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 28-March 1, 2013

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 28-March 1, 2013, at 333 Willoughby Ave., 9th Fl., Conference Room C, Juneau, Alaska.

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair, February 28, 2013, at 9:03 a.m. Those present constituting a quorum of the board, were:

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

Mr. Holm noted the board had a vacant public member position.

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

Sher Zinn, Licensing Supervisor
Brian Howes, Senior Investigator- via telephone
Al Kennedy, Investigator- via telephone
Jun Maiquis, Regulation Specialist
Dan Branch, Assistant Attorney General
Don Habeger, Director

Visitors present:

Caren Robinson
Patricia Senner

Agenda Item 1 **Review Agenda**

The board reviewed the agenda and no changes were made. Mr. Holm noted Caren Robinson would be present for Agenda Item 9.

On a motion duly made by Lori DeVito, seconded by Dirk White, and approved unanimously, it was

RESOLVED to approve the agenda as written.

Agenda Item 2 **Review Minutes**

The board reviewed the minutes from the November 15-16, 2012 meeting. No changes were made.

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

RESOLVED to approve the minutes of the November 15-16, 2012 meeting.

The board chair signed the minutes.

Agenda Item 3 **Ethics Disclosure**

There were no ethics violations to report

Agenda Item 4 **Division Update/Expense Report**

The board reviewed the expense report. Ms. Zinn explained the attached notification from Sara Chambers regarding the explanation of the increase in indirect expenses. The board made no comment on the information.

Agenda Item 6 **FDA Conference**

Mr. Holm gave an update of the FDA conference he attended in December, in Washington, DC, regarding compounding pharmacies. State boards of pharmacy were invited to attend the one day meeting. The state boards in attendance concluded it was the state's purview to regulate compounding pharmacies. Mr. Holm noted the board worked on the issue prior to the conference.

Mr. Cotter said he did not want to do business with any compounding pharmacy in the future unless they were PCAP accredited. He said he felt the board's current regulations were not tight enough for sterile compounding and the board should require the pharmacy to meet USP 797 standards. The board further discussed the issue and determined to table the discussion to a future meeting.

Agenda Item 5 **PDMP Update**

Brian Howes joined the meeting via telephone for the Prescription Drug Monitoring Program update. Mr. Howes stated the PDMP had a new vendor which would start in March. The new system will use the person's license number instead of the NPI number. For those currently using the PDMP, there would be an option of using the NPI or the license number. Test data would start March 15th.

Mr. Howes asked the board to consider initiating a regulation to allow pharmacists and prescribing practitioners to use delegates to access the PDMP database. The board discussed responsibility of obtaining the information since privacy issues were involved. Would the pharmacist or the pharmacy technician be responsible? It was determined each individual who accessed the database would be responsible for obtaining the information. Mr. Holm stated there may not be statutory authority to allow delegation of access to the PDMP, if so the attorney general's office would notify the board after review of the regulation project.

The discussion turned to Pre-paks. Mr. Howes asked the board if they would consider writing a policy that would allow pre-packaged controlled substances dispensed for emergency purposes with no more than a 72 hour supply, to be exempt from reporting. He further noted that a lot of people are not reporting them because they think they are already excluded from reporting. Medication that is directly administered is excluded from reporting. Hospitals give patients up to 72 hours of medication or until a pharmacy may be open to fill a prescription. Mr. Cotter noted the prescription would be entered into the database, and that only two or three more tablets off of the count would not be significant.

It was decided Mr. Howes would draft a policy for the board to review later in the meeting. The policy would include an exemption for reporting pre-paks of controlled substances not to exceed a 72 hour supply.

It was noted the funding for the PDMP was to end August 2013 unless funding was appropriated by the legislature.

Break- off the record at 10:26
On the record at 10:50

Agenda Item 7 **Regulation Projects**

Dan Branch, AAG, and Jun Maiquis, Regulation Specialist, joined the meeting to discuss regulation projects. The project included 12 AAC 52.450, regarding inspection of pharmacies located inside the state that have a license in another state, and pharmacies considered "high risk", which would include compounding pharmacies, home infusion facilities, and hospital pharmacies. The board discussed the draft and made some changes that clarify when the inspection happened. It was determined the application for a new license would include a question asking if the pharmacy was a "high risk" pharmacy, if so, then they must submit a current physical inspection report of the pharmacy, or have current accreditation from a board approved certifying body. Pharmacies located outside of the state, must include a current physical inspection report prior to licensing and if they are a "high risk" pharmacy, the inspection report must include specific

areas that must be addressed to be determined by the board, or current accreditation.

For clarification, Mr. Cotter asked if a new pharmacy inside Alaska would submit a self inspection report with the initial application, then have a physical inspection which would be triggered by the first renewal notice. Mr. Holm answered "correct". Mr. Cotter further stated that the pharmacy would then not be inspected until after the first renewal of that pharmacy, and only if the inspector or investigator had the time. What would happen if the investigator did not have the time to do it? Mr. Holm said that there would have to be a provision that would exempt them from the inspection if there were unforeseen circumstances on the board's part for the inspection. Mr. White noted that there should be a fee for those that would require a physical inspection.

Mr. Cotter said that some out of state facilities may have an inspection more than once in a renewal period and the board should require the facility to submit all inspection reports prior to renewal, which could include an inspection for cause.

Mr. Cotter asked what would trigger a physical inspection if a licensed pharmacy in the state decided to start sterile compounding in the middle of a renewal period. How would the board know that it needed to be inspected. Mr. Branch stated the department could investigate a pharmacy at any time, and the board could add language requiring a pharmacy to notify the board prior to starting "high risk" activity. He asked the board if the wording could be added to (d) to say "A pharmacy shall advise the board in writing within 60 days of first receiving a pharmacy facility license issued by another state, or initiating a high risk service." The board agreed that would be acceptable.

Mr. Cotter asked if "high risk" pharmacies that are currently licensed, have to have a physical inspection prior to the next renewal. The board determined no, not until the next renewal is received.

On suggestion by Mr. Branch, the board decided to add an "absent for good cause" clause.

Mr. Holm noted there should be a broader definition for "high risk", that would allow the board to determine which ones have priority over others for inspections. The board would deal with it at a future meeting.

The board decided new applicants for out of state and in state pharmacies that are considered "high risk", must have a physical inspection prior to licensing, and during each renewal period, or they may submit a current accreditation from a board approved certification body.

Mr. Branch will rewrite the draft regulations for the board to review later in the day or tomorrow.

Mr. Holm brought up the issue of delegating reporting to the PDMP to staff members. He said that new legislation was being considered which would require a prescriber to check the PDMP prior to writing a prescription and there would be a criminal penalty if they didn't do it. The prescriber would need to delegate to a staff member, such as a nurse, to check the PDMP as the practitioner would not have enough time. The board wanted to institute a regulation for delegating the task to another person, but that would be at a later meeting. Mr. Holm asked if Mr. Branch could determine if the board had statutory authority to do so.

Lunch- Off the record at 11:58 a.m.
On the record at 1:02 p.m.

Agenda Item 8 **Investigator Report**

Al Kennedy, investigator joined the meeting via telephone. Mr. Kennedy gave the investigative report, noting there were matters that needed to be discussed in executive session. He stated he was working on out of state pharmacy renewals with 'yes' answers. Some pharmacies had 300 employees that needed to have background checks.

Anne Gruening joined the meeting at 1:07 p.m.

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

RESOLVED to go into executive session in accordance with AS 44.62.310(c)(2), for the purpose of discussing a consent agreement for case #2012-000921and other investigative matters.

Board staff to stay during executive session.

Off the record at 1:09 p.m.
On the record at 1:22 p.m.

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

RESOLVED to accept the consent agreement for case #2012-000921.

The consent agreement was for Kelli Marden.

Mr. Holm signed the consent agreement, and it was noted the original signed page would be sent to Mr. Kennedy in the Anchorage office.

Mr. Holm said he had received a call from someone at the North Slope Borough and they said the DEA would not renew a DEA registration for a Native Facility pharmacy unless they were licensed by the Board of Pharmacy. He said further that most of the pharmacies on the North Slope did not have licenses through the Board. The central pharmacy was owned by the Native Health Corporation but the satellite pharmacies were owned by the boroughs. The DEA had determined that controlled substances would not be able to be shipped to remote areas unless they had a DEA registration and licensed by the board. Mr. Holm said to expect license applications coming into the office for central pharmacies and remote pharmacies.

Agenda Item 9 **Legislative Report**

Don Habeger, Division Director, joined the meeting to listen to the discussion, and in particular the board's stance on continuance of the PDMP.

Caren Robinson, lobbyist for AkPha joined the discussion.

The board noted the funding for the PDMP would have to come from legislative appropriation. Further, the board chair stated a change in who could access the database would have to happen to allow pharmacists and prescribers to delegate the authority to a staff person, because of the time involved.

HB 6 &SB 8- The board discussed the pharmacy audit bill. It was noted the bill had changed since last year.

Mr. Holm said Tammy Wilson would be introducing the board's out of state wholesale distributor bill by the end of this year. It looked like next year would be when it would be heard in committees.

SB 53- The bill would require a prescribing practitioner to consult with a pain specialist prior to prescribing an opiate substance for 120 milligrams or more in a 24 hours period. It was noted there were only 16 or so pain specialists in the state and most of them are in the Anchorage area. That would make it difficult for a consultation if the patient had to see the specialist face to face.

Ms. Robinson noted there was another working draft with Representative Keller which would require practitioners to check the PDMP prior to prescribing a controlled substance. Until the legislature determines how to pay for the PDMP, the bill would probably not go anywhere this year.

Mr. Holm asked Mr. Habeger about the naturopath regulation in process. Mr. Habeger noted the division had received over 2500 comments on the regulation change and were being reviewed which would take quite some time.

The board reviewed HB 7, CS SB 84, HB 53, and HB 84. Mr. Cotter said he would support HB 84, military education and training for certain professions, such

letter to the legislature opposing the bill, as the training would not be equivalent to training received through educational means. If it passes, each board would have to determine the type of training that would be equivalent and put into regulation.

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

RESOLVED to support SB 8, the pharmacy audit bill, with the current wording.

Mr. Holm said he would like to have the winter meetings in Juneau so the board had access to legislators. He had several meetings with legislators prior to the board meeting which have been very helpful in relaying important board issues. The board would discuss the issues at the November meeting that they would want to discuss with legislators during the winter meeting.

Agenda Item 10 **New/Old Business**

New Business-
Mr. Cotter brought up the issue of the 1500 hours of internship required to obtain a pharmacist license. Currently at least 500 hours must be non-educational related hours. Mr. Cotter believes the 500 non-educational hours are very hard to obtain for most pharmacists and would like the board to consider changing the regulation to allow all hours to be educational related. One instance he noted was a pharmacist he wanted to hire who graduated from a school in Montana, obtained a license in Montana, but does not have the 500 hours of non-educational related internship hours, does not qualify according to current intern regulations. Mr. Cotter noted information he had obtained from a website for different state requirements which he gave to the board. Thirty four states require 1500 hours, but do not require any to be non-educational related. He felt the current regulations are too restrictive and keep Alaska from being able to recruit new graduates. It was noted that most schools require more than 1500 hours of internship for a pharmacy degree.

Ms. DeVito noted the 500 hours outside of school requirements were to give the intern experience in a pharmacy outside of a school setting.

After discussion, the board decided to change the intern requirement to allow all 1500 hours of internship to be completed without the restriction of 1000 hours in an educational setting.

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

RESOLVED to repeal 12 AAC 52.080(c).

Roll Call- DeVito-nay, Gruening-yea, Cotter-yea, White-yea, Holm-yea. Kim-abstention

4 yeas, 1 nay, 1 abstention

For the record, it was noted only section (c) was to be stricken from the regulation.

Mr. Kim wanted to discuss automatic dispensing systems, also known as ADM's. He stated that the board had not discussed the matter in awhile and wanted to know what the board thought of them. Should the board look into what other states are doing? Mr. Holm said the board had determined the ADM's in physician offices were under the purview of the Medical Board and the DEA does not want them to contain controlled substances. Possibly the DEA would address that in the future. Mr. White suggested the board should spend an hour at the next meeting to further discuss the matter. Mr. Holm mentioned some of the board members could get information to bring to the next board meeting.

Mr. Kim asked the board if they wanted to discuss a pharmacist who worked a 12 hour shift. Some places were requiring it and he thought it was too long. Mr. Cotter noted the study of nurses that worked 12 hour shifts, the outcome was it was too long and that mistakes could happen with that long of a shift. Too many medical errors happened. Mr. Holm mentioned that was a labor law, and the board should not get involved at this time. It was not the board's purview to regulate employer's hours. Ms. Gruening said she did not think an employer could require an employee to work that long unless the employee agreed to it. It was decided to look into the labor laws and take the issue up at the next board meeting.

Break- off the record at 3:09
On the record at 3:22

Agenda Item 11 **License Application Review**

The board reviewed the 'yes' answer applications.

The board reviewed the pharmacy technician license applications. It was noted one applicant has been employed by a pharmacy for awhile and the board would like clarification from the PIC regarding what duties she has had in the pharmacy.

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

RESOLVED to approve pharmacy technician license applications for Crystal Bijak, Samuel Eames, Colette Milton pending clarification from the PIC of Ms. Milton's role in the pharmacy prior to licensing

and that she has not been working as a technician, and Sean McDaniels.

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

RESOLVED to approve the out of state pharmacy applications for Davita RX, LLC, in CA and Davita RX, LLC, in TX pending clarification of the type of pharmacy including sterile compounding and all others that may apply on the application.

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

RESOLVED to approve the out of state pharmacy application for Optum RX, Carlsbad, CA.

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

RESOLVED to approve the pharmacist applications for Peter Simonich and Robert May, pending receipt of verification of licensure from New Mexico and Massachusetts, and an explanation why he did not disclose those states on the application.

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

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

Pharmacists approved-

Colleen Cochran
Stephen Day
Karolina Griswold- pending verification of one year of practice, MPJE passing score
Luan Le- pending MPJE passing score, Verification of licensure from MO
Linda Morehouse- pending MPJE passing score
Edward Tarter- pending verification of an additional 1000 hours of internship
Aimee Young
Jane Wilson- pending $200 license fee, MPJE passing score
Ekaterina Yuvasheva

The board recessed until 9:00 a.m. on March 1st.

Off the record at 4:45 p.m.

Friday March 1, 2013

Call to Order/Roll Call

The meeting was called to order by Dick Holm, Chair, March 1, 2013 at 9:07 a.m. Those present constituting a quorum of the board were:

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

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

Sher Zinn, Licensing Supervisor

Visitors present: None

Agenda Item 12 **Review Agenda**

The board reviewed the agenda and noted Agenda Item 14, AkPha Report, was deleted.

Agenda Item 13 **Correspondence**

An additional item was added to the correspondence. The board reviewed a request for approval of ProTrainings, LLC CPR and First Aid course. The course is conducted on the internet. The course information noted it "follows the same guidelines as the American Heart Association and American Red Cross". The board noted they do not approve or endorse specific courses. The course must be approved by current standards in the regulations. It was noted that it may be a valuable course, but if it does not meet the regulatory requirements, may not be used for the allowable one hour of continuing education credit. It was further noted the board does not allow internet based CPR courses.

Travel issues were brought up. Ms. Zinn explained the policy regarding third party reimbursement for travel. The state accounting system does not have a way to account for third party reimbursement and allocate it to the board's travel fund and therefore, any reimbursement would go into the state's general fund. Mr. Holm noted that the board is required to attend meetings for the National Association of Boards of Pharmacy as part of the board's membership duties. If

the board does not attend the required meetings, the board may not be a member.

NABP correspondence was discussed. NABP has a specific training program for inspections of pharmacies. Mr. Holm noted the board would have to look into the cost to see if the board could send the investigator to attend. The board may have a three day meeting to cover criteria and write the inspection form that would be required. The board may want to have a panel consisting of board members and public pharmacists to develop the inspection criteria.

The board reviewed the remaining correspondence.

Agenda Item 15 **Public Comment**

No one was present for public comment.

Break- off the record at 10:04 a.m.
On the record at 10:15 a.m.

Agenda Item 7 **Regulations**

The board discussed the changes to the regulation project Dan Branch and Jun Maiquis had re-written from the previous day.

Mr. Cotter noted the regulation does not require the pharmacy to submit a copy of the physical inspection report every time they had an inspection. The board members agreed that all physical inspections must be submitted to the board and wanted it added to the draft regulation.

It was noted 12 AAC 52.130(b)(4) would have to be amended to require a physical inspection report for a "high risk" pharmacy. The current regulation requires "an inspection report or a self-inspection report".

The board wanted all out-of-state pharmacies to submit a physical inspection report with the initial application for a pharmacy license, as well as in state pharmacies. Ms. Zinn noted that would have to be part of the regulation for review of an application for registration under 12 AAC 52.130 and 12 AAC 52.020 for clarification for a new license or registration. Also either add to (f) of the draft regulation, "In order to apply for a new registration under AS 08.80.158 or renew a registration, a pharmacy shall provide the board with proof that its facilities were inspected during the", or make a separate section as the draft had for in state pharmacies. The draft only references renewals for an out-of-state pharmacy, and not initial licensure.

The board discussed (c) and decided it needed to be reworded as it appeared confusing. Ms. DeVito reworded it to read, "If a high risk pharmacy does not hold a facility license issued by another state and it holds a current accreditation by an

accrediting board acceptable to the board, it is exempt from meeting the inspection requirements of (a) and (b) of this section".

Add (4) to (h) -any other facility considered "high risk" by the board.

It was decided to have the draft reworded and the board would hold a teleconference to review it before going out for public comment.

The board further discussed the requirement of an out-of-state pharmacy submitting every physical inspection report. The board wants to know when a pharmacy has or has not passed an inspection, especially if they are a compounding pharmacy. If the report shows non-compliance, the examiner would send a letter to the facility notifying them they need to submit an action plan to correct the deficiencies and a new physical inspection report showing they are compliant within 30 days. The investigator would review the non-compliant inspection report and gather information from the other board. If necessary the board would have the ability to suspend a license until the pharmacy is compliant with their state laws.

The board discussed a regulation for the PDMP access by a designated agent of a pharmacist or prescribing practitioner. Mr. Cotter said the individual accessing the database should be the one responsible for their actions. Mr. White noted that possibly there should be a disclaimer when registering for the database that the person accessing the database is the person responsible for the information, either entering or accessing existing information.

The board decided to have Dan Branch write the regulation for a designated agent to access the database as noted in his email response to the board. The only change would be the last line that required the pharmacist or practitioner to be the responsible party for the agent. The board felt any person accessing the database should be individually responsible.

Agenda Item 17 **Mandatory Reporting**

The board reviewed one mandatory conviction report under 12 AAC 52.991 and found there was no issue.

Agenda Item 16 **CE Audit**

Ms. Zinn noted there were several continuing education (CE) audits where the licensee signed the renewal application certifying they had already completed the required CE's, but the certificates showed that some or all of the courses they completed were after they signed and submitted the renewal form. The statute requires the licensee to satisfy the CE requirements prior to being renewed. Ms. Zinn asked the board what they wanted to do with those licensees. The board determined they would get a letter of warning that they had not complied with the statute and if it happened again, the board would take action.

The board reviewed the CE audits. The board discussed having the license examiner review the CE audits and approve without the board's approval at a meeting. The board would review only those audits that did not meet the requirements in regulation. It was noted the regulations are clear regarding the requirements and the board felt the examiner would be able to complete the task of the review and approval as the examiner already reviews and compiles for board signature. The examiner would review the CE's and those that are compliant would be approved by the examiner, those that did not meet compliance would be forwarded to the paralegal for processing, and if found to not be in compliance would be discussed during a regularly scheduled board meeting.

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

RESOLVED to approve the CE audit and delegate future CE audit reviews and approval to the licensing examiner and require board review only on questionable audits that do not fit the requirements in regulation.

Agenda Item 17 **Mandatory Reporting**

The board reviewed one mandatory conviction report under 12 AAC 52.991 and found there was no issue.

Agenda Item 18 **Office Business**

The board signed the wall certificates and travel authorizations.

It was moved to adjourn the meeting.

Off the record at 11:20 a.m.

Respectfully Submitted:

Sher Zinn, Licensing Supervisor

Approved:

Dick Holm, R. Ph., Chair

Date: 5-10-13