

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 16-17, 2012**

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 16, 2012, at the Atwood Building, 550 West 7th Ave., Suite 1270, and February 17, 2012, at the Anchorage Marriott Hotel at 820 West 7th Ave., Juneau room.

These final minutes were prepared by the staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:04 a.m. Those present constituting a quorum of the board, were:

CJ Kim, R. Ph.
Lori DeVito, R. Ph.
John Cotter, R. Ph.
Dick Holm, R. Ph.
Dirk White, R. Ph.

Anne Gruening and Ted Mala were not present at the meeting.

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

Sher Zinn, Licensing Supervisor
Brian Howes, Senior Investigator
Al Kennedy, Investigator
Don Habeger, Director

Visitors present:

Signe Anderson, AAG
Laura Fox, AAG
Lis Houchen, NACDS
Daiana Huyen, Walgreens

Agenda Item 1 Review Minutes

The board reviewed the minutes from the November 17-18, 2012 meeting. No changes were made.

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

RESOLVED to approve the minutes of the November 17-18, 2012 meeting.

Agenda Item 2 Ethics Disclosure/Goals and Objectives

The board had no ethics disclosures to report. The board reviewed the Goals and Objectives.

1. The board will continue to educate licensees regarding the Pharmacy Practice Act and pharmacy regulations.
2. The board will continue to provide input and comment on any proposed legislation/regulations involving medications or pharmaceutical care.
3. The board will continue to promote effective patient counseling by licensees.
4. The board will continue to assess and evaluate the Multi-state Pharmacy Jurisprudence Examination (MPJE).
5. The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.
6. The board will continue to assess and evaluate the licensing of pharmacy technicians.
7. The board will continue 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.

Review Agenda-

The board reviewed the agenda and decided to add Automated Dispensing Machines to Old Business.

Mr. Holm noted the agenda stands as noted.

Agenda Item 3 Expense Report

Ms. Zinn reviewed the expense report for the board and stated the board would go into the renewal period with a small deficit. One question the board had was the large "indirect" expense of \$134,443 to the board. Ms. Zinn noted the large amount was mostly due to the rent the division pays for office space which was due this quarter. Ms. Zinn explained further what other types of expenses were included in the indirect expenses.

Mr. Holm noted he had received a phone call from Director Habeger who said the renewal fees would stay the same for the upcoming renewal period.

Agenda Item 7 Correspondence

Ms. Zinn said she had a question for the board regarding prescribing practitioners purchasing drugs from a pharmacy. She noted she had two phone calls in the last few weeks regarding physicians purchasing drugs from pharmacies for office use. Ms. Zinn asked the board if physicians could purchase the drugs for more than emergency use from pharmacies, or must they purchase from a wholesale distributor. Mr. Cotter said they could but it must be limited to five percent of controlled substances due to Federal law. The board noted the definition of a wholesale distributor. Ms. Zinn read 12 AAC 52.695, PROVISIONS NOT APPLICATIONS, "The following activities do not constitute wholesale distribution of prescription drugs for which a wholesale drug distributor license is required by 12 AAC 52.610 –12 AAC 52.690: (5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this paragraph, "emergency medical reasons" includes a transfer of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12-consecutive-month period", which states the pharmacy can sell to another pharmacy for "emergency medical reasons" but the regulation does not list physician or prescribing practitioner. The board decided to amend 12 AAC 52.695(5) to read-

The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a retail pharmacy to another retail pharmacy or practitioner, as defined

under 08.80.480, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy or practitioner during any 12-consecutive-month period.

The board discussed the correspondence from the NABP and had no comments or recommendations.

Break- Off the record at 9:50 a.m.
On the record at 10:05

Agenda Item 4 PDMP Update

Brian Howes joined the board for the Prescription Drug Monitoring Program update. Mr. Howes noted some pharmacies have had problems with the DEA registration number. The DEA number may only be used for one entity and if you had more than one person in the pharmacy using the pharmacy DEA registration number, the system would not allow it. He further noted he is working with the software company on use of the NPI number as a sub account. Mr. Howes stated there are still “bugs” but they are being worked out with the company. Mr. Howes said the IHS would start submitting data to the PDMP. He said he would do an outreach program on use of the PDMP with other prescribing practitioners such as ANP’s and veterinarians.

Mr. Howes said they still had \$163,000 from the original grant, and monthly program expenses are between \$5000 and \$6000. The grant is supposed to end in August 2012 but he stated he would apply for another grant for maintenance costs. Another grant would also be available for enhancement of the program. He asked the board to think about what they would like to enhance the program.

Mr. Holm asked if there was much utilization of the program. Mr. Howes stated the first month had about 180 queries, 40 were from dispensers. Most of the queries came from the valley and the Fairbanks area. He also noted that Homer had a “big jump”.

Agenda Item 5 License Application Review

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

RESOLVED in accordance with AS 44.62.310(c)(2), to go into executive session to discuss license applications. Staff to remain during executive session.

Off the record at 10:25 am
On the record at 11:22 am

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

RESOLVED to deny the pharmacy technician license for Thomas Garrett in accordance with 12 AAC 52.140(b)(2) and 08.80.261(a)(4). Specifically, 12 AAC 52.140(b)(2) states “certifies that the applicant has not been convicted of a felony or other crime that would affect the applicant’s ability to perform the duties of a pharmacy technician safely and competently”, and 08.80.261(a)(1)&(4) 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; (1) has secured or attempted to secure a license through deceit, fraud, or intentional misrepresentation; (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.”

Noted was Mr. Garrett’s convicted of a felony of “attempted assault”, and failure to disclose a conviction of a DUI.

It was further noted the board denied the application at its November 2011 meeting but failed to cite the correct statute and regulation.

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

RESOLVED to approve the pharmacy technician license application for Erin Simoneau.

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

RESOLVED to deny the pharmacy technician license application for Kevin Garner in accordance with 08.80.261(a)(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”, and 12 AAC 52.140(b)(2) “certifies that the applicant has not been convicted of a felony or other crime that would affect the applicant’s ability to perform the duties of a pharmacy technician safely and competently”.

It was noted Mr. Garner was convicted of two felonies for manslaughter and DUI.

On a motion duly made by Mr. Kim, seconded by Mr. Cotter and approved unanimously, it was

RESOLVED to approve the intern license application for Darryl Willmore pending receipt of the Declaration of Sponsorship form and the jurisprudence questionnaire.

On a motion duly made by Ms. DeVito, seconded by Mr. Kim, and approved by roll call vote, it was

RESOLVED to approve the intern license application for Kevin Subler.

Roll call vote- Kim-yea, DeVito-yea, Cotter-yea, Holm-yea, White-abstain.

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

RESOLVED to approve the out-of-state pharmacy application for University Compounding.

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

RESOLVED to table the pharmacist application for Donald Schumacher until the next meeting.

The board decided to send the application back to the investigator to follow up with Mr. Schumacher. The work history on page two of the application started in 2006 when Mr. Schumacher was originally licensed in 1994, therefore the application was incomplete. The board also stated they would like the investigator to follow up on letters of reference in which there were no signatures showing the persons had actually signed the letter, and one letter from a pharmacist who had not actually worked with the applicant.

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

RESOLVED to approve the pharmacist license application for Susan Hayes pending passage of the MPJE.

Agenda Item 6

Old Business

The board discussed a regulation to ban Automated Dispensing Machines. They discussed whether they had the statutory authority to ban the systems. Ms. Zinn noted during a regulation change the board should note the statutory authority that pertains to the regulation. Mr. White noted AS 08.80.030. POWERS AND DUTIES OF THE BOARD. (a) The board is responsible for the control and regulation of the practice of pharmacy, and this falls under the practice of pharmacy. Mr. White stated they are acting like a pharmacy. Also noted were

(4) which states “adopts regulations to carry out the purposes of this chapter”, and (10) which states “issue licenses to persons engaged in the manufacture and distribution of drugs and related devices”. The board noted the NABP correspondence in regards to ADMs which refers to other states having banned the use of ADMs based on the mandatory counseling rule.

Mr. Holm stated possibly a regulation that would define automated dispensing machines and then a regulation stating the board does not recognize the machines as a valid way of dispensing prescription medication. However, it would not include institutional pharmacies.

Mr. Cotter noted his first look at the use of the machines would be to say no, but then there might be uses for them in certain situations. Mr. Holm noted the valid option would be a remote pharmacy. Ms. DeVito said it was a safety issue and if allowed, could get out of hand. Mr. Holm noted the regulation should state they could be used in remote pharmacies and institutions and banned for any other use.

It was decided to have other state definitions at the next board meeting to draft the regulations as noted.

Lunch- Off the record at 12:00 p.m.
On the record at 1:15

Agenda Item 8 AG Office Legal Opinion

Signe Anderson and Laura Fox joined the meeting to discuss the legal opinion the board had requested regarding licensing of Native Health Care Facilities. Ms. Anderson requested the board go into executive session in accordance with AS 44.62.310(c)(3)&(4), noting protected attorney client privilege.

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

RESOLVED in accordance with AS 44.62.310(c)(3)&(4), to go into executive session to discuss protected attorney client privileged information.

Board staff to remain during executive session.

Off the record at 1:18 p.m.
On the record at 2:50 p.m.

Agenda Item 9 Investigator Report

Al Kennedy, investigator joined the meeting to discuss the investigator report. Doug Bartko also joined the meeting. Mr. Bartko had been invited by the board

to discuss his license being reinstated to a full unrestricted license. The board had concerns regarding Mr. Bartko being out of pharmacy practice for several years. Mr. Holm noted he would like to see Mr. Bartko take more classes and get back into the pharmacy business gradually and perhaps have another pharmacist work with him to answer questions and any concerns regarding change in pharmacy practice noting Mr. Bartko had been out of practice for several years.

Mr. Kennedy noted they had done 12 pharmacy inspections and 10 were closed out. The DEA did an inspection regarding a complaint and found that most of the problems they encountered were from Federal guidelines, and the only problem that would be state related was allowance of unlicensed person's access in the pharmacy. He noted Agent Sanchez from the DEA was going to back to the facility to do another inspection. Most of the complaints they had regarding the facility had been corrected.

The pharmacy inspection forms are based on the self-inspection report. They question the PIC or the pharmacist on duty. One problem noted was the licenses posted in the pharmacy were from the internet, and they cautioned them they must have the actual license on the wall. Discrepancies are noted in a memo to the pharmacist in charge noting they have 30 days to comply with the discrepancies.

Mr. Kennedy noted the medical marijuana clinic starting up in Anchorage. They are looking for an office for the physician that comes up from California to issue medical marijuana cards.

Don Habeger, director, asked to join the meeting to address the board regarding two bills in the legislature which would give naturopaths prescriptive authority. Mr. Habeger asked the board if they have changed their stance regarding dispensing prescriptions written by naturopaths. The board noted they are not aware of any changes and that naturopaths do not have prescriptive authority. Mr. White noted he has been in Alaska since 1985 and has never filled a prescription written by a naturopath. Mr. Holm noted the misconception may be in the naturopath community where they do not understand that a legend drug is a prescription drug. Mr. White noted for clarification that a legend drug is a prescriptive drug. A controlled drug is a subset of a legend drug which requires a DEA registration from the Federal government. Mr. Habeger asked the board if they had any objection to him stating on the record in a hearing that the board concurs there has not been a reinterpretation of the position regarding naturopath prescriptive authority. The board agreed they had no objection. Mr. Holm noted it was not a change in the position but a lack of enforcement. Mr. White noted that the board was not aware it was happening, and Mr. Habeger noted that the division is complaint driven and if no one makes a complaint, no one knows it is going on. Mr. Holm said the naturopath community had been trying to get prescriptive authority since 2004, showing they knew they did not have prescriptive authority. Mr. Holm noted he was on a task force in 2004 with

then Senator Seekins. The task force discussed requiring 60 hours of pharmacology prior to a naturopath having authority to prescribe, the naturopath could not dispense from their office for self administration, and a formulary should be developed by a panel consisting of physicians, pharmacists and naturopaths.

The board discussed the bill in its current state and noted several drugs that could be considered "derived" from a natural substance, including digitalis, digitoxin, testosterone, and even some chemotherapy drugs. The board also discussed an advisory board for developing and updating a formulary. Mr. Cotter noted if naturopaths get prescriptive authority, it needs to be monitored and controlled.

Dirk White left the room at 3:40 and returned at 3:42.

Lori DeVito left the room at 3:42 and returned at 3:48.

Agenda Item 10 Application Review

The board reviewed two applications.

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

RESOLVED to table the out-of-state application for Meds at Home and review during a mail ballot.

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

RESOLVED to approve the pharmacist application for Ron Erkens pending the verification of licensure from Washington.

Agenda Item 6 Old Business

The board discussed the renewal jurisprudence questionnaires. The board was tasked to write new questions and bring to the meeting with the specific regulation citation. The board will send the questions with the citation to Mary Kay Vellucci to amend the questionnaire for the renewal forms.

The board discussed and decided to have a line on the pharmacy renewal for the PIC's email address, and website if the pharmacy had one.

Ms. Zinn noted the renewal forms will have a bar code on the form which is specific to the licensee. The application with the bar code could then not be copied and used for other licensees, or the fees would be receipted to the licensee whom the bar code is specific to.

Agenda Item 10 Regulations

Ms. Zinn noted the fee project from the last board meeting would not be public noticed for several more months.

The board discussed the Shared Pharmacy Services regulations. It was brought to the attention of the board that out-of-state pharmacists may only have a contract with an institutional pharmacy in this state, and was that the board's intent. After discussion the board decided to keep the regulation as it was.

Ms. Zinn noted from the complexity of the Shared Pharmacy regulation requirements, there would need to be two separate applications. One would be for retail pharmacies and one would be for institutional pharmacies.

The board recessed at 4:35 p.m.

Friday February 17, 2012

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair, February 17, 2012 at 9:04 a.m. Those present constituting a quorum of the board were:

John Cotter, R. Ph.
Lori DeVito, R. Ph.
CJ Kim, R. Ph.
Dick Holm, R. Ph.
Dirk White, R. Ph.

Anne Gruening and Ted Mala were not present at the meeting.

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

Sher Zinn, Licensing Supervisor

Visitors present:

George D. Loertscher
Ronald Herman
Julie McDonald
Daiana Huyen
Bob Albertson
Angelina Lovell

Valerie Card King
Margaret Soden
Barry Christensen
Lis Houchen
Dan Nelson
Amber Briggs
Bill Altland
Catherine Kowalski

Agenda Item 12 **Review Agenda**

No changes were made to the agenda.

Agenda Item 13 **Public Comment**

Laura Nichols spoke regarding a recently licensed travelling physician who had been issuing medical marijuana cards with various fees to the public. She noted it was particularly alarming because the physician did not live in Alaska. Daiana Huyen from Walgreens pharmacies stated that several pharmacists were concerned their home addresses were on the website. Ms. Zinn noted that current state law considers the mailing address as a public record and must be available to the public. The only exemption the division had would be for someone who had a court order against another person. The licensee would submit a copy of the court order with a request to have their address removed from the website. Ms. Zinn also noted the licensee could use their business or practice address as the address of record which would be the address shown on the website.

Bill Altland noted he would like to have known what the AAG had said regarding the licensing of native healthcare facilities opinion that was discussed the day before. He also noted it should have been on Friday's agenda since it would have been something everyone at the convention would want to listen to. Mr. Holm noted that since the opinion had not been finalized yet, the discussion was conducted during executive session so no one in the public would have been able to listen to the discussion. The opinion would be made public as soon as the board received the opinion from the AAG's office.

Lis Houchen noted the board discussed on Thursday possibly making regulations regarding Automated Dispensing Machines. Mr. Holm noted the DEA had asked the board to look into regulating the ADMs. The board will work on regulations at the next meeting. He noted the board was not in favor of the ADMs outside of an institutional pharmacy. He further noted that the board had no purview over physicians dispensing from their offices, but hoped the medical board would "follow suit".

Julie McDowell asked the board if there was anything in the Affordable Healthcare Act that the pharmacists would need to know. Mr. White stated he

was not aware of anything in the act other than the AAG's opinion that may address something in it. Ms. McDowell then asked the board what to do with falsified prescriptions. The board determined that the prescription should not be destroyed but kept in case of a legal investigation. Mr. Cotter noted that when a forged prescription is received by a pharmacy, the police should be contacted and asked what they would like the pharmacy to do with the prescription.

Agenda Item 14 **New Business**

Dirk White addressed the board regarding community pharmacy accreditation. He noted it was "on the horizon" and if your pharmacy is not accredited, you would not be reimbursed by a third party payer such as Medicaid or Medicare, or PBM's. The APHA and NABP are working on the pharmacy accreditation. He stated to the audience if they want to be part of the solution, contact the APHA and NABP. Mr. Holm noted he was against it and it is a revenue source for them. He further stated the association and board should make themselves heard. Mr. White noted the board should have a statute or regulation that stated the accreditation is not recognized and pharmacies could not be penalized if they were not accredited. A member from the audience stated the board should be the accrediting body and not the NABP, the board agreed.

Mr. Holm noted for the audience that the board would be holding four meetings a year instead of the typical three.

Agenda Item 15 **Ronald Herman-Medical Marijuana**

Ronald Herman from the Iowa Drug Information Network had a power point presentation of medical marijuana. Dr. Herman was tasked by the Iowa Board of Pharmacy to find the facts concerning studies of the use of marijuana for medical purposes. The presentation included his findings.

Break- Off the record at 10:52 a.m.

On the record at 11:08 a.m.

Agenda Item 16 **Legislative Update**

Mr. White noted SB 175 and HB 266. Both allow naturopaths prescriptive authority. He stated if anyone had concerns about the bills, to contact their legislator. Mr. Holm noted the board thinks the current language is too broad and too general. He stated before the board would support the bill, they would like to see a formulary developed from a committee of pharmacists, naturopaths and physicians. The board also had concerns regarding naturopaths dispensing from their office. He noted the board supported verification of education with enough pharmacology to ensure they can prescribe.

Mr. White addressed HB 259 which would require oversight of pharmacy audits by third party payers. He said at this time, there was not a companion bill in the

senate. He encouraged those in the audience to contact their legislators. Barry Christiansen asked the board if they would draft a letter in conjunction with the association in support of the bill. Mr. Christiansen stated that auditing pharmacies by third party payers does not protect the health and safety of the public which is the Board of Pharmacy's mission. Mr. White agreed with Mr. Christiansen and stated that without the oversight of the audits the bill would give, it may impact the protection of the public by reducing primary healthcare if a pharmacy had to close their business and leave the community. It may essentially leave the community without proper pharmacy services.

On a motion duly made by Mr. White, seconded by Mr. Cotter, and approved by roll call vote, it was

RESOLVED to send a letter to the legislature in support of HB 259.

Roll Call- DeVito-yea, Cotter-yea, White-yea, Holm-yea, Kim-abstain

Mr. Holm would write the letter and send to the examiner for completion.

Agenda Item 17 Office Business

The board signed the wall certificates and TA's.

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

RESOLVED to adjourn the meeting.

Off the record at 11:40 a.m.

Respectfully Submitted:

Sher Zinn, Licensing Supervisor

Approved:

Dick Holm, R. Ph., Chair

Date:_____