

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

ALASKA STATE BOARD OF PHARMACY

MINUTES OF MEETING
September 23-24, 2010

These 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 September 23-24, 2010 at the Atwood Building, 550 West 7th Ave., Suite 602.

Agenda Item 1 Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:03 a.m. Those present constituting a quorum of the board, were:

Anne Gruening, Public Member
Leah Handley, Public Member
Richard Holm, R. Ph.
Dirk White, R. Ph.
C. J. Kim, R. Ph.

Absent:

Steven Johnson, R.Ph.
Mary Mundell, R.Ph.

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

Mary Kay Vellucci, Licensing Examiner
Brian Howes, Senior Investigator
Susan Winton, Senior Investigator
JoAnna Williamson, Investigator
Don Habeger, Division Director

Visitors present:

Mark Billingsworth, Attorney
Nancy Davis, AkPha

Agenda Item 2 Review of Agenda

The board reviewed the agenda. There were no changes.

Agenda Item 3 Review of Minutes

The board reviewed the minutes from the May 20-21, 2010 meeting. No edits or changes were indicated.

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

RESOLVED to accept the minutes of the May 20-21, 2010 Pharmacy Board Meeting as written.

The board also reviewed the minutes from the August 20, 2010 teleconference. The phrase "considering the cost to the public" was removed from the motion because 1) there was no cost to the public for this advertising and 2) cost to the public is considered when a motion is adopted.

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

RESOLVED to approve the minutes of the May 20-21, 2010 Pharmacy Board Meeting as amended.

Agenda Item 4 Ethics Disclosure/Goals and Objectives

The Revised Proposed Changes to Ethics Regulations in Title 9 of the AAC were distributed in the board packets. The members acknowledged their receipt and had no additional comments.

Ms. Handley reported she had been in touch with Jason Hooley at Boards and Commissions regarding a potential conflict of interest based on her employment as a CNA and dental assistant. She was told this role was likely to be interpreted as having a "financial interest" in the health care field. Mr. White stated her salary did not have any bearing on increasing profit level or margin, nor did Ms. Handley's position involve hiring or recruiting. Ms. Vellucci suggested a letter be written to Mr. Hooley explaining this point, including Ms. Handley's job descriptions. All board members agreed Ms. Handley's insights and contributions to the Board of Pharmacy and the public were valuable and the goal was to retain her as a public member.

There were no other Ethics matters or violations.

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

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 was 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 drug monitoring program.

Agenda Item 4

Division Update

The board members reviewed the Annual Report and the Expense Reports of September and May 2010. Ms. Vellucci explained the Personal Services Expenses in the Expense Reports were defined as the costs incurred from internal coworkers such as the paralegal, regulations specialist and those who assisted with processing renewals.

Mr. Holm reviewed the Annual Report. A discussion ensued about the number of licensed pharmacists in Alaska and the declining job market for pharmacists down South. This was particularly true in metropolitan areas or "prime locations" and for new graduates. Mr. Kim commented moving expenses were still customarily employer-paid for new hires in the Anchorage area, but sign-on bonuses were no longer provided. The more rural areas of Alaska, historically underserved, would benefit by this trend because positions were still available, generally speaking.

Registration of Wholesale Distributors legislative project was discussed. Mr. Holm requested this be added to the agenda of the next board meeting.

The board had no other questions or comments.

Agenda Item 5

CE Audit

The board reviewed the proposed Non-Disciplinary Consent Agreement, Decision and Order for Case No. 2010-0000639 as well as her certificates of continuing education.

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

RESOLVED to accept the Non-Disciplinary Consent Agreement, Decision and Order for Case No. 2010-0000639.

This motion applied to pharmacy technician, Ashley Martinez.

Agenda Item 6

Correspondence

General Correspondence: An article on Hepatitis C Infection Control addressed tattooing as a major route of hepatitis C infection. Ms. Handley commented this information should be provided in the school systems as part of their health education. Ms. Vellucci informed the board this article will be included in the October, 2010 board packets for the Board of Barbers and Hairdressers (which includes Body Art) for their consideration.

The board clarified written prescriptions did not have to be stored in the pharmacy per se, although they did have to comply with HIPPA and Security standards. Mr. Kim commented some insurers require prescriptions be kept for seven years and Mr. White added Medicare wanted to be able to audit up to eleven years.

There was a brief discussion about locating the regulation, possibly with the SEC Stark Act, which speaks to potential illegalities related to the use of Automatic Dispensing Systems. It was suggested Mr. Johnson may be able to identify this. Ms. Vellucci will contact him.

A correspondence from an attorney with Locke Lord Bissell & Liddell LLP in Austin Texas was reviewed by the board. The inquiry was essentially about the licensing requirements to establish an off-site call center for a large pharmacy. Mr. Holm pointed out the key factor was accessing patient information. If an incoming call required the answerer to view patient information, it would then be HIPPA protected information and subject to Alaska licensing requirements. Also, if ultimately an out of state pharmacy was being operated (under the guise of a "call center"); the facility must be appropriately identified and licensed as such. Beyond that, the board determined the correspondence was too vague to reply with any other degree of specificity.

NABP: The board was made aware exam scores were now available on the NABP website and there will soon be a link to the scores on the Alaska Board of Pharmacy website. As a result of that conversation, Mr. Holm asked about online license renewals. Ms. Vellucci informed the group there was a concerted effort to renew online but a technical problem with posting payments was not be resolved in time for pharmacy renewals.

A September 9th NABP memo introducing the Government Affairs Department and listed their goals was reviewed by the board. They will be contacting each state board to identify state-specific pharmacy practices and issues.

Break: Off record at 10:30 a.m.
On record at 10:46 a.m.

Agenda Item 7

MPJE Item-Writing

The board reviewed correspondences from Maria Boyle at the NABP regarding the MPJE State Specific Review Process and made the following points in response:

- It was an extremely time consuming process.
- It required focusing without distractions.
- Realistically, it could not be accomplished in the home setting.
- Reference materials were needed.
- Since there are nearly 2,000 questions to review, it could not be done in one sitting.
- The on line materials provided to perform this task were difficult to use due to the large amount of text in small areas over multiple columns.

Mr. Holm stated this task was formerly done at a convention in Chicago designated for this purpose. The necessary reference materials were provided and consulting with colleagues was available. The pharmacist board members agreed this method was more conducive to the task at hand. A board member suggested the NABP add one or two days after the annual conference in late February for MPJE item-writing. This would address the concerns identified by the board. Mr. White and Mr. Kim may be available for item-writing, however, the board's position was to first pursue a setting which addresses their concerns, such as suggested above. This information will be forwarded to the NABP by Ms. Vellucci.

Lunch: Off record at 12:10 p.m.
On record at 1:12 p.m.

Agenda Item 8

New Business/Violation Issues

The board considered the current processes by which violations were reported to the Division and reviewed by the board. The board expressed several concerns. First, when infractions were board-reviewed, the board may only see the most recent event unless a document required for board review, such as the Investigative Memo, mentioned prior infractions. The board wanted a list of the cumulative violations and penalties for a given licensee during their review. This information will be routed to Investigations per Ms. Vellucci.

Secondly, Alaska has no inspectors and is self-inspected. A discussion about possible solutions ensued and Hawaii's violation reporting regulations were reviewed by the board. Chapter 436B Professional and Vocational Licensing Act, 436B-19 requires the Hawaii Board of Pharmacy to be notified of any disciplinary decisions within thirty days. The pros and cons of this approach were discussed and existing Alaska regulations regarding violation reporting were visited.

Mr. Holm stated, and the others agreed, a regulation project similar to Hawaii's was indicated. The rough text of the regulation would be "require the licensee or applicant to report in writing to the Alaska Board of Pharmacy any disciplinary decision issued against the licensee or the applicant in another jurisdiction within thirty days of the disciplinary decision." There was discussion about whether this would require a statute change or a regulation project. Ms. Vellucci agreed to research regulation about violations across license types, consult with the Regulations Specialist and Investigations and then report back to the board.

Agenda Item 9 Old Business/Reinstatement of Expired Pharmacist Licenses

If a pharmacist was applying for reinstatement of an Alaska license that was been expired for two to five years, the applicant was not required to submit of Verifications of Licensure (aka "letters of good standing") or Employment Verification for the period the license is lapsed. Mr. Kim explained how this created gaps of relevant information and the potential risk associated with it. The board then reviewed the pharmacist licensing requirements for licenses expired more than five years and the requirements for an initial licensing.

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

RESOLVED to add to 12 AAC 52.310 (c) requirements for reinstatement of a pharmacist license expired between two and five years 1) submit an official verification of licensure from each state in which the applicant has ever held a license, regardless of whether or not it has expired and 2) provide verification that the applicant has continually practiced pharmacy in another state under a license issued by the authority of that state for the period that the license has been expired and by meeting the requirements of 12 AAC 52.090 (a).

Agenda Item 10 AkPhA Report

Ms. Davis reported since May there had been five live oncology lectures at Providence, which were available by remote teleconference to other locations in the state. The Diabetes Dispatch, a quarterly home study, was also available during this time. AkPhA will be providing ONS Chemo & Biotherapy course on September 27-28 and Immunization Delivery on October 6th. On May 10-11, 2011 the Alaska Immunization Conference will be held for the first time. The Alaska Diabetes Conference will be held on December 1st-3rd. The State Convention will be held February 18-20 at the Anchorage Downtown Marriott. CPR recertification and "Delivering MTM services in the Community" certificate program will be available.

The first National Take Back Day will occur in Anchorage on Saturday September 25th. A discussion ensued about how this is being implemented throughout the state.

From the Pharmacy Education Committee, Creighton has opened five pharmacy slots for Alaska students and will provide preceptor training/live CE at the 2011 convention. The association plans to lobby for a position at UA to advocate for pharmacy. The AkPhA Technician Advocacy committee requested the PTCB provide more testing sites in Alaska for technicians planning to take the PTC Exam. PTCB was considering adding Juneau as the additional site. ACPE and NABP were developing a continuing pharmacy education tracking system that will authenticate and store data for completed continuing education.

Lunch: Off record at 12:14 p.m.
On record at 1:12 p.m.

Agenda Item 11 PDMP

The PDMP 8/24/10 revised PDMP regs were distributed in the board packets. Mr. Howes joined the meeting. Mr. Holm noted the regs had not yet gone out to public notice. Mr. Habeger informed the board there was an interim procedure in place at the commissioner's office. Because of this, regulation projects were on hold until approximately mid-November.

Mr. Holm initiated a conversation about Solicited Profile Requests 12 AAC 52.875 (c) (1) *"all requests shall be made in person to the office of the board's agent"* and (d) *"any profile generated by the board will be available at the office of the board's agent."* He stated this was inconvenient for people outside of Anchorage. Personal identification needed to be accomplished in a manner that equally accommodated residents of all parts of the state, regardless of location. Providing a notarized statement with photo identification and using certified return receipt postal mail was agreed upon as an acceptable alternative. Mr. Howes would revise the regs on these points and distribute to board members. They could then be reviewed and adopted if acceptable during tomorrow's session or via teleconference.

Agenda Item 12 Regulation Projects

Mr. Branch joined the meeting via teleconference.

Shared Pharmacy: The regulations adopted at the May meeting were filed at the Governor's office and became effective September 11, 2010. The Statutes and Regulations were updated.

Job Shadowing: Mr. Branch routed a revision to 12 AAC 52.250 (a) (b) which contained some grammatical corrections to (b), the requirements for a student less than eighteen years old and (f) the definition of "preceptor." The Job Shadowing documentation form was also reviewed by the board and accepted.

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

RESOLVED to adopt 12 AAC 52.250 Job Shadowing in Pharmacy as amended, considering the cost to the public.

Remote Pharmacy: Mr. Branch stated he initially had concerns about the board's statutory authority with the Ten Mile Rule restriction in 12 AAC 52.423. He consulted with multiple colleagues and attorneys and determined the regulation, including the Ten Mile Rule, could pass legal scrutiny. To this end, the Board of Pharmacy also needed to adopt a resolution describing how 12 AAC 52.423 also serves the board's Statement of Purpose *to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy.* He then listed the following recommendations for regulatory changes:

1. Add regulatory standards to determine whether granting a remote pharmacy license would be in the public interest. A version of this concept was in the May, 08 regulations. It stated the purpose of the regulation was to serve a community which had no access to an established pharmacy or face to face contact with a pharmacist.

2. Add to 12 AAC 52.423 (b) (1) language stating the central pharmacy must comply with 52.420 (Security) and 52.425 (Telepharmacy System for a Remote Pharmacy) in order to obtain licensure.
3. Add a requirement that remote pharmacy licenses must be renewed to continue operation, as with other pharmacy licenses. This was discussed during the February 09 board meeting. The purpose was to state the required response if a brick and mortar pharmacy opened within a ten mile radius after the remote license was granted. Mr. Branch stated Texas grandfathers in the remote pharmacy if this occurred. Wyoming, however, only permitted the remote pharmacy to practice through the end of the licensure year if a pharmacy opened within a 25 mile radius.
4. Define or remove the term *trade area* in 12 AAC 52.423 (c) so the meaning of "community" is clear.
5. Include an exemption to the Ten Mile Restriction in the event the brick and mortar pharmacy was not serving all the members of the community, such as a pharmacy on a military base.

Mr. Branch offered to work 1:1 with the licensing examiner or a board member on these recommended changes. Mr. Holm suggested, and the other board members agreed, Mary Mundell may be interested in this project. The board as a whole was extremely pleased with Mr. Branch's work on the remote pharmacy regulations and Mr. White described it as a "home run."

Medical Marijuana: Mr. Holm stated the goal of this regulation project was to provide a safer means of providing medical marijuana for Alaskans. This required establishing a safe, clean source of marijuana that was grown in the State of Alaska, creating quality control measures to scrutinize the product, providing medical marijuana in a pharmacy by prescription and tracking the recipients. When these objectives were met, pharmacists would then feel safe and compliant dispensing it. A discussion occurred identifying the necessary statutory and regulatory changes in order to accomplish these goals.

Mr. Branch said, according to the Alaska Supreme Court and the Medical Marijuana Initiative, there was no requirement for marijuana to be prescribed. There were also no provisions for it to be legally purchased, leaving growing the only option. Mr. Holm added, and Mr. White agreed, the low limit on the number of allowable plants did not meet the needs of people who use it for medical purposes. It could not be harvested fast enough. This forced patients to purchase an unsafe product from the street and put them in harm's way. There are no controls on street product and frequently it contains substances such as meth, PCP and other illicit additives. It was also noted for the record Alaskan prescribers were in fact writing prescriptions for medical marijuana which could not be filled. Mr. Branch illustrated the contradiction in laws by reiterating, per the Supreme Court, a prescription was not required. Mr. Holm stated it was within the authority of the State of Alaska to change this contradiction and require a prescription for medical marijuana. Mr. Branch added the Medical Marijuana Statutes did not negate the criminal liability found in Title 11, although they did provide an affirmative defense for the patient, the caregiver and the prescriber in the event of criminal prosecution.

For the Board of Pharmacy to have statutory authority in this regard there would need to be three different statutory changes: the Criminal Statutes in Titles 11 needed to extend the affirmative defense to a pharmacist; the Medical Marijuana statutes in 17.37 which defined its use and procedures; and the Board of Pharmacy's 08.80 statutes so pharmacists could not be prosecuted for dispensing medical marijuana. The road blocks needed to be identified and removed with exception. The Board of Pharmacy then needed to create new regulations regarding Medical Marijuana. He anticipated there would also be coordination with the prescribing boards.

Mr. Branch suggested two ways of doing this. First, get the involvement of the Commissioner of Commerce and ask for this to be an official governor's bill. The Department of Law would then draft the legislation. Second, acquire a sponsor in the legislature to take on the project. They have their own legal team who would draft the bill.

Mr. White said the best option, as he saw it, was to get it on board as a governor's bill, then get co-sponsors on both sides of the house and senate. Mr. White and Mr. Holm stated they know interested legislators.

Mr. Branch pointed out the Dept. of Commerce had a time limit for filing new legislation. Mr. Habeger, Division Director, informed the board that time has come and gone. Information from the boards has already been gathered, routed through the Commissioner's process and was now at the Administrative level.

Ms. Vellucci mentioned Medical Marijuana was identified specifically as a Recommendation for Proposed Legislation for FY 2011 in the Board of Pharmacy's Annual Report and asked if this would further the goal of the board. Mr. Habeger said there wasn't model legislation before them to work through and we were beyond the point where draft legislation could be constructed. He added Investigations wanted an Omnibus Bill which was apparently taking priority. Therefore it wasn't likely this stream was available to the Board of Pharmacy.

Mr. White said we could identify sympathetic legislators to introduce to this and follow that path. He added there were people in South East Alaska who were trying to set up dispensaries. That was precisely what the board was trying to avoid. For this reason, time was of the essence. Mr. Branch said he did not think a dispensary could legally be done. Mr. White replied it was not legal in California either but a blind eye was being turned. There are 1,100 dispensaries in Los Angeles alone, according to Mr. Holm.

Mr. Branch could not do any legislative drafting without it going through the Bill File, the Commissioner Office, the Governor's Office and the AG. If the board got someone from the legislature interested in this bill, s/he could have the Legislative Legal Attorneys, who are expert drafters, create the actual bill. He thought the complete set of goals already identified by the Board of Pharmacy would be of great benefit toward this end. Technically, the work done by Legislative Legal would be confidential to the legislator and neither Mr. Branch (Department of Law) nor Administration would have access to it. This requirement, however, could be waived. Mr. White asked if this project would present a conflict of interest, or any variation thereof, should a pharmacist or pharmacist board member become involved in it at as a political activity. Mr. Branch stated sponsoring legislation was common among board members and practitioners and there was no conflict.

It was noted pre-session submissions for legislation are due January 1. Although legislation could be introduced at any time, pre-session submissions have the best

likelihood of success. Mr. Habeger offered to talk to the Department's legislative liaison to determine if he thinks it would have acceptance in Administration. He will report to Ms. Vellucci so the information can be forwarded to the board members. Mr. White said he would present this to AkPhA's legislative committee as well. Mr. Branch said he was available for questions as the board worked through this process

Temporary Pharmacist Regulations and Changes to CS II Prescriptions: Mr. Branch answered procedural questions about how to repeal the obsolete regulations regarding Temporary Pharmacist Licensing Regulations and add regulations to clarify what items can be changed on a CS II prescription. These topics would be revisited on September 24th.

Mr. Branch disconnected from the meeting.

Break: Off record at 2:30 p.m.
On record at 2:52 p.m.

Agenda Item 13 Public Comment

There were no participants for public comment.

Agenda Item 14 Tabled Renewals and "Yes" Application

JoAnna Williamson, Investigator, joined the meeting.

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

RESOLVED to go into executive session in accordance with AS 46.62.310 (c)(4), to discuss the license application for Mini Pharmacy and Tabled Renewals.

Board staff, Investigator and Mark Killingsworth to remain for the discussion regarding Mini Pharmacy. Board staff and Investigator to remain for the discussion regarding Tabled Renewals.

Off the record at 3:50 p.m.
On the record at 5:30 p.m.

Licensing decisions were read into the record:

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

RESOLVED to approve the Out of State Pharmacy application for Mini Pharmacy.

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

RESOLVED to approve the Out of State Pharmacy Renewals for Arkansas Valley AccuMed license #746 and Custom Prescription Shoppe license #624.

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

RESOLVED to deny the Out of State Pharmacy License Renewal #740 for COLLEGE PHARMACY under the following statutes and regulations:

Statute 08.80.157 LICENSING OF FACILITIES

- (d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest;
- (g) A licensed facility shall report to the board
- (4) conviction of an employee of violation of a state or federal drug law;
- (h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:
 - (1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;
 - (2) a felony conviction under federal, state, or local law of an owner of the facility or pharmacy or of an employee of the facility or pharmacy;

Regulation 12 AAC 52.920 DISCIPLINARY GUIDELINES

- (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:
 - (2) dispensing drugs to an individual or individuals in quantities, dosages, or for periods of time that grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; this paragraph does not apply to prescriptions dispensed to persons with intractable pain or to a narcotic drug dependent person in accordance with the requirements of 21 C.F.R. 1306.07, as amended as of February 6, 1997;
 - (3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

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

RESOLVED to deny the Out of State Pharmacy License Renewal #695 for FRANCK'S COMPOUNDING LAB under the following statutes and regulations:

Statute 08.80.157 LICENSING OF FACILITIES

- (d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest;

Regulation 12 AAC 52.920 DISCIPLINARY GUIDELINES

(a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

(2) dispensing drugs to an individual or individuals in quantities, dosages, or for periods of time that grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; this paragraph does not apply to prescriptions dispensed to persons with intractable pain or to a narcotic drug dependent person in accordance with the requirements of 21 C.F.R. 1306.07, as amended as of February 6, 1997;

(3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

(5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;

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

RESOLVED to deny the Out of State Pharmacy License Renewals #790 and #679 for PRIME THERAPEUTICS under the following statutes and regulations:

Statute 08.80.157 LICENSING OF FACILITIES

(d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest.

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(4) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

Statute 08.80.261 DISCIPLINARY SANCTIONS.

(a) 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,

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the applicant's or licensee's supervision that does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(7) is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety for the public because of

(A) professional incompetence;

(E) other factors determined by the board;

(11) violated state or federal laws or regulations pertaining to drugs or pharmacies;

(14) engaged in unprofessional conduct, as defined in regulations of the board.

Regulation 12 AAC 52.920 DISCIPLINARY GUIDELINES

(a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

(1) knowingly dispensing a drug under a forged, altered, or fraudulent prescription drug order;

(3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

(4) acquiring, possessing, or attempting to possess prescription drugs in violation of AS 08.80, AS 11.71, or this chapter;

(5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;

(6) refusing or failing to keep, maintain, or furnish any record, notification, or information required in AS 08.80 or this chapter;

(13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter;

(15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;

(18) violating AS 08.80.315 dealing with the confidentiality of records;

(c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee

(1) willfully or repeatedly violates AS 08.80 or this chapter; or

(2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk

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

RESOLVED to deny the Out of State Pharmacy License Renewals #698 for EXCELLRX PA DBA Hospice Pharmacia, # 930 for EXCELL RX & # 684 for ExCellRX Inc. under the following statutes and regulations:

Statute 08.80.157 LICENSING OF FACILITIES

(d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest.

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(4) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

Statute 08.80.261 DISCIPLINARY SANCTIONS.

(a) 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,

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities; federal legend drugs;

(11) violated state or federal laws or regulations pertaining to drugs or pharmacies;

(14) engaged in unprofessional conduct, as defined in regulations of the board.

12 AAC 52.920. DISCIPLINARY GUIDELINES. (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

- (3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;
- (4) acquiring, possessing, or attempting to possess prescription drugs in violation of AS 08.80, AS 11.71, or this chapter;
- (5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;
- (6) refusing or failing to keep, maintain, or furnish any record, notification, or information required in AS 08.80 or this chapter;
- (8) making a false or fraudulent claim to a third party for reimbursement for pharmacy services;
- (10) making a false or fraudulent claim concerning a drug;
- (13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter;
- (20) offering, giving, soliciting, or receiving compensation for referral of a patient;

Recess until 9:00 a.m. Friday, September 24, 2010
Off the record at 5:50 p.m.

Friday, September 24, 2010

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair at 9:02 a.m. Those present constituting a quorum of the board, were:

Anne Gruening, Public Member
Leah Handley, Public Member
Richard Holm, R. Ph., Chair
C. J. Kim, R. Ph.
Dirk White, R. Ph., Vice Chair

Absent:

Steven Johnson, R.Ph.
Mary Mundell, R.Ph.

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

Susan Winton, Senior Investigator
JoAnna Williamson, Investigator
David Newman, Investigator

Agenda Item 15

Review of Agenda

The pending motions regarding temporary pharmacist licensing and changes to CS II prescriptions were added to the agenda after the break.

Agenda Item 16

License Applications

The records from the Application List of the board packet were distributed to the board members for review.

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

RESOLVED to approve the pharmacist license applications for

Jennifer Cropp: no items pending.

Callista Carlton: no items pending.

Margaret Davis: pending passing MPJE score and Verification of Work Experience.

Jed Foutz: no items pending.

Katelyn Hilton: pending passing Naplex score.

Natasha Hoerrmann: pending passing MPJE score.

Jami Jain: no items pending.

Callie Ann Jones: Verification of Non Educational Intern Hours.

Rachel McEldowney: pending passing MPJE score & Verification of License from CA.

Marilee Obritsch: pending passing MPJE score.

Monica Orsborn: pending passing MPJE score, \$200 license fee, Verification of Work Experience.

Emily Purrenhage: no items pending.

Anthony Que: pending passing MPJE score.

Maria Seeke: pending passing MPJE score, Verification of License from WY & transcripts.

Michael Stamper: pending passing MPJE score.

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

RESOLVED to approve the Collaborative Practices for

Bernie's Pharmacy: no items pending.

Providence Medical Arts Pharmacy R462: no items pending.

Providence Medical Arts Pharmacy R460: no items pending.

Target R466: pending plan to provide practitioners with each patient record under the protocol.

Target R450: pending plan to provide practitioners with each patient record under the protocol and documentation of the two year limit.

Target R444: pending plan to provide practitioners with each patient record under the protocol and documentation of the two year limit.

Review of license application reviews with “yes” answers would occur after the Investigative Report.

Agenda Item 17 **Investigative Report**

Ms. Williamson introduced Mr. Newman as the new investigator for the Board of Pharmacy. Ms. Williamson will be the investigator for the Nursing Board. Mr. Newman described himself as a retired attorney. He is also the Investigator for the Medical Board, Psychologists, Professional Counselors, Social Workers and Marital and Family Therapists.

Ms. Williamson distributed the Investigator’s Board Report. She reviewed the closed, new and open complaints and explained the new number structure for investigative cases. It was noted there was an overall decrease in the number of open complaints and investigations.

A plan was made for the licensing examiner and pharmacy investigator to touch base monthly, prior to sending mail ballots to the board members, to stay current on the status of investigative case work.

Agenda Item 13 **License Applications**

The board referred to the pharmacy applications with “yes” answers in the board packets. Ms. Winton joined the meeting.

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

RESOLVED to go into executive session in accordance with AS 44.62.310(4), to discuss investigative and licensing matters.

Board staff, investigator to remain.

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

RESOLVED to approve the pharmacy technician applications for Stacey Ryherd and Danielle Miller.

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

RESOLVED to approve the pharmacist applications with “yes” answers for Jessica Tilbury pending proof of intern hours and passing exam scores and Sarah Munson pending verification of work experience and passing MPJE score.

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

RESOLVED to deny the Out of State Pharmacy License Renewal #653 for AETNA SPECIALTY PHARMACY LLC under the following statutes and regulations:

Statute 08.80.157 LICENSING OF FACILITIES

- (g) A licensed facility shall report to the board
- (4) conviction of an employee of violation of a state or federal drug law;
- (h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:
 - (1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

12 AAC 52.920. DISCIPLINARY GUIDELINES.

- (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:
 - (13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter.

Break: Off record at 10:54 p.m.
On record at 11:15 p.m.

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

RESOLVED to approve the pharmacist application with “yes” answer for Jacquelyn Goldberg.

On a motion duly made by Ms. Handley, seconded by Ms. Gruening, and approved unanimously, it was

RESOLVED to approve the pharmacist application with “yes” answer for Jim Lampkins.

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

RESOLVED to approve the Out of State Pharmacy license application for KV Vet Supply.

Ms. Winton left the meeting.

Agenda Item 12

Regulation Projects (cont'd)

Temporary Pharmacist Regulations: Each aspect of pharmacist licensing was discussed by the board. Ultimately, given the improvements in technology, no specific requirement was identified as being consistently responsible for delaying issuance of a pharmacist license. It was reiterated this regulation was obsolete and only served to create misunderstandings about Alaska pharmacist licensing options.

On a motion duly made by Ms. Handley, seconded by Ms. Gruening, and approved unanimously, it was

Resolved to send for public comment the repeal of 12 AAC 52.100 Temporary Pharmacist License and its correlated references in 12 AAC 52.010 (a) (2) and 12 AAC 52.090(b)

The board acknowledged Statute 08.80.150 addresses Temporary Licenses. They requested feedback from the Regulations Specialist to determine how temporary licenses can be repealed given that statute. The board requested this public comment be advertised in the standard manner.

Changes to CS II Prescriptions: Mr. Holm stated there continues to be misunderstandings and misinterpretations about the changes to CSII prescriptions allowed by the DEA. One obstacle was locating the allowed changes among the volumes of DEA documents, manuals and related materials. He read into the record (below) the exact text proposed to be added to the Board of Pharmacy Controlled Substances regulations. The group agreed to the wording below and directed this text be sent out for public comment.

On a motion duly made by Ms. Handley, seconded by Ms. Gruening, and approved unanimously, it was

Resolved to send for public comment the following text be added to the Board of Pharmacy Controlled Substances regulations: "A pharmacist can modify or add the following information to Schedule II prescriptions after oral consultation with the prescribing practitioner (not his agent):

- 1. Date of issue – may be added but not changed**
- 2. Patient's address**
- 3. Drug strength**
- 4. Drug dosage form**
- 5. Drug quantity – may be modified in conjunction with change in strength only, but not to exceed the original total dosage prescribed**
- 6. Directions for use**

A pharmacist may never change the name of the drug (except to generic), name of the patient or the signature of the practitioner."

The board requested this public comment be advertised in the standard manner.

Agenda Item 20

Federal Facilities

Peter Putzier from the AGO prepared a written statement to be read in Executive Session on this subject.

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

RESOLVED to go into executive session in accordance with AS 44.62.310 (4), to discuss matters involving consideration of government records from the Attorney General's Office.

Board staff to remain.

Off the record at 11:50 a.m.
On the record at 11:59 a.m.

Agenda Item 19 Automatic Dispensing Systems

Board packets included a September 2, 2010 Summary regarding Automatic Dispensing Systems written by Ms. Vellucci and a July 29, 2010 Medical Board Meeting item regarding physician self-referral. Ms. Vellucci stated, as noted in the summary, the definition of "Physician Dispensing" was necessary to move forward on this issue. She will draft a letter to the Medical Board requesting this definition, submit it to Mr. Holm for review and then route it to the Medical Board for consideration and response.

Agenda Item 20 Office Business

The board scheduled the 2011 meetings in Anchorage on

February 17-18, May 19-20 and Sept 22-23.

The board considered the AkPhA State Convention, schedule February 18-20. Mr. Holm stated several reasons it would be beneficial to have the licensing examiner at the convention. He will route an email Don Habeger, Division Director via Ms. Vellucci asking for authorization for this expense in behalf of the board. It was noted the licensing examiner will already be in Anchorage for the February board meeting, therefore the additional costs will be minimal. Mr. White suggested a motion be made on the record to document the board's support.

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

RESOLVED to make a formal request to the Division for funds to allow the licensing examiner to attend the Alaska State Pharmacists Association convention February 18-20, 2011.

The board elected the following officers for 2011:

Chair- Dick Holm

Vice Chair- Dirk White
Secretary- Christopher Kim

The board signed the wall certificates and made arrangements for Travel Authorizations.

The board adjourned at 12:24 p.m.

Respectfully Submitted:

Mary Kay Vellucci, Licensing Examiner

Approved:

Dick Holm, Vice Chair
Alaska Board of Pharmacy

Date: _____