone know they would have enough pharmacology. Ms. Mundell stated she was hesitant to give another group of people the ability to prescribe controlled drugs. There already are enough problems with controlled drugs. Ms. Bueler

noted she did not understand why naturopaths wanted to prescribe drugs because their philosophy is "natural". The board decided they would write a letter if it looked like the bill would start moving through the committees. The letter would state the hesitations they had which included the committee not submitting a final report, enough pharmacology, accreditation questions, etc. Ms. Zinn noted the division would be introducing an omnibus bill in the next session and the board may add licensing of out-of-state wholesale distributors as well as any other changes to the Board of Pharmacy Statutes they would like to pursue.

Agenda Item 9 Regulations

The board revisited the Shared Pharmacy Services proposed regulations. Ms. Bueler noted she had brought the information from the March 2007 board meeting when the board first discussed proposing regulations for shared pharmacy services. She stated the board patterned most of the draft regulations after the Arizona regulations for Shared Services. She further noted Arizona did not define Shared Services unless they had put it in another area of the regulations. Indiana's regulations called it "Centralized Processing of Prescription Drug Orders", which had the meaning "the processing by the pharmacy of a request from another pharmacy to do the following; fill or refill a prescription, perform processing functions including dispensing, drug utilization review, claims adjudication, refill authorizations, therapeutic interventions." Ms. Bueler read Michigan and Utah's regulations which were similar in wording to Indiana's definition. Ms. Bueler asked the board if they should call it Centralized Prescription Processing as the other states had and put a definition similar to those read. Mr. Givens noted the other language still kept the definition broad. Ms. Bueler stated she would like to see a definition of the services and perhaps change it to Centralized Processing Services. Mr. White noted he liked the wording of centralized better than shared pharmacy services. Ms. Mundell stated she would like to define it for legal purposes. Mr. Givens read the definition in the statutes for "practice of pharmacy" which already defines "pharmacy services" therefore he did not think the board should put a definition in the proposed regulation. Ms. Bueler stated the regulation should be clear so telepharmacy would not be confused with shared pharmacy services. Mr. Givens stated it was already defined and if someone were to come from out-of-state wanting to use the services, it would already be defined in "practice of pharmacy". Mr. Holm noted that if the board were to put a definition in, there would have to be a "catch all" so it would not be too limited, such as "other pharmacy services". Mr. White asked if it was in the best interest of the public health to adopt the proposed regulations. Mr. Bueler stated that after the discussion, she was ready to adopt the proposed regulations as they were. Mr. Givens stated the board should think about examples so they would not have to come back at a future meeting and say "the intent was not to allow that". Ms. Bueler stated the board should think about the different ways pharmacies would want to use the shared pharmacy services and if the board wanted to include out-of-state pharmacies or allow in-state only. Ms. Mundell stated she felt the

board should start with allowing shared pharmacy services in-state only and add out-of-state later if the board thought it was necessary. Mr. Givens stated that if JCAHO decided tomorrow they had to have 24 hours pharmacy services, there would not be anyone in-state currently who could do the pharmacy services for ANMC and therefore they would have no options. Ms. Mundell said the question for the board was, does it want only in-state pharmacies to participate in shared pharmacies so that all pharmacists and technicians would be licensed by the state where the board would have more control over them, or does the board want to allow out-of-state pharmacies also to participate in shared pharmacy services with only the pharmacy licensed. Mr. Holm said it was safer to keep the shared pharmacy services in-state. Ms. Mundell said she could see a time when JCAHO would require all hospitals to have 24 hour pharmacist coverage and at that time the board could add a regulation that would allow hospitals "to go across state lines because we don't have the ability for pharmacists to do that now". Mr. Givens stated the board should set it up for the patient. He saw no difference between a licensed out-of-state pharmacy dispensing medication to patients in Alaska and shared pharmacy services, either the pharmacy or the pharmacist would be licensed. Ms. Mundell asked Ron Miller if Safeway would require a pharmacist out of the state to be licensed by Alaska if they entered into a contract for shared pharmacy services. Mr. Miller said they would be required to hold an Alaska pharmacist license as part of a business contract.

Break-

Off the record at 10:41 a.m.

On the record at 11:03 a.m.

Ms. Mundell noted the board would now discuss the 10 mile rule proposed regulation for telepharmacies and continue the shared pharmacy services discussion later in the meeting. Gayle Horetski, assistant attorney general, and Jun Maiquis, regulation specialist, joined the meeting via telephone for the discussion. Ms. Mundell gave the background of the regulation change to the public in attendance and read the information contained in the board packet from the States of Wyoming, Texas and North Dakota. The statute from Wyoming would not allow a telepharmacy to operate within a 25 mile radius of a licensed pharmacy. She further noted that in North Dakota, if a telepharmacy existed in a community and a pharmacy wanted to open in that community, the telepharmacy license would lapse at renewal allowing the pharmacy to operate solely in the community because the preferred standard of care would be face to face contact with a pharmacist as opposed to a telepharmacy where the pharmacist would be on a computer screen. She read the Indian Health Service draft manual mentioned earlier in the meeting which stated an Indian Health Clinic could not serve non-eligible beneficiaries if there was "reasonable alternative healthcare services" within a 30 mile radius of the Indian Health Services clinic. Reasonable alternative healthcare services would include a private health care facility which would offer healthcare from physicians, dentist, surgeons, pharmacists and optometrists, etc. Ms. Bueler noted the information from other states would give a geographical precedence and further stated the intent of the telepharmacy

regulations adopted by the board, was to serve an underserved community. The board had talked in the past of defining an "underserved community". However it would be simpler to put in a geographic rule. Mr. Givens said he was on the telepharmacy committee with Mark Bohrer and Bill Altland when they had first proposed using a 10 mile geographical rule in the original proposed regulations. After listening to the public comment at a meeting, the board decided to take out the 10 mile rule. The board should not go against what the board had already decided. If the board feels telepharmacy is safe for a remote site, then why is it not safe elsewhere? Mr. Givens described the telepharmacy system ANMC had used for three years with 18 remote villages. The pharmacist at ANMC reviews the order and sends the order electronically to a machine at the remote site. Then the community health aid takes it out and gives it to the patient. The health aid can get into the cabinet to stock it. If it is opened after hours when the pharmacist is not on duty, the pharmacist would know and would communicate with the health aid the next day. He stated the system was a huge improvement compared to the way healthcare had been delivered in the past. He further stated that if the board did not think it was safe care, then the board should repeal the regulation. Mr. Holm noted the board sees telepharmacy as a valuable tool but should not be considered the same standard of care as a pharmacist in the community. Ms. Bueler asked if the precedence from other states would allow the board to institute their own mileage rule. Ms. Horetski said she had read the information from other states regarding the mileage rules and noted that Wyoming had a statute that stated a telepharmacy may not be located within 25 miles from a licensed pharmacy. A statute from another state would have no legal significance in Alaska. The board must look AS 08.80 to decide who could be licensed. In the absence of a specific statute that would reference a remote pharmacy, the board would have to look at AS 08.80.030, Powers and Duties of the Board, and the Statement of Purpose, AS 08.80.005, "It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy". Any amendment to a regulation would be looked at by the Department of Law for the statutory authority by the board. What would be the purpose of the regulation? There must be legitimate governmental purpose, then would there be a rational relationship between the purpose and what the actual language of the regulation said. What is it about the 10 mile distance from a licensed pharmacy that would make it safer for the public? What would be the link between the 10 mile distance and the charge of the board to safeguard the public health and safety? Ms. Mundell said the issue would be a minimum standard and in most communities the minimum standard would be a pharmacist, and when you can not have the minimum standard the alternative would be to provide pharmacy services through telepharmacy. In that instance the only person that you would be able to see physically would be a pharmacy technician. In a community that had a pharmacist, a telepharmacy system would not be appropriate because the minimum standard would be a pharmacist dispensing medication to a patient which would be considered regular pharmacy practice. Ms. Horetski noted the regulation did not say that, but said within 10 miles. Ms. Mundell stated that if telepharmacy was the only means of the community to

deliver pharmacy services then that is what needed to happen, but if a pharmacist were located in the community, that would be the minimum standard of care. The minimum standard of care should not be a technician. If it were, it would not be conducive to the health and welfare of the community. Ms. Horetski said, "It seems as though you are using 10 miles as equal to no other pharmacist in the community". Ms. Mundell stated the board had talked about that at the last meeting. That an underserved community would be where no other pharmacy services were available so in place of defining underserved community by census or by how many people were in the community, the 10 mile rule was used. Mr. Givens stated it seemed like a conundrum where on one side the board said telepharmacy services are good for a patient but on the other side telepharmacy services are not good for the patient if there is a pharmacist in the community. He stated the board needed to decide if telepharmacy was safe or not. Mr. Holm stated it was never the intention of the board for a telepharmacy to replace or be equal to a pharmacy with full pharmacy services. It would be a safe means of supplying medication where there are no other medications but should not replace a full services pharmacy. Ms. Bueler said she wanted to reiterate the intent of the board was to allow telepharmacy to serve an underserved community such as small villages. If the board were not allowed to put something in the regulation whether it was a geographic description or census description, what would stop a large chain pharmacy from going into any community and provide telepharmacy services to all of their pharmacies in the state with the pharmacists sitting in one central location? Dr. Young read the NABP Model Rules for a remote pharmacy which stated "A coordinating pharmacy shall demonstrate to the board that there is limited access to pharmacy services in the community prior to engaging in the practice of telepharmacy via the remote pharmacies and remote dispensing site". Ms. Bueler asked the board if they should put that in the regulations and look at each application individually. Mr. Givens said the Safeway in Ketchikan wanted the telepharmacy license to dispense medication only on Sundays because no other pharmacy was open at that time and thought that would be a need that could be filled by the telepharmacy. Ms. Mundell stated that Ron Miller had wanted the telepharmacy because of staffing problems. They could not find a full time pharmacist for the Ketchikan pharmacy. Mr. Miller stated the market place should decide what was best. Mr. Givens said it should be up to patient if it would be safe and effective care. If it wasn't, then the telepharmacy regulations should be repealed. John Wanek in the public audience stated that there was a hospital in Ketchikan, therefore the argument that no pharmacy services were available on Sunday was not valid. If the pharmacies in the community were closed, they could go to the hospital emergency room for care. That is not limited pharmacy services. Ms. Bueler recommended the board put in the regulation the NABP Model Rule spoken of earlier in the discussion and look at each application on a case by case basis. Ms. Mundell asked Ms. Horetski if the model rule for a remote pharmacy would work to define underserved community. Ms. Horetski said that drafting a rule focusing on underserved community would be more rational than using a 10 mile limit. Ms. Horetski noted the board should adopt further guidelines defining what the board meant by limited access and

how would the applicant show that. The public notice was broad in scope for the change but would recommend the board send it out for public notice either as a supplemental notice or a new public notice because the board would want to hear from members of the profession and members of the public. Ms. Mundell asked if the board could define the community with the 10 mile limit. Wasilla would be considered part of the Anchorage community, so how would the board define community. Ms. Horetski said you can't draw a 10 mile circle around a community because you may or may not include the entire community. The criteria to define a community would have to be part of the regulation. Ms. Bueler stated she would like to see the NABP Model Rule put in the regulation, then an ad-hoc committee work on the criteria to define community. Mr. Givens said if the attorney general came out with the decision on whether tribal facilities needed to be licensed, then they would have to submit the applications for their 18 telepharmacy locations and the board could look at them on a case by case basis to determine if they meet the criteria and it would give the board leeway in making the decisions. He further stated the board should table the regulation and work on criteria at the next meeting. He said perhaps the board could look at a minimum amount of hours per week the community had pharmacy services to determine underserved. Mr. Holm said he would like to adopt the wording without criteria for a broader scope. Ms. Horetski said that would not be her recommendation. What does the board mean by limited services? Would it be no services at all, the services are too far away, or not available to that particular patient population. They are legitimate interpretations and if the board did not define limited access or community, there are no standards. She said her recommendation would be for the board to table it, come up with criteria and send it out for public comment to get the profession's opinion on the regulation. That would be her recommendation to any board. Ms. Mundell stated the board had discussed the regulation to the point it was time for someone to make a motion.

On a motion duly made by Mr. Holm, seconded by Mr. White, it was

RESOLVED to adopt the proposed regulation in 12 AAC 52.425(c)(3).

Discussion followed.

Ms. Bueler stated she would like the board to adopt the 10 mile rule but with the NABP wording and establish criteria which could include geographic as one option, at a later time. Ms. Horetski recommended the board add a new section for licensure requirements for a remote pharmacy to include the wording, "The board will approve an application for a remote pharmacy license under the following conditions", and then list the conditions.

On an amendment duly made by Mr. Holm, seconded by Mr. White and approved unanimously by roll call vote, it was

RESOLVED to add a new section, 12 AAC 52.423, for Conditions for Approval of a Telepharmacy License, to include the wording “a Central Pharmacy shall demonstrate to the board that there is limited or no access to established pharmacy services in the community”, and other licensing requirements, and considering public comment, delete 12 AAC 52.425(c)(3) in the public noticed regulations.

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

RESOLVED to table the Shared Pharmacy Services proposed regulations until the next meeting.

Mr. Holm noted that this was Ms. Bueler and Mr. Givens last meeting. Ms. Bueler had dedicated the last eight years to the board and Mr. Givens had dedicated the last four years to the board and wanted to publicly thank both of them for their service.

Ms. Bueler noted the tentative meeting dates for the remainder of the year were May 8-9 and September 25-26.

Ms. Mundell signed the adopted minutes of the September 20-21, 2007 meeting. The board signed the wall certificates.

The meeting adjourned at 1:14 p.m.

Respectfully Submitted:

Sher Zinn, Licensing Examiner

Approved:

Mary Mundell, R. Ph., Chair
Alaska Board of Pharmacy

Date: _____