

Draft

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
November 17-18, 2011

These **DRAFT** 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.

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 November 17-18, 2011 at the Division of Personnel, 619 E. Ship Creek Road, Anchorage Alaska.

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:07 a.m. Those present constituting a quorum of the board, were:

John Cotter, R.Ph.
Lori DeVito, R.Ph.
Anne Gruening, Public Member
Richard "Dick" Holm, R. Ph.
Dirk White, R. Ph.

Absent:

CJ Kim, R.Ph.
Ted Mala, Public Member

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

Don Habeger, Division Director, via telephone
Brian Howes, Investigator & PDMP Program Manager
Gary Keiser, Investigator
Alvin Kennedy, Investigator
Mary Kay Vellucci, Licensing Examiner

Visitors present:

Nancy Davis, AkPhA
Bernie Klouda, Bernie's Pharmacy

Agenda Item 1 Review of Agenda

Chair Holm noted for the record the meeting location was changed from the Atwood Building to the Division of Personnel at 619 E. Ship Creek Road in Anchorage, and the appropriate Public Notice measures were taken.

Chair Holm stated he wanted to amend the agenda to include the following items:

1. Review of Naturopath prescriptive authority
2. Licensing of out of state wholesalers
3. University of Nevada/Reno Survey/Boards and Commissions
4. Contract received by National Rx Partners.com/Shared Pharmacy Services.

Upon a motion duly made by Ms. DeVito, seconded by Ms. Gruening, and approved unanimously, it was

RESOLVED to approve the agenda as amended.

Agenda Item 2 Review of Minutes

The board members noted several typographical errors in the September 2011 minutes, but there were no substantive changes.

Upon a motion duly made by Ms. DeVito, seconded by Ms. Gruening, and approved unanimously, it was

RESOLVED to approve the September 2011 minutes after correcting the typographical errors.

Ted Mala entered at 9:12 a.m.

University of Nevada/Reno Survey: Members noted the survey author states the survey was commissioned by Boards and Commissions, has "state permission" to solicit members and is described as optional. They added "they do not give up easily" when a reply to the survey was not provided. The members asked Ms. Vellucci to contact Boards and

Commissions to inquire further about this and get the results of the survey.

Chair Holm noted the relevance of the 1981AG opinion in the board packets which speaks to the reasons for the existence of the board. He informed the members this content is still relevant. The board exists for the protection of the public, not for the benefit of the members' our employers or the practice of pharmacy. Any other approach is considered a conflict of interest. He then explained, for the record, the circumstances under which a member should recuse him/herself from voting.

Agenda Item 3 Division Update

Chair Holm provided a brief history of the board's role during the last renewal period for the benefit of new member. A consequence of renewals was the board's September 2011 three-point Formal Request to the Division. The purposes of the request were to find a funding source other than licensing fees to recover the legal debt which accumulated from the last renewal period and enact a budget line item, such as *Contingency Expenses*, that would permit a board to save for future anticipated and unanticipated expenses.

Don Habeger, Division Director, joined the meeting via polycom and the content of the Formal Request was read into the record.

Mr. Habeger replied as follows:

- Some of the elements of the Formal Request are still in the planning phase, therefore a complete answer cannot be provided at this time.
- Recently one profession in the Division responded "rigorously" to a request for public comments that included an increase in licensing fees.
- There has been an increase in the Investigative expenses for the division, which Mr. Habeger had to justify to Administration and Senate Finance.
- These items have created "quite a bit of discussion" about how fees are created in professional licensing groups, particularly those that are smaller in number.
- "The pathway forward has to be legislative."
- Current statutes do not allow for an additional allocation, whether it is for Investigations or Pharmacy.
- The next stage of resolution is projected to begin with the next legislative session.

Chair Holm replied the board was aware the solution was legislative in nature and asked Mr. Habeger if a bill was going to be introduced. Mr. Habeger said he did not know at this point in time.

Mr. White asked if a fiscal note had been created. Mr. Habeger replied the hearing was October 31st and therefore the numbers aren't compiled. The Law agreement with CBPL for FY12 is \$950k and Administrative Office RSA is \$200k.

Mr. Holm asked if the fines levied to individuals and groups, which now go to the General Fund, could be identified on expense reports provided to the legislature so they are aware of the financial contributions made to the State General Funds via the Pharmacy and other boards... *" the legislature can also see the revenue coming into the state from the boards, not just what is going out."*

Mr. Holm asked if there was anything the Board of Pharmacy can do to assist in attaining the objectives outlined in their formal request. Mr. Habeger replied Representative Mia Costello is the Chair of the Finance Subcommittee for the Division and Department. He believed she would be interested in what the perspective of the Pharmacy Board members.

Discussion and description occurred about direct and indirect line items on expense reports.

The board thanked the Director for his quick response in approving funds for the 4th Board of Pharmacy meeting.

Other Division items tabled until November 18th

Agenda Item 5 Investigations

Investigator Gary Keiser introduced Alvin Kennedy, the new investigator for the Board of Pharmacy. Mr. Kennedy gave a brief description of his professional background. Chair Holm encouraged Mr. Kennedy to contact board members as needed in the mutual pursuit of the public interest and justice.

The November 2, 2011 Investigator's Board Report was distributed and the contents were summarized by Mr. Keiser. Since the last meeting, eight cases were closed. Four open investigations and five open complaints are in process.

The members asked the investigators how the upcoming renewals with "yes" answers will be managed. Ms. Vellucci offered to acquire a copy of the recently revised policy which speaks to this and route it to the board members the following day.

Chair Holm provided the investigators and members with correspondence requiring further evaluation from Investigations.

Chair Holm abstained from participation in Case No. 2011-000693.

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

RESOLVED to go into Executive Session in accordance with Alaska Statute 44.62.310 (c) (2) to discuss licensing.

Board, investigators and staff to remain.
Off record at 10:22 a.m.
On record at 10:38 a.m.

Upon a motion duly made by Mr. White, seconded by Mr. Mala, and approved unanimously, it was

RESOLVED to accept the Consent Agreement for the pharmacy technician application in case number 2011-000693.

This case refers to Tamara Gardner. The original Consent Agreement was signed by Chair Holm and given to the Investigator.

Break: Off record at 10:40 a.m.
On record at 10:50 a.m.

Agenda Item 6 AkPhA

Nancy Davis, Executive Director, joined the meeting to discuss the CPE Monitoring Program. She asked the members to encourage employees and colleagues to create their NABP profiles. Not every state will participate in the CPE Monitoring Program and not every licensee will enroll. Other details about the CPE Monitoring Program were discussed.

I Board members regard pharmacy technician education, on any level, to be beneficial and worthy of credit. It was noted Alaska Licensed Pharmacy Technicians can take CEs designed for pharmacists and receive credit for CE Board Audit. The PTCB may not accept this for their requirements and the ACPE does not.

Ms. Davis said Ron Herman, Clinical Director at the Iowa Drug Information Network has written a Medical Marijuana Report which Ms. Davis forwarded to Ms. Vellucci to route to the board members. He will be at the convention in February and offered to attend the Board of Pharmacy meeting. Chair Holm and the other members agreed to invite him to participate at the board meeting.

The draft regulations for *12 AAC 52.350 Audits of Records by the Board* were reviewed and discussed. Further discussion was tabled.

Agenda Item 3 Ethics Disclosure/Goals and Objectives

There were no ethics violations to report.

It was noted for the record that CJ Kim's continued participation on the board has not been determined as a conflict of interest and therefore he will remain an active member.

The board noted the goals and objectives and made no changes.

The board will continue to educate licensees regarding the Pharmacy Practice Act and pharmacy regulations.

The board will continue to provide input and comment on any proposed legislation/regulations involving medications or pharmaceutical care.

The board will continue to promote effective patient counseling by licensees.

The board will continue to assess and evaluate the Multi-state Pharmacy Jurisprudence Examination (MPJE).

The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.

The board will continue to assess and evaluate the licensing of pharmacy technicians.

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 was generally used for attendance at the District Seven NABP meeting.

The board will continue to evaluate the impact of current regulations and the need for new regulations.

The board will continue to evaluate regulations regarding collaborative practice, and to establish procedures for reviewing/approving appropriate protocols for collaborative practice.

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 drug monitoring program.

Agenda Item 7 Correspondence

Naturopaths: The board packets contained a series of correspondence from an out of state compounding pharmacy regarding Alaska Law in relation to ND prescriptive authority.

The chair reminded the members and audience that Naturopaths do not have prescriptive authority in Alaska, nor do they have a board. He said they have been trying to enact legislation to change this for seven to eight years. In the past, he said, "everyone has looked the other way" regarding some of their practices, such as administering B12 by injection (B12 by injection is with prescription only.) He said Naturopaths' practices have recently come to the attention of the AG's office. A case is currently in front of a Law judge, and decision is expected to be rendered in February or April.

Chair Holm said he has been working as a consultant in this case. The AG's office has taken the initiative to say "if it's a legend drug or device, a naturopath cannot prescribe it." The naturopath involved in the case has provided them with a list of products naturopaths want to use in their practice. Chair Holm is individually reviewing each product on the list and classifying it as a legend (prescription) or non-legend (OTC) product. He added some naturopaths misunderstand the definitions of "prescription drug," "legend drug" and "controlled substance."

He stated NDs are ordering prescription products from Out of State Wholesalers but the Alaska Board of Pharmacy has no purview over Out of State Wholesalers due to lack of statutory authority. The board has been attempting to resolve this for over five years, but the project has not yet caught the attention of the legislature.

A Cease and Desist letter was sent to one Out of State Wholesaler for providing legend drugs to an Alaska licensed ND.

Action Items:

1. After the decision about the case is delivered, all Alaska pharmacy licensees must be notified in writing about the outcome.
2. The governor's office and legislature are urged to act on establishing statutes for the Alaska Board of Pharmacy to license Out of State Wholesalers. This is necessary to protect the public health and safety by regulating and controlling medications coming into Alaska.

DEA: Estevan Sanchez at the Seattle DEA submitted information to the board. The board referred the matter to investigations.

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

ANTHC: The members reviewed a correspondence from a Statewide Recruitment Manager at ANTHC regarding the Federal Health Care Improvement Act and how it impacts licensing. The members were informed the correspondence was referred to Law.

NABP: Community Pharmacy Accreditation: Mr. White stated he told Tom Menighan at a recent convention that this topic is a state's rights issue. He added third party payers are advocating for this and implementation may decrease the public's access to independent pharmacies. Currently participation is voluntary, but it may become mandatory to be classified as a "preferred provider." The board agreed to revisit this during the February 2012 meeting with the intent of preventing third party payers from reducing access to the public perhaps by making an Alaska license equivalent to National Community Pharmacy Accreditation.

Mr. White pointed out the Draft Resolutions for the NABP for the member's consideration, which were reviewed by the members. No comments were made.

Agenda Item 8 Public Comment

The Chair called for public comments. None were made.

Agenda Item 9 License Applications, Routine

The board members reviewed the routine pharmacist applications and Collaborative Practice Applications.

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

RESOLVED to approve the Pharmacist License Applications for

Jimmie Allison pending verification of intern hours, verification of MT license, passing MPJE;
Jon Bernhoft pending board review;
Jeanette Bidondo pending passing MPJE;
Stacy Harrington pending passing MPJE, transcripts, verification of WA license;
Jenice Jacobs pending verification of intern hours and verification of HI license;
Mathew Kirkland pending verification of intern hours and verification of HI, CA and FL licenses;
Michael Pickering pending passing MPJE, transcripts, verification of OK and IA licenses;
Catrina Schwartz pending passing MPJE;
Joseph Terriff pending passing MPJE, verification of ID, NV licenses.

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

RESOLVED to approve the Collaborative Practice Applications for

Carrs Pharmacy 1813 License number PHAR 324,
Carrs Pharmacy 1829 License number PHAR 361,
Costco Pharmacy #10 License number PHAR 339,
Harry Race Pharmacy License number PHAR 244.

Agenda Item 10 Regulations

The 11/15/11 draft regulations were reviewed and discussed.

The intention of the intern/sponsor regulations was discussed at length. A sponsor is required at each location where the intern works and the role of the sponsor to oversee the intern's work. Due to time constraints, further discussion on the draft regulations was tabled.

Agenda Item 11 Prescription Drug Monitoring Program

The board members reviewed and deliberated the revised version of the regulations from the Department of Law for *12 AAC 52, Article 9: Controlled Substance Prescription Database*. The word "licensed" was deleted from 12 AAC 52.890 for consistency in terminology with the rest of the regulation. No other changes were requested.

Upon a motion duly made by Mr. White, seconded by Ms. DeVito, with consideration for the cost to the public, and approved unanimously, it was

RESOLVED to adopt 12 AAC 52, Article 9: Controlled Substance Prescription Database, after deleting the word "licensed" in 12 AAC 52.890.

Break: Off record at 3:15 p.m.
On record at 3:35 p.m.

Forms for the PDMP program were reviewed by the board members and Program Manager to assure the intent of the regulations is captured. Discussion occurred about acceptable forms of identification for documents used for the PDMP. Accordingly, revisions were made.

Mr. Howes stated patient and prescriber education has been a recent emphasis. The kick off date for the PDMP is January 1, 2012. About 200,000 scripts are registered and approximately sixty participants have applied for access. Mr. Howes will be at the AkPhA State Pharmacist Convention in February and dispenser forms will be made available. Mr. Cotter asked how negative transactions will be captured in the database and Mr. Howes agreed to research this. Mr. Howes agreed to create a draft annual report to the legislature, as required in statute, and route it to the chair. He will also be applying for another grant.

12 AAC 52.895 Patient Request to Correct Information in the Database: The members reviewed the draft language and found it to be acceptable. Further reply was tabled until the other areas of the draft regulation are reviewed on November 18th.

Advisory Committee: Tabled until February 2012.

Data Purge for Controlled Substance Database: The board considered the Data Purge Regulation draft language submitted by Mr. Howes. They requested the draft language be sent to the Department of Law for review and comment.

Agenda Item 12 License Applications, Other

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

RESOLVED to go into Executive Session in accordance with Alaska Statute 44.62.310 (c) (2) to discuss licensing matters.

Board and staff to remain.

Off record at 4:12 p.m.

On record at 4:55 p.m.

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

RESOLVED to approve the out of state pharmacy license applications for T.S. RX Inc., El Rey RX Inc. and Coastal Express Pharmacy Inc.

Upon a motion duly made by Mr. White, seconded by Mr. Mala, and approved unanimously, it was

RESOLVED to approved the pharmacy technician applications for Brandon Romaine and Pattairya Greathouse.

Upon a motion duly made by Mr. White, seconded by Mr. Mala, and approved unanimously, it was

RESOLVED to deny the Pharmacy Technician application for Thomas Garrett based on 12 AAC 52.075 Good Moral Character.

The members substantiated this denial based on a felony conviction for Attempted Assault in the First Degree. The board members stated it was also relevant that the victim sustained a permanent injury and Mr. Garrett did not disclose a subsequent DUI in his application.

The board recessed at 5:05 p.m.

Friday November 18, 2011

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:00 a.m. Those present constituting a quorum of the board, were:

Lori DeVito, R.Ph.
Richard Holm, R. Ph.
Dirk White, R. Ph.
John Cotter, R.Ph.
Anne Gruening

Absent were Ted Mala and CJ Kim.

Agenda Item 13 Review Agenda

No changes were made to the agenda.

The chair asked for comments in response to the PDMP document *What Providers Need to Know*, distributed by Mr. Howes on November 18th. Members agreed the content was appropriate and the document is approved for use.

Agenda Item 10 Regulation Projects (continued)

12 AAC 52.120(b)(3)(A) Intern License Application Educational Requirements: The members reviewed the current educational requirements for licensing interns in 12 AAC 52.120 (b)(3)(A) and the 11/15/11 draft regulation created for board review. Members stated five year programs are nearly obsolete. The current configuration and duration of various pharmacy curriculums were discussed in detail, as well as the projected future educational requirements for a pharmacy degree. The intent of the regulation, said the members, is to educationally qualify for an Alaska Intern license after completion of the first year of the professional pharmacy curriculum. Ultimately, the board accepted the language as in the draft dated 11/15/11.

12 AAC 52.120(e) Intern License Application: The board then reviewed the draft language created to clarify an Alaska- licensed pharmacist is required for each Intern work location. The board opted to change the following language:

- "as a" was deleted from the draft.
- "each" is to replace "all."
- "locations" is to replace "assignments."

Add: *12 AAC 52.120(f)*: All sponsorship declarations must be filed at the Board of Pharmacy and a new intern license issued prior to the start of work at each new location.

12 AAC 52.240 Pharmacist Collaborative Practice Authority: The members agreed the intention was met with the deletion of several words and phrases from the draft regulations.

The chair stated, and others agreed, pharmacists prefer to work directly with physicians in Collaborative Practice Plans because this results in more actual collaboration. He noted the membership of the Medical Board has changed since the dispute over Collaborative Plans and perhaps this was a good time to "mend some bridges." The Medical Board should be made aware pharmacists can be helpful to them in their practice. Current Collaborative Practice regulations, realistically, strongly promote an ANP as the principal prescriber and discourage a physician filling this role. The board members want pharmacy licensees to work directly with medical board licensees. Nurse Practitioners with prescribing authority are in the middle. He asked Ms. Vellucci to draft a letter to the medical board to that effect. Mr. White stated, and others agreed, soon this will be forced upon medical professions by the Accountable Care Organizations (ACOs). All agreed this approach is in the best interest of the public.

12 AAC 52.460 Prescription Drug Order Information: The members noted (d) should be changed to "2-7" for consistency.

12 AAC 52.895 Correcting Justice Information in (PDMP) Database: Mailing and physical address were added to (1) (B)

The 11/15/11 draft regulations for *12 AAC 52.350 Audits of Records by the Board* were revisited. The intent is to incorporate CE data that will be provided by the CPE Monitoring Program, beginning January 1, 2012. Ms. Vellucci acknowledged the assistance provided by the NABP in creating this draft language and noted it was forwarded to Dan Branch at the Department of Law for further review. The board agreed to the verbatim draft language.

No changes were recommended to the draft language of

- *12 AAC 52.200 Pharmacist in Charge*
- *12 AAC 52.350 Audit of Records by the Board.*

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

RESOLVED to make the following edits to 11/15/11 draft regulations and then public notice to all licensees:

12 AAC 52.120(e) Intern License Application: delete "as a"; replace "all" with "each"; replace "assignments" with "locations," add "(f) All sponsorship declarations must be filed at the Board of Pharmacy and a new intern license issued prior to the start of work at each new location."

12 AAC 52.240 (j) Delete beginning with "a new collaborative practice..." through end of (j); (k) Delete "renewal" in both usages.

12 AAC 52.460 (d) replace "(c) (2)-(6)" with "(c) (2)-(7)"

12 AAC 52.895 (1) (B) add "and physical" address.

The members requested a response at the February meeting to pending inquiries pending from September:

- 1) Does the Board of Pharmacy have statutory authority to create a regulation project similar to the Iowa Drug Repository?
- 2) What would it take for the Board of Pharmacy to have control of medication across the state, regardless of their location?

Break: Off record at 10:35 a.m.
On record at 10:48 a.m.

Agenda Item 14 Old Business

Mail Ballots: The members briefly reviewed the written information and instructions created by Lara Brown, Publications Technician, which addressed the new procedure for online monthly mail ballots. They were informed the methods were scrutinized by IT and other division staff to assure the security of the information on the server and two separate passwords will be required. The process and documents were well received, and the members had no further questions.

Intern Questionnaires: For the benefit of the newer members, Chair Holm said the objective is to create a new bank of questions for the intern questionnaire. Currently there are 40-50 new questions. Mr. Cotter, a

agreed to create ten additional questions and route them to Ms. Vellucci. The questionnaire will be updated accordingly. Initial research has been done to place the intern questionnaire on the board's web server. This will be revisited after the division's new databases are installed and well functioning.

Agenda Item 16 New Business

Pharmacist and Pharmacy Technician Renewal Jurisprudence Questionnaire: The intern questions discussed in Agenda Item 14 will be edited as needed for scope of practice and used with renewals for pharmacists and pharmacy technicians. The Chair asked the members to review the existing renewal jurisprudence questions prior to the next board meeting by screening for relevancy and editing as indicated.

The board members reviewed and discussed the revised SOA *Policy and Procedure #28, Subject: "Yes" Answers on License Applications and Renewals* in relation to the 2012 renewal procedures and form revisions. Ms. Vellucci stated she has notes about revisions for the renewal forms and agreed to provide drafts to the board members by December 31st. The drafts will be discussed during the February meeting.

Formal Request to the Division: The members unanimously agreed to the content of the following four point formal request:

- 1) *Business cards:* Board members need business cards by the February meeting. If there is a reason they cannot be provided, please explain.
- 2) *Credentialing:* From time to time, board members need to prove they are, in fact, members of the Alaska Board of Pharmacy. Ms. Vellucci asked what they had in mind by "credentialing" and was told it should be official identification including a photo, lamination, name and affiliation with the Alaska Board of Pharmacy. The Chair added at any time a member may be called upon to assist in an investigation or conduct an inspection. There is reason to believe this will occur in the near future. The person or facility being inspected or investigated has the right to ask for professional identification and the board members must be able to readily provide it. The chair noted the board member's authority goes beyond the authority of an investigator and they have the right to inspect any pharmacy at any time. The members suggested the Division look at the identification provided to investigators as a sample. It was noted that not all boards may need this type of credentialing.

- 3) *IPads or Tablets:* The pharmacy board members want to beta test implementation of I pads or tablets for board business. This would eliminate reams of paper, reduce the cost of conducting board business and help assure confidentiality of information. Currently emails and other board business are being routed to members' personal computers which have the potential for confiscation in a legal action. A board member's participation in board business litigation could result in the confiscation of his/her computer(s), which would also cripple the running of his/her personal business and contain other personal information. A dedicated I pad or tablet would be a secure method of receiving emails and other board business. Because the membership on the Board of Pharmacy is relatively small, they could beta test for other professional licensing groups, assess benefits and address any problematic areas. If implemented division-wide, the savings realized from the buying power of the State of Alaska would be substantial. Chair Holm stated the Fairbanks City Council researched this at the municipality level and the cost savings were significant.

- 4) *Renewal form online availability:* The board requested renewal forms be available on line on April 1st. Ms. Vellucci told the new members the renewal form release date was driven by the date the fees were approved by the legislature, the attempt to make the online renewals available and the statutory requirement to make renewals available within thirty days of the license expiration date.

Agenda Item 18 Office Business

The board members signed wall certificates and submitted Travel Authorizations.

Adjourned 11:45 a.m.

Respectfully Submitted:

Approved:

Mary Kay Vellucci,
Licensing Examiner

Dick Holm, Chair
Alaska Board of Pharmacy

Date: _____