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

MINUTES OF MEETING
January 29 – 31, 2014

By authority of AS 08.01.070(2) and in compliance with the provisions of Article 6 of AS 44.62, a scheduled meeting of the Board of Pharmacy was held August 22 - 23, 2013, at 550 W. 7th Ave., Suite 602, Anchorage, Alaska.

The meeting was called to order by Dirk White, President, at 9:05 a.m.

Call to Order/Roll Call

Those present, constituting a quorum of the board, were:

Anne Gruening – Public Member – Juneau
Taryl Giessel – Public Member – Eagle River
John Cotter – R. Ph. – Fairbanks
Richard Holm – North Pole
Dirk White – R. Ph. - Sitka

Board Members not in attendance:

Lori DeVito – Soldotna
C. J. Kim – Anchorage

In attendance from the Division of Corporations, Business & Professional Licensing, Department of Commerce, Community and Economic Development were:

Donna Bellino, Licensing Examiner – Juneau
Don Habeger, Division Director – Juneau

Visitors Present:

Amy Hall	Gerald Brown
Lis Houchen	Barry Christiansen
Daniel Essim	Caren Robinson

Agenda Item 1- Review Agenda

Due to the January meeting being held in Juneau over three half day meetings, the board reviewed the agenda for all 3 days. It was noted that the only change will be

on Thursday January 30, 2014. Mr. Andre Neptune, Director of Pharmacy and Rehab Services for Providence Alaska Medical Center requested to address the board regarding a policy change to the hospital. Mr. Neptune took the 2:30 time slot left open for the AKPha report. Mr. Neptune will be calling in and speak with the board telephonically.

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

> **RESOLVED to approve the agenda with the change for Thursday January 30, 2014**

Agenda Item 2- Minutes

The Board reviewed the minutes from the November 21-22, 2013 meeting.

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

> **RESOLVED to approve the minutes from the November 21-22, 2013 meeting with no changes**

Agenda Item 3- Ethics

Mr. White called for any ethics disclosures to make. No ethics disclosures to report.

Agenda Item 4 – Division Update

Sara Chambers, Operations Manager for the Division called in telephonically to address the board regarding 2nd Quarter Report of Revenues and Expenditures. The board had no issues with what was reviewed. Ms. Chambers also thanked outgoing chair Richard Holm for his hard work and dedication to the board and that it was a pleasure working with him and wished him the best of luck.

Agenda Item 5 – Investigative Report – Investigator Kennedy

Investigator Kennedy presented the Investigative Report from November 21, 2014 to January 28, 2014. Including cases, complaints, and intake matters, since the last report, the Division opened 5 files and closed 6 Pharmacy Board matters.

Off the record at 10:00 a.m.
Back on record at 10:15 a.m.

Agenda Item 6-PDMP Report – Investigator Howes

Investigator Howes first presented and reviewed the report he put together to the 28th Alaska State Legislature from the Alaska Board of Pharmacy regarding Prescription Drug Monitoring Program. Known as AKPDMP, it is a statewide electronic data base that gathers information from in-state and out-of-state pharmacies (or dispensers) on dispensed prescriptions for controlled substances.

Federal funding for AKPDMP ended on August 31, 2013; per legislative requirement the Board is requesting that this be addressed by the Legislature. A "Reimbursable Services Agreement" or RSA, from Alaska Department of Health & Social Services (HSS) has allowed for continued operation, but it is a limited time agreement.

It is Investigator Howes understanding for FY 2015 budget; Governor Parnell has made provisions for funding the AKPDMP as a budget item. The report includes a few aspirations to maximize the AKPDMP for future availability and utility of data to the widest range of appropriate end users potentially. Investigator Howes reviewed the following stated in the report:

~Enact legislation to maintain sufficient funding over time
~Provider education, enrollment, and use of PDMP (mandate, some States do mandate PDMP enrollment)
~Delegate access (this under review with AAG and will be discussed In the upcoming agenda item)
~Send unsolicited reports and alerts to appropriate users.
~Improve data timeliness and access; increase reporting to weekly
~Streamline certification and enrollment processing
~Optimize reporting to fit user needs
~Publicize use and impact of PDMP via websites, presentations, and report
~Integrate PDMP reports:

*Health information exchanges
*Electronic health records

*Pharmacy dispensing systems

The Board concurred with Investigator Howes on the above ideals to help to improve AKPDMP.

Investigator Howes noted for the Board that in 2013 there was a tremendous increase in the total number of solicited reports in utilization by providers of the AKPDMP. There was a 524% increase on the amount of people that have used it. Pharmacists are using it more than the prescribers.

Investigator Howes made a point to discuss with the Board the thresholds of the system. PDMP's typically use a threshold of a number of prescribers from whom a patient has obtained a controlled substance prescription, and a number of pharmacies that have dispensed the prescriptions in a specified period of time, often six months, but sometimes one month. The BJA grant has had the AKPDMP reporting numbers for 5/5 or 10/10 (prescibers/pharmacies). The system/program does not make judgment calls, thresholds are used as ballpark for when they can do an unsolicited report by sending it out to the providers to let them know that the system is seeing this 5/5 or 10/10 as an issue, and would like if you so choose, to take a look and see if it something you feel concerned about in your prescribing or dispensing. Investigator Howes advised that a threshold was never really established and asked the board to determine what the threshold should be for Alaska. Most states use the 5/5.

Mr. Holm suggested that the board set a threshold at this meeting. Investigator Howes welcomed that and then Mr. Holm recommended to Chairman White that a motion be made to adopt the 5/5 (prescribers/pharmacies) threshold in a three month period for AKPDMP.

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

RESOLVED to approve that the threshold of 5/5 in a three month period for AKPDMP reporting.

Investigator Howes can send an email if enrolled in the system to the provider and prescriber involved with patient information to the providers that are listed as prescribing or dispensing to that patient. This email does not make judgments, but asks them to take a look at what was reported based on the threshold that the Board has established. Otherwise a letter would be sent.

Mr. Cotter asked when an email is sent and since the pharmacist has to log on and is notified there is an email, how does the pharmacist get tied to the pharmacy. There could be four pharmacists in a pharmacy, does only the PIC get the email, and then how it is differentiated if you send an email message that the appropriate pharmacist receives it? Mr. Cotter used the example, you have five pharmacists in a pharmacy all be registered in the database, do all five pharmacists receive it, one pharmacist get it, or no one receive it, versus sending a letter to the pharmacy. Mr. Howes has to do some querying and get back to the board that detail.

The Board and Investigator Howes discussed ways to improve the enrollment process, plus the education of providers (prescribers & dispensers) can aid with the estimation of compliance being 80%. The process for checking compliance is a manual process involving verifying status, proper DEA numbers utilized, checking for entity or individual name changes and this is what Investigator Howes spends a good amount of his time doing.

Chairman White requested that Investigator Howes review Director Habeger's response back to Representative Mark Neuman's letter regarding the AKPDMP. Investigator Howes will review response to verify statistics and information provided are current and correct. Ms. Bellino will forward a copy for review.

Agenda Item 7 – Regulation Review

On Monday January 27, 2014 Ms. Bellino received two emails from Assistant Attorney General Todd Araujo. The first email is in regards to the last regulation project for the six pharmacy regulations that were proposed to be amended. These regulations were sent to public notice and were previously approved by the Board at the August 2013 Board of Pharmacy meeting. In his email, AAG Araujo advised back to the Board what specific regulations need to be reconsidered by the board and revised as needed.

The second email is regarding Regulation **"12 AAC 52.860, Conditions for access to and use of database"** specifically. Ms. Bellino distributed a copy of the two emails to the Board for review before AAG Araujo joined the meeting telephonically.

Ms. Bellino called AAG Araujo's office and he joined the meeting telephonically. AAG Araujo started with the first email responding to following Regulations:

12 AAC 52.020 - Facility License

12 AAC 52.130 – Review of Applications for Registration of Pharmacies Located Outside Of the State
12 AAC 52.150 – Inspection of Pharmacies
12 AAC 52.865 – Requirement for Dispensers
12 AAC 52.995 – Definitions

12 AAC 52.020 - Facility License, AAG Araujo this Regulation was proposed to be amended by adding a new subsection (f). The new subsection would require an applicant to submit a "physical inspection report for a high risk pharmacy" under **12 AAC 52.020(f)**. AAG Araujo said there were a couple issues either identified by AAG Araujo and/or by Steve Weaver one of the gatekeepers for Legislative/Regulatory Affairs Division. The issues boil down to a couple items: 1-as it relates to "High Risk Pharmacy" is not a properly defined term at this point. There was an effort to define the term in **12 AAC. 52.020(h)** and after a discussion with Mr. Weaver both are of the view that the definition of "high risk pharmacy" is a bit lacking in a lot of respects. Instead of providing a definition it provides a list of facilities that the board believes would come within the "high risk pharmacy" category which in itself is problematic. 2-the other aspect that gave AAG Araujo and Mr. Weaver some pause was on **12 AAC. 52.020(h) (4)** any other facility considered high risk by the board. Both believe this gives the board unfettered discretion to define what might also come within the "high risk" category. 3-another issue is with the physical inspection report. While the new regulation **12 AAC 52.020(f)** cross references a physical inspection report under **12 AAC 52.150(f)** there is really no parameters or clarity with regard to that physical inspection report because **(f)** doesn't actually mention a physical inspection report and so it is unclear as to the Board's intent in that regard if in fact (f) was an oversight or is it necessary to dig down deeper on **12 AAC 52.150(f)** to further define what a physical inspection report entails and what that encompasses.

The board decided to review and discuss one regulation at a time.

Mr. Holm asked if he could ask some questions about what AAG Araujo just reviewed. Mr. Holm then made the comment that it appeared that some of the objections were based on a lack of understanding of the pharmacy profession. For instance, the section on "high risk pharmacy" or definition, these are facilities yes, but if it was worded differently if we said any pharmacy engaged in these activities would kind of cover the same thing, because hospitals are understood to do IV's and mix IV's, sterile compound facilities or any home infusion facility those are what we consider high risk because they involve sterile work. AAG Araujo stated that he has no particular objection to those three types of facilities: hospitals, sterile compounding facilities and home infusion facilities qualifying as a "high risk

pharmacy" it is that there is no definition that is provided. Mr. Holm stated that it is a definition. Mr. Holm then asked what if we say any facility that engages in these functions. Ms. Giessel then stated that the definition is encompassed by the duties they are performing in what they are providing not necessarily the facility in and of itself. Ms. Giessel then asked if there is a way we can word that that would allow for that. AAG Araujo said there is a way to word it so that we are describing what we are trying to encompass as opposed to simply trying to fashion a definition that encompasses what amounts to just a list.

Mr. Cotter asked if number (4) - any other facility considered high risk by the board, if that defined the process of what you are doing, i.e. sterile compounding, you define the high risk and have the statement which would include hospitals, sterile compounding facilities, home infusion facilities would that clarify it at all. AAG Araujo advised it would be a lot closer to the mark. In putting number (4) aside for the moment, AAG Araujo advised you want a general description of what the defined term is, i.e. "high risk pharmacy" means X, Y or Z, and then in terms of what is included there it is not uncommon for a board of your type to define certain things that would no doubt be included within that definition, but currently as written there is no definition. Mr. Cotter then stated it is easy enough to accomplish.

Mr. Holm then asked if AAG Araujo was asking for the board to come up with a definition or is he going to create a definition that is acceptable. AAG Araujo advised that is generally the board's prerogative to draft these regulations and the Department of Law relies on the board's expertise as you outline regulations in that regard. Mr. Holm advised that in the past they worked with the previous AAG due to limited time available to work on these types of things and they would explain to the AAG what the board wanted and the AAG would come up with the language necessary to accomplish it. AAG Araujo will work with the Board Chair Dirk White to come up with intent of the language if not the exact language to put in the regulations.

12 AAC 52.130 – is proposed to be amended by adding a new paragraph **(5)** the new paragraph would require an applicant to submit a "physical inspection report" for a "high risk pharmacy" required under **12 AAC 52.150(f).** AAG Araujo advised they had very similar concerns and some of the same issues regarding the "physical inspection report" and at some point we will have to go back and make the proper changes to bring that within some acceptable formatting.

12 AAC 52.150, Inspection of pharmacies – Again this has the same issue with the "high risk pharmacy" and another overarching issue is we seem to be requiring more from an out-of-state pharmacy than what we require of in-state pharmacies

and this is not allowable. Mr. Holm explained to AAG Araujo that the reason we require an inspection report from out-of-state pharmacies is that whenever we license a pharmacy from out of the state we are relying that pharmacy is being regulated properly and efficiently by their particular board in their home jurisdiction. The inspection report is the only way we can put the responsibility on their home state Board of Pharmacy to regulate and make sure their pharmacies are in compliance and have an inspection. This is the reason why we require the report.

Pharmacies in our state we can and do inspect at any time. We do not have the funds or the man power to inspect out-of-state pharmacies.

Mr. Cotter stated that the aspect on the "high risk" component is as Mr. Holm stated that out-of-state pharmacies just have to provide an inspection report, all the in-state "high risk" pharmacies are going to be required to be inspected. They both will be inspected per a regulatory period it is just by slightly different methods. One from the out-of-state pharmacy that has to provide a report and the in-state pharmacies will be inspected by us. Mr. Cotter then stated he does not see a discrepancy in that.

Mr. Holm agreed that there isn't a discrepancy if anything there is more required of in-state pharmacies because they are going to be required to pass an inspection. We are only asking for an inspection report from the out-of-state pharmacy. It is the only way we know if there are any issues with an out-of-state pharmacy.

AAG Araujo then asked if the physical inspection that is contemplated in 12 AAC. 52 150(b) will also be required of in-state pharmacies prior to licensing? Mr. Holm answered no, but you have to pass an inspection before you can renew your license before the next licensing renewal period. Ms. Giessel then stated we are trying to capture all of them into inspection, it hasn't been there previously. Mr. Holm stated we have a problem with getting pharmacies inspected in a timely fashion so that licenses are not held up. The in-state "high risk" pharmacies are being flagged so our investigator who does the inspections knows what pharmacies have priority for inspection. Our investigator is being trained now on how to inspect a "high risk" pharmacy.

AAG Araujo then restated his concern that under 12 AAC. 52 150(b) the difference between in-state and out-of-state is still an uneven playing field by requiring a current inspection report prior to licensing but do not require the same from in-state pharmacies prior to licensing.

Mr. Holm stated we have to start some place and that most states do inspections on a regular basis of all their pharmacies and so we are asking for the most current inspection report. Mr. Holm then advised that in-state pharmacy inspections have not been done in Alaska for almost 30 years when they were performed it was the actual board members who did the inspections. Since then we operated under an honor system by having in-state pharmacies complete a "Self Inspection" report. Under the current circumstances with what is going on in the country we can no longer rely on that and since we are moving into a new realm if you will, we will have a problem only with the upcoming license renewal period this June. There is no way that our investigator can complete a physical inspection before licensure this time. Going forward it is the board's intent to require a pharmacy inspection be done before a pharmacy opens and the license is issued.

With the renewal licensing period coming up so quickly and due the current regulations changes not ready for implementation, the Board with AAG Araujo agreed to level the playing field and eliminate the discrepancy between in-state and out-of-state with a regulation change that will now require an inspection for in-state pharmacies before licensing for the next renewal period.

12 AAC 52.865 Requirement For Dispensers – Per AAG Araujo's email this regulation is proposed to be amended by amending subsection (c). The proposed change makes certain exceptions for the applicability of the requirement in **12 AAC 02.920(b)** for time computation. It appears the intent of this proposed amendment was not to exempt the two listed circumstances from the requirement in **12 AAC 02.920(b)** relative to time computation, but instead to exempt the two listed circumstances from the reporting requirement contained in the first part of (c). Statute **17.30.200, Controlled substance prescription database (a)** requires every prescription to be contained in the controlled substance prescription database and thus there is no ability by the Board to allow those to avoid the reporting requirement.

The Board entered into a discussion with AAG Araujo regarding this. Mr. Cotter then advised the law may allow it through regulation **12 AAC .52.720 – Emergency Room Outpatient Medications** which is what this regulation change was based on Hospital emergency rooms in off hours giving patients a starter pack when pharmacies would be closed. So they would give you a 24 hour supply of medication that you start on until the next day when the pharmacy opens. That is what the intent of it all is. The aspects in **12 AAC .52.720** are that emergency room outpatient medication has to do more with the process. You can argue whether or not the small amount of the medication given is a prescription or not. Mr. Cotter

said he could argue that they are not a prescription but simply a starter pack similar to physician samples.

AAG Araujo referred back to **Statute 17.30.200(a)** and as it's written does not allow for this type of change because the PDMP database is designed to capture every prescription. The board argued back is whether it is a prescription or not because there is no prescription written and nowhere in **12 AAC 52.720** does it refer to a prescription. Mr. Cotter stated the logic behind this regulation change is twofold:

1- The doses dispensed are insignificant, the quantity given is 2 -6 tablets
2- All of these patients would receive a prescription in addition to the couple tablets given and then that prescription when filled would be entered into the database

So the intent of the activity it's either insignificant, a couple tablets, less than half a dozen most likely, but if there are any larger volumes associated with it there would be a prescription with it and that would get entered into the database so it does capture the event.

AAG Araujo stated that **Statute 17.30.200** does not draw a line between the quantity of what is in **Regulation 12 AAC 52.720** 72 hour supply and a full prescription.

AAG Araujo will circle back with council and dig a little deeper to see if there is any room at all in **Statute 17.30.200** to accomplish this regulation change for the up to 72 hour supply not having to be reported.

AAG Araujo asked the board that as it currently stands as a practical matter under **12 AAC 52.720(4)** and those scenarios described there, are they required currently or do they have to as a matter of practice to report those things to the board. Mr. Holm advised that they did not have to report it to the board, but the whole confusion is because of the new laws under PDMP there is a question of whether it has to be reported or not. The Board is looking at that as the board, you don't have to report it and since the board is in charge of PDMP the board feels they should be able to clarify it. AAG Araujo stated again that he will take a look to see if there is room to accomplish this.

The board also clarified that this in regard to an institutional facility, emergency room dispensing under **12 AAC 52.720** so a doctor's office can't use this as an excuse to not report.

In summary AAG Araujo stated that if the law under **AS 17 30.200** restricts you from any exemptions like the regulation change that the board would like to amend it would require a legislative fix and therefore we could not do anything to accomplish that via a regulation. AAG will confirm that or not and let the Board know.

12 AAC 52.995 – The proposed definitional change to "dispenser" does not read logically and AAG Araujo will work with Board Chair White to come up with a definition of "dispenser" that will pass muster from legislative affairs.

In summary the only regulation that was cleared was **12 AAC 52.310 – Reinstatement of An Expired Pharmacist or Pharmacy Technician License**

AAG Araujo requested that the board withdraw the other regulations with the exception 12 AAC 52.310 and move them to a second regulation project for further review by AAG Araujo.

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

> **RESOLVED to approve 12 AAC 52.310 as stated in AAG Araujo's email dated 1/27/14 and withdraw all other proposed regulation changes in the current regulation project and move them to a second regulation project for continued review.**

Due to the review of the current regulation project taking longer than anticipated and a time constraint before the meeting recesses, the board reviewed the remaining topics under Regulation Review to see what could be accomplished in the time remaining. The board decided to review and approve B under Regulation Review, proposed fee regulations.

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

> **RESOLVED to approve the regulation project for 12 AAC 02.310(a) Board of Pharmacy Fees**

The board's decision was to table and work into the agenda for either Thursday or Friday's agenda the following items:

Regulation for Pharmacist to Technician Ratio

Review proposed regulation change to 12 AAC 52.100 Temporary Pharmacist License

Agenda Item 8 – Legislative Review

The board reviewed HB6 and SB8 Pharmacy Audit bills with Caren Robinson and Ms. Robinson provided to the board an overview as to the status of the bills and reviewed meetings that will be going on regarding the bills. Ms. Bellino advised that the letter the board requested be sent in support of the pharmacy audit bill was hand delivered to the representatives. The board is in favor of this bill and hopes that it will pass and become law.

Mr. Holm advised that there are two other legislative issues that the board is seeking support to further them along. One is the licensing of out-of-state wholesale distributors. There is a draft bill written and the hope is to find a sponsor to introduce the bill. Ms. Giessel stated that there is some confusion as to the validity of a draft. Mr. Holm produced a copy of the unnumbered draft bill and gave it to Ms. Bellino to make copies for the board.

The other item per Mr. Holm is a housekeeping issue because now under current state insurance laws "pharmacist" or "pharmacies" are not recognized as a provider under the anti-discrimination clause. Being omitted is one of the ways PBM's can discriminate against pharmacists because it is not in the state law. Mr. Holm was advised from some legislators that this item will have to be introduced as a separate bill. In the federal acts "pharmacist or pharmacies" are listed and this could pose a problem in the future with this discrepancy. Due to the shortness of time left in the legislative session this item may not be able to be accomplished for this session.

Lastly, the board reviewed an email received from Ryan Ruggles, Regional Pharmacy Manager, Safeway Inc. The email included a rough draft of the legislation seeking to revise the definition of "practice of pharmacy" to include licensed pharmacists who are immunization certified be included in the "practice of pharmacy". This would require a statute change and the board is in support of including it in the definition of the "practice of pharmacy". The Alaska Pharmacist Association is also in support of this definition change. Caren Robinson advised the board to pull together a draft by the end of this session and plant the seed about the education of this change when in discussions with legislators to gain support for it.

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

RESOLVED to recess the meeting to 1:00 p.m. on Thursday 1/30/14

Off the record at 12:26 p.m.

Thursday January 30, 2014

The meeting was called to order by Dirk White, Board Chair, at 1:13 p.m.

Call to Order/Roll Call

Those present, constituting a quorum of the board, were:

Anne Gruening – Public Member – Juneau
Taryl Giessel – Public Member – Eagle River
John Cotter – R. Ph. – Fairbanks
Richard Holm R. Ph. – North Pole
Dirk White – R. Ph. - Sitka

Board Members not in attendance:

Lori DeVito, Soldotna
C.J. Kim, Anchorage

In attendance from the Division of Corporations, Business & Professional Licensing, Department of Commerce, Community and Economic Development were:

Donna Bellino, Licensing Examiner – Juneau

Visitors Present:
Virginia Geary
Amy Hall
Daniel Essim

Agenda Item 1 Review Agenda –

The board reviewed the agenda for Thursday 1/30/14. The only change noted was the addition of Andre Neptune, Director of Pharmacy for Providence Hospital in Anchorage who will address the board telephonically. Chairman White advised that he will try to work in the writing of the Technician to Pharmacist ration at the end of the meeting today.

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

RESOLVED to approve the amended agenda for Thursday 1/30/14 as written

AGENDA ITEM 2 – Sterile Compounding Inspection

Mr. Cotter presented and reviewed a preliminary Sterile Compounding Inspection Report that he and Lori DeVito another board member who is not in attendance at this board meeting have been working on for the upcoming renewal period.

Mr. Cotter and Ms. DeVito after reviewing other states inspections forms chose to utilize the state of California's inspection report as the model from which this preliminary report was created due to it being one of the most comprehensive inspection reports. Mr. Cotter made a table sheet that the left hand column has the California Inspection standards so have the inspection element and the appropriate standard that support the element. On the right hand side is Alaska. The first number of pages has compounding, not sterile compounding information and Mr. Cotter skipped over that. Mr. Cotter started the comparison with element #7 Training of Compounding Staff with the Alaska standard next to it. One of the problems Mr. Cotter came across is that every time we quote a standard you can go back to regulation, but when you get into Sterile Product Standards you cannot do the same thing. It simply is an attachment without a numbering system included to get to the line element. Secondly, we have general statements without definitive requirements, i.e. for how many years to keep training records or you have to maintain the temperature of your refrigerator, but it does not specifically state a temperature. More specific standards need to be behind the element so when the investigator goes to inspect a "high risk" pharmacy he/she has a specific standard to be inspecting against. Mr. Cotter's concern is when we start writing up deficiencies is whether or not there is enough behind in regulations to support it. Upon review of Mr. Cotter's comparison of the preliminary inspection report, Ms. Giessel stated that our information should be a lot more quantitative for our investigator to acquire good data from an inspection. Mr. Cotter stated that in-state compounding pharmacies are doing what the California inspection report asks, it is just that Alaska regulations do not drill down to the specifics and they should.
The board is in agreement that more specific regulations need to be developed for sterile compounding and will look further into starting it even if it means rewriting the whole section currently used for compounding. Mr. Cotter suggested for the

interim to develop a simplified version of the inspection form that can be used starting this fall and then for the longer term develop an inspection form that is inclusive of more specific standards and also research to include any changes from the recently enacted by HR 3204, the "Drug Quality and Security Act".

Mr. Cotter and Ms. DeVito will continue to work on a consolidated version and will have something to present at the next meeting.

Mr. Holm stated that we may need to work with the Regulation Specialist on how to turn what the compounding pamphlet that is in the regulations now, be utilized for compounding regulations that are more specific and less subjective.

Agenda Item 3 Letter from FDA Commissioner regarding HR 3204, the "Drug Quality Security Act" –

The board received a letter dated January 8, 2014 from Margaret A. Hamburg, M.D. Commissioner of Food and Drugs concerning the "Drug Quality and Security Act that become law on November 27, 2013. This letter was sent to all 50 State Board of Pharmacies, and was written to ask how state boards could encourage compounded pharmacies located outside their state that ship compounded sterile drugs in your state to register with the Food and Drug Administration (FDA) as outsourcing facilities under new legislation. According to the letter the FDA believes that the registration of pharmacies as outsourcing facilities will help the FDA identify and more effectively regulate these facilities.

The board reviewed the letter received and Mr. Cotter suggested that the letter be sent to Assistant Attorney General Todd Araujo to review the component of FDA registration as an "outsourcing pharmacy" and incorporating that into "high risk" pharmacy requirements rather than submission of an inspection report. Change that requirement of FDA registration as an "outsourcing pharmacy" or compounding pharmacy whatever specific elements are needed for the inspection report. Other Board members are in agreement and requested Ms. Bellino forward a copy of the FDA letter to AAG Araujo.

AGENDA ITEM 4 – Correspondence

The board received an email from Jim Pound who is with Representative Keller's office regarding the growing concern over the use of opiates in the state of Alaska. Out of that concern HB 53 was introduced in the legislature. Throughout the process the bill grew in content and confusion and Representative Keller's office would like to work with the board to change that and make this a document that will

accomplish what is intended by addressing the database which is most important to the process. Mr. Pound when on to add "that without it the entire concept is moot".

On January 30, 2014 Mr. Pound sent another email for board review that included a very rough draft of proposed changes **to Article 5. Controlled Substance Prescription Database -** Section 200 controlled substance prescription database. **Sec 17.30.200 Controlled Substance Prescription Database.**

Mr. Holm advised that he had been in a meeting with Mr. Pound and Representative Keller about this subject this morning before the afternoon BOP meeting. Mr. Holm said the tone of that meeting was a bit spirited at times and he addressed their questions and concerns as best he could. Mr. Holm reviewed the draft he received at the meeting with Mr. Pound and Representative Keller and it appears that it has now morphed into a PDMP reform bill and there is no mention of consultation for receiving an opiate prescription in it anymore. Mr. Holm also told Mr. Pound and Representative Keller in their meeting that the Board and the Pharmacy community would be up in arms in general about it and would not support it as written.

Director Don Habeger and Micaela Fowler, Legislative Liaison joined the meeting to speak with the board about the email and draft. Mr. Holm reiterated to Director Habeger that the bill morphed into reforming the current PDMP program and would not work as currently written.

The board would like to work with Mr. Pound from Representative Keller's office through the Alaska Pharmacist Association Lobbyist Caren Robinson. Ms. Robinson was also in attendance with Mr. Holm at the morning meeting. The coordinated effort between all interested parties would strive to come up with a revised bill that could also include other modifications to the PDMP program that the board deems necessary.

Director Habeger stated that Representative Neuman's office is also interested in the PDMP program and sent a letter requesting information about the PDMP program. The board reviewed the letter and forwarded a copy to Investigator Howes for his input on Director Habeger's information that will be provided in his response back to Representative Neuman's letter.

Director Habeger asked the board for a response back to Mr. Pound through staff to have it put on the record. If the board chooses not to go on the record at this time then Director Habeger will state that no decision was reached and is under review. Chairman White advised Director Habeger that the board will offer the work with

Representative Keller's office with the assistance of Caren Robinson the AKPhA lobbyist.

AGENDA ITEM 5 – Providence Alaska Medical Center, Andre Neptune, Director of Pharmacy and Rehab Services

Mr. Neptune called in telephonically to speak to the board about two things:

1) The hospital administration's policy or guideline drafted regarding the use of expired medications and when that might happen.
2) To address a practice that has been in place for a long before his tenure as Director, but should be brought to the board regarding provisioning drugs from the pharmacy in Anchorage to a sister facility in Seward. There are some questions if they are doing it correctly based on a conversation with the DEA as it pertains to being a manufacturer or a wholesaler.

Mr. Neptune began with the Expired Medication Administration guideline and why they had to develop it. It began in the summer 2010 with an acute shortage of IV Naloxone and the hospital was a point in their supply where they were running out of drug in-date and a lot drug that was going out of date and that point where they were potentially looking to use the expired Naloxone in a resuscitative effort on a patient in their emergency department. After consultation with their Pharmacy and Therapeutics Chair, Chief Medical Officer, and after review of the federal government's shelf life extension program data, the decision was made to keep the expired Naloxone on hand should they run out of drug that was in date should they decide to use it.

Mr. Neptune described to the board two instances from last year where patients were in the middle of therapy where there were shortages with drugs used for both patients. One patient was receiving chemo therapy, and the other patient was a Cystic Fibrosis patient. In the case of the Cystic Fibrosis patient the drug needed that there was a shortage with is based on cultures and sensitivities and in the opinion of the provider was the only drug was going be effective in treating that patient. In the case of a patient on chemo therapy the patient had already completed 2-3 cycles of chemo therapy and there was a shortage of the drug needed. The hospital had the drug needed but it was due to expire at the end of the month. The patient's next course of therapy was scheduled for the beginning of the following month and a decision needed to be made. The options were to halt treatment and wait, hope for more of the drug to become available, or treat the patient. In both

those cases and after consultation with both the provider and the patient the hospital elected to use the out of date medication.

Mr. Neptune wanted to provide these examples to put in context as to why this guideline was developed. What concerns Mr. Neptune is that these critical drug shortages may continue, because in the past two years there are many drugs the hospital uses that continue to be in critical supply and that is why it was decided to keep the expired drugs in the event and as the last option they might need to use them. In the case of the Naloxone the hospital did not need to use the expired drug.

The guideline is meant to provide a framework within which the hospital would hopefully make good decisions about when in this unfortunate circumstance the hospital would have to use an expired medication. There is a procedure included in the guideline that talks about who makes the decision, when would the hospital choose to do this. The hospital states it would not do this if there was an alternative, if there were non-expired drugs available. This is not a convenience issue, this not about we can't get any today so we are going use the expired drug, this is about there simply isn't any and the hospital believes that it is critical in the care of patient that the hospital might choose use an expired medication.

The guideline was vetted through all providers within the hospital, the pharmacy and therapeutics process and received that committee's acknowledgment, and approval, and the Medical Executive committee. All agree and said it makes sense and is reasonable and requested that Mr. Neptune bring this to both the board of pharmacy and board of nursing.

Mr. Cotter asked if the guideline was run through legal. Mr. Neptune responded that Risk Management Department did look at it and were on board that a guideline was needed, some kind of standard around which there was a framework for making decisions that would not be deemed cavalier and would provide the hospital some sense of protection that if the hospital decided to use an expired drug in a very discerning way.

Mr. Cotter asked how the hospital determines the expiration date once it expires beyond the date on the medication because typically to get a truly extended expiration date you have had to maintain all the storage condition data, temperature, and humidity over the life time of the product and realistically the hospital wouldn't have that. Mr. Neptune advised that is true. Mr. Cotter advised there is a time frame you can use the medication which will give you a six month window and you would re-evaluate, but in six months is it still good, in a year is it still good. Mr. Neptune advised that those are questions that the hospital struggles

with, but there are resources that the hospital can utilize, i.e. the federal government shelf life extension program that lists many drugs they have evaluated. Mr. Neptune stated that it is hard to say with certainty whether or not the drugs are still good, but their thought is that they would do their best to look at technical literature, chemical literature, any information from the manufacturer around stability of the drug itself and the hospital would have to weigh the risk and benefit to the patient. If they don't use this drug what might be the outcome to the patient especially if it is deemed lifesaving. If the patient is going to truly die if the hospital withholds this therapy and there is a risk that they could be helped by giving it that risk benefit needs to be evaluated closely. Where possible if the patient is available to participate in that conversation they would that patient and their provider to be involved.

Mr. White asked if Joint Commission has made any statement on this guideline. Mr. Neptune responded that he has not heard or received anything about specifically notifying the Join Commission.

Mr. Neptune reiterated he will be presenting this guideline to the board of nursing because at the point end of this care often there is a nurse who may be asked to administer potentially an expired drug. Mr. Neptune did speak before the board of nursing a couple of years ago about having to develop this type of guideline and the nursing board's concern was the hospital would be asking nurses to administer expired drugs and their thought was if a nurse refused is the authorizing/prescribing provider going to administer these drugs. Mr. Neptune said in some cases that may have to happen.

Ms. Giessel asked if the nurses concern was liability and Mr. Neptune advised yes and felt it was a fair question and concern. Mr. White asked if the medical board has been approached on this and Mr. Neptune advise no, but he certainly could.

Mr. Holm stated that the board is aware and has been aware of the continuing drug shortages. Mr. White reiterated that the board is aware of the situation and has experienced it at the hospital in Sitka and it is unfortunate this is ongoing issue that hospitals try to provide the best care under these circumstances. The board stated that it certainly understands the situation. Mr. Holm asked if Mr. Neptune has considered going to one of laboratories that can test and recertify their potency of the outdated medications. Mr. Neptune advised that he has not investigated that due to his belief the cost would be prohibitive. Mr. Neptune said he would look into it and Mr. Holm said that the costs should be more reasonable since compounders are expected to do this. Mr. Neptune ended the discussion by saying that he wanted the

board to be aware of the circumstance and the hospital wants to be responsible for addressing it.

Regarding the second issue Mr. Neptune spoke to the board about a clinic in Valdez that was visited last fall by the DEA for a site visit. As part of that site visit the DEA reviewed some 222 forms executed between the clinic and the hospital. The clinic purchased some medications from Providence Valdez Medical Center and that brought them to the medical center because what they were seeing on the 222 forms was that the hospital was distributing partial packages of controlled substances to the clinic. Mr. Neptune then provided an example; usually a unit dose package of Percocet is bought in boxes of 100, there are 10 cards of 10 tablets and little unit dose containers, and so for the purposes of example, the clinic needed two Percocet tablets so the hospital through a 222 form dispensed 2 Percocet tablets to the clinic (sold them two tablets). The DEA came back and said that is was not legal, and that by doing that you are technically now repackaging that Percocet and the only way that you should be able to sell the Percocet pursuant to a 222 form being executed is in the package quantity you can buy from a wholesaler. A formal letter was sent to Valdez from the DEA that stated you can't do this and cited them for selling partial packages. Mr. Neptune got involved when Valdez Providence contacted him as the Director of Pharmacy services in Anchorage and asked him to review their response. It was then Mr. Neptune realized that the practice that the DEA is citing them for, selling partial quantities of a package is fairly common place. Providence Medical Center in Anchorage has been provisioning drugs to Providence Seward Medical Center for the last 20 years and that has included both controlled and non-controlled substances. This prompted Mr. Neptune to contact some of his peers in Washington and Idaho and mostly all said that if a smaller quantity is all that is needed, then that is the quantity they received. Mr. Neptune also reached out to the System Director of Pharmacy in Washington State who believes this is coming out of Federal law that the breaking down of the package of 100 could be deemed the function of a wholesaler or manufacturer because the term repackaging is under the purview of a manufacturer and in the definitions of a manufacturer the repackaging, labeling, packaging is in that description.

Mr. White stated that this appears to be a federal issue and outside the purview of the state. Mr. Neptune stated that in Washington as long as organizations of a common entity, Providence for example; is doing that distribution within the same organization you have not been deemed a wholesaler. Alaska BOP regulations recognize intra-company sales. Mr. Neptune then stated that he believes with the exception of controlled substances he is on solid ground in what he is doing to support the Seward facility and has been selling to them partial packages of unit dose tablets and stopped doing that with controlled substances per the DEA.

In Washington hospitals within a common system have received exemptions for their board of pharmacy to allow them to do that. Our pharmacy regulations state you are not a wholesaler as long as it is intra-company or between hospitals with a common entity. So Providence to Providence, Mr. Neptune stated he believed he is ok in doing that. The board concurred with that. Mr. Holm asked who in the DEA advised this information and that Mr. Neptune should check higher up the chain to see if he receives the same answer. Mr. Neptune will contact the DEA in writing to see if he can get better clarity on this and will let the board know.

Break:
Off the record at 3:00 p.m.
Back on the record at 3:15 p.m.

AGENDA ITEM 4 – Correspondence Continued

The board reviewed the remaining correspondence and included in the correspondence was a Report of Theft from Harry Race Pharmacy, Sitka, AK. for 3 tablets of Methylphenidate HCL ER 18 MG Tablets. The board also reviewed an email received from CAC (Citizen Advocacy Center) with an invite to join. The board is not familiar with this organization.

The board also reviewed an email from Target regarding proposed changes to their pharmacy model and computer upgrades. The board did not see any issues with their changes.

NABP Correspondence:

NABP Correspondence was discussed. NABP advised of 2014 Pre-NAPLEX Enhancements, Fee Adjustment. NABP wanted to notify the boards of pharmacy regarding changes to the Pre-NAPLEX. Effective March 1, 2014, to provide candidates preparing to take the North American Pharmacist Licensure Examination (NAPLEX) with additional practice, the number of test items included in the Pre-NAPLEX will increase from 50 to 100. The Pre-NAPLEX will still be available in two forms, so that candidates opting to take the practice exam twice will receive two different sets of practice examination questions. Also beginning on March 1, 2014 Pre-NAPLEX fee will increase from $50 to $65. Pre-NAPLEX fee for vouchers purchased by schools and colleges of pharmacy will increase from $50 to $55.

NABP also advised there is a MPJE Item-Development workshop – March 20-21, 2014.

AGENDA ITEM 6 – License Application Review –

The board reviewed applications for approval.

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

RESOLVED to approve the following Collaborative Practice Plans

Walmart Store #10-3814, Juneau, AK
Walmart Store #10-2711, Kodiak, AK
Walmart Store #10-2722, Fairbanks, AK
Walmart Store #10-2710, Ketchikan, AK
Walmart Store #10-4359, Anchorage, AK
Walmart Store #10-2070, Anchorage, AK
Walmart Store #10-4474, Kenai, AK

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

RESOLVED to approve the following Pharmacy Technician "YES" Answer Applications

Karen Spurgeon – Pharmacy Technician
Kristina Dawn Sullivan – Pharmacy Technician

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

RESOLVED to approve the following Out-of-State "YES" Answer Applications
BriovaRx-Indiana – Out-of-State Pharmacy Registration
Aetna Rx Home Delivery, LLC – Out-of-State Pharmacy Registration

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

RESOLVED to approve the following Drug Room Application

Center for Drug Problems

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

RESOLVED to approve the following Pharmacist Applications

Eric Embury – Pending NABP Application, passing MPJE score and VOL from NC
Michele Heuer – Pending transcript, Verification of 1 year of practice, Passing MPJE score
Jonell Hutsell – Pending Transcript, VOL from WA, WV, CA, NY, OR and Passing MPJE score

AGENDA ITEM 7 – New/Old Business –

Newsletter – The board discussed starting the newsletter again. The board asked is there is a fee associated with the newsletter. Ms. Bellino will check and advise the board.

DVM's Exemption from PDMP - The board at the November board meeting had discussions with Jim Delker DVM, Alaska Veterinary Medical Association telephonically regarding exempting Veterinary Practitioners from PDMP Reporting. From that meeting Dr. Delker forwarded additional information to the board for their review that further supports this change. After the discussion with Dr. Delker and reviewing the additional information the board made the following decision.

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

RESOLVED to not consider Veterinarians for exemption from PDMP Reporting

12 AAC 52.100 Temporary Pharmacist License –

At the August 2013 board of pharmacy meeting the board revised the regulation to be in better compliance with HB 84 Military Training Credit/Temporary License. Jun Maiquis presented a draft of the change for the boards review and verification of the changes.

The board reviewed the changes to **12 AAC 52.100(c)** A temporary license is valid for 90 days. For good cause shown to the board's satisfaction, that will extend the temporary license for an additional period not to exceed 60 days.

The board confirms the change to **12 AAC 52.100(a)(8)** submits a verification of a current license in good standing to practice in another state or other jurisdiction with licensing requirements at least equivalent to those of this state.

Ms. Bellino will advise the above to the Regulation Specialist, Jun Maiquis.

The board discussed briefly the Pharmacist to Technician Ratio and tabled it to Friday's meeting for further discussion and review.

The board recessed until 9:00 a.m. on Friday January 31, 2014.

Off the record at 4:50 p.m.

Friday January 31, 2014

The meeting was called to order by Dirk White, Board Chair, at 9:08 a.m.

Call to Order/Roll Call

Those present, constituting a quorum of the board, were:

Anne Gruening – Public Member – Juneau
Taryl Giessel – Public Member – Eagle River
John Cotter – R. Ph. – Fairbanks
Richard Holm R. Ph. – North Pole
Dirk White – R. Ph. - Sitka

Board members not in attendance:
Lori DeVito, Soldotna
C.J. Kim, Anchorage

In attendance from the Division of Corporations, Business & Professional Licensing, Department of Commerce, Community and Economic Development were:

Donna Bellino, Licensing Examiner – Juneau
Visitors Present:
Sher Zinn
Todd Araujo
Amy Hall
Gerald Brown

Agenda Item 1 Review Agenda –

The board reviewed the agenda and will add the review of the Pharmacy to Technician Ratio to be discussed before agenda item #5 Office Business.

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

RESOLVED to approve the agenda with the change to move the Pharmacist to Technician Ratio

Agenda Item 2 Public Comment –

Chairman White called for Public Comment and no one was present for public comment.

Agenda Item 3 Licensing of Opioid Treatment Facilities Nonprofit/For Profit –

All attendees listed below were invited to the Board of Pharmacy meeting to discuss the licensing of Opioid Treatment facilities in Alaska for both nonprofit and for profit. In addition to the Board and Ms. Bellino the following participated in the discussion:

Al Kennedy, Investigator – Telephonically from Anchorage
Brian Howes, Investigator – Telephonically from Anchorage
Randal Burns, Mental Health Clinician III - Telephonically from Anchorage
Holly Byrnes, Health Program Manager – Telephonically from Fairbanks
Tony Ruscella, Director of Business Development CRC Health Group
Debra Cummins, Regional Director, CRC Health Group
Laurie Lower, CRC Licensing Manager

Investigator Kennedy started the discussion by providing some brief history for how this came about. Ms. Bellino received some inquiries via email and forwarded the emails to Investigator Kennedy for guidance. Investigator Kennedy reviewed the emails and went to the Alaska Statutes and Regulations and thought the new opioid treatment programs and facilities that were going to be coming into Anchorage and a couple that are already here within Alaska, may be required to have a "drug room" license based on what was described. In doing so it seemed to stir up a hornets nest so to speak, because some of them who have been in business for a while felt like they never had to have the board of pharmacy involved in what they do and were concerned that there would be an additional expense for them and felt they should

be grandfathered in. Investigator Kennedy then reached out to Assistant Attorney General Todd Araujo and asked his opinion on what was proper. Based on the original group that inquired via email, Investigator Kennedy and AAG Araujo agreed they would have to register as a "Drug Room". The Zipperer Medical Group who also facilitates opioid treatment as part of their medical practice contacted Ms. Bellino inquiring if it would have to be licensed as a drug room as well. Ms. Bellino received a letter from the attorney for the Zipperer Medical Group that explained exactly who, what, why and how they operate. Ms. Bellino forwarded the letter to Investigator Kennedy and he reviewed it with AAG Araujo and Investigator Howes. All agreed that if what they say they are doing based on the letter the, Zipperer Medical Group is not in violation. They are not dispensing out of a facility, but out of a doctor's office. Doctors can dispense from their office. The facilities within the state under HSS would like to ask the board if they can be "grandfathered" in and not be required to have to be licensed. CRC Health Group that is opening an Opioid treatment facility in Alaska also questioned why they would have to register as a "drug room" in our state.

Mr. Holm then asked are the facilities that would like to be "grandfathered" in, do they dispense differently than the Zipperer Group. Mr. Kennedy answered that the HSS treatment facilities provide the medications to patients within an institutional facility, not a doctor's office. That is the difference with the Zipperer Group. HSS facilities irrespective of being a state facility will have to follow the state statutes and regulations. Ms. Giessel asked if the distinction is between a doctor's office and an institutional facility. Investigator Kennedy cited **AS 08.80. 400 - OTHER LICENSEES NOT AFFECTED** that makes that distinction. Mr. Cotter asked how they are registered with the DEA? Mr. Kennedy advised that at this point he did not know and he has not reached out to the DEA yet because he wanted to see how things played out and then he will contact the DEA and he can then provide a complete recap. Mr. Cotter then asked Mr. Kennedy if the facility is registered as a facility with a non-physician charge or is it registered as an alternative practice sight of the physician that is signing off on the DEA. Mr. Kennedy advised the HSS is the entity that licensed these facilities and he is not sure how they are licensed through them. Mr. Kennedy advised that you have to have a certain type of clearance through the DEA for drugs used in opioid treatment and he had not fully looked into that yet. Mr. White asked if AAG Araujo would like to add to the conversation and AAG Araujo under scored a few of the things that Investigator Kennedy already ran though. That the purpose of the meeting is part fact finding to identify which side of the ledger they may fall on. In regards to the Zipperer Group based on the representation their position is based on three claims: 1) they are not an institutional facility, 2) they do not dispense, only prescribe, and 3) under section 400 irrespective of one and two they fall outside the rubric none the less. It appears based on the information

provided to us from the various entities that the Zipperer Group falls within a different category and so we will have to chase down some of these facts and then present it to the board to make the final determination. Mr. Holm advised a correction regarding point #2 that they prescribe and administer in a facility which is two different things they do not dispense to take outside or away from the facility but they do administer the drug which is a different function than just prescribing., just for clarification. AAG Araujo did discuss and review the difference between prescribing, administering and dispensing. Mr. Holm then when on to state and ask Investigator Kennedy that if it is in the Medical boards regulations that a dispensing physician should be dispensing personally to the patient and not delegating to another person in the office to do so. Mr. Kennedy advised the he will have to check to confirm that for further clarification. Mr. Holm stated he thought that to be the case.

Chairman White then asked is AAG Stacie Kraly if she would like to add anything. Ms. Kraly advised she is here as an interested party as to how the board will evaluate whether or not a license is required. Ms. Kraly had spoken with AAG Araujo earlier that the department looks at it as a cart and horse kind of a thing. The department approves these facilities for methadone treatment, but not unlike providing services and say like in an assisted living home you cannot place someone in an assisted living home before they are licensed, so the question of licensure is a kind of a condition precedent to whether or not they would approve the facility as a methadone treatment. They have other issues and considerations with respect to our regulatory framework around methadone treatment facilities, the approval process and how we interact with SAMSHA and the Federal Government. Those are broader more complicated issues that they are working on as well. The question that HSS would like to know is whether or not the board will consider the Zipperer Groups position, will it trigger the drug room licensure requirement or not. Once decided then they can go to the next phase, which if you need to be licensed and you are not then we can approve you, but if you don't need to be licensed then we make an independent evaluation on whether or not they would make the approval.

Mr. Holm stated that the board's ultimate goal is public safety and it is challenging to know all that goes on outside the board's circle of influence. If the board can interpret anything within the guidelines as under their purview it should be done.

Gerald Brown, Rph attending the meeting as a visitor, asked to make a statement. . Mr. Brown gave his opinion to help delineate this issue and to help the board with their consideration on this issue. Mr. Brown stated that he understands physicians under their purview to dispense through their offices, but when it becomes a facility then he believes it is no longer under the purview of the physician. It is now under

the purview of the state, which becomes the board of pharmacy. Therefore he believes a drug room license is needed.

Ms. Giessel asked if requiring these facilities to register as a drug room, is there an undue burden then placed on them? Other board members responded that the requirements are the license and application fees for a drug room and a consulting pharmacist or pharmacy would have to be obtained and there is a cost associated with that. Ms. Giessel said did not seem that it was too much of a burden.

Mr. Cotter agrees with what Mr. Brown stated, but asked how these facilities are registered, and if they are the practice site of the physician it gets cloudy, if it is not a practice site of the physician and they simply are practicing out of that facility then the facility should be licensed as a drug room. However, if the facility is registered as an alternative practice sight of the physician then it gets cloudy and this is why he brought this up regarding the registration with the DEA.

Chairman White asked Holly Byrnes and Randall Burns if they would like to add to the discussion. Mr. Burns addressed the board to see what the board is thinking as to what direction the board is leaning towards. Chairman White reiterated that the board will have to do some further research, but it looks like it is falling down on the side that a drug room license will be needed for the health and safety of the citizens and for the proper control and maintenance of medications of this class that there is some oversight.

Holly Byrnes, Division of Behavioral Health advised that she is available for any additional information request the board may need regarding their OTP's and her role with OTP's as the Alaska state opioid treatment authority.

Chairman White then asked CRC to explain how their license is set up with the DEA. Mr. Ruscella deferred their Licensing Manager Laurie Lower to answer. A DEA schedule II and III license from the DEA, this license allows them to dispense methadone at their clinics. If a controlled substance registration is required like it is in some other states they also have that when necessary.

Mr. Cotter asked if the DEA license was issued to the facility. Ms. Lower answered that the license is issued to the facility.

Mr. Holm asked Ms. Lower how often a DEA inspection is required. DEA conducts a pre-opening inspection, then on an average every 18 months to two years.

Chairman White asked who in their facility writes the prescription, the dispensing protocol and where does the dispensing authority originate from. Ms. Lower stated that dispensing methadone in most states is not regulated by the board of pharmacy. The ability to dispense the methadone is approved from the DEA.

Mr. Ruscella then went on to add that a prescription isn't actually physically written it is an order on the chart and the patient is dispensed the medication from the in house dispensary. The DEA license of a physician is not used to dispense the medication. The DEA license granted by the DEA for the OTP for the facility itself is what is used to dispense the medication out of the dispensary, like orders on a chart in a hospital even though CRC is not a hospital or an in-patient facility.

Ms. Giessel asked Mr. Ruscella if a physician or a pharmacist consulting are involved with this process that is dictating or overseeing treatment. Mr. Ruscella advised there is an MD who is licensed in Alaska as a medical director. They would be the one who is writing the order on the charts to dispensing the medication.

Holly Byrnes added that per federal regulation 42 CSR(8) one of the requirements at 8.2 for all OTP's is they must have a medical director who is licensed to practice medicine in the jurisdiction that the opioid treatment program is located and assumes responsibility for all medical services.

Ms. Giessel asked if the physician is on-site and interacting with the patient at all. Ms. Byrnes said yes that is correct. They must see the patient face to face to provide the diagnosis and assessing what level of medication is required.

Chairman White asked Mr. Ruscella if the patient is seen by a physician off-site then go to the treatment facility or are they seen by a physician on site. Mr. Ruscella answered the patient is seen by the physician on-site where they conduct a full physical, urine drug screen as well as certain blood tests if needed and required as a contract of the services. The physician has a full functioning office at the facility and meets the patient there. Mr. Ruscella advised CRC usually contracts with the physician and they are not there every day Monday through Friday as they would be in a physician's practice, but they contract with them for a couple days per week for 3-4 hours a day and they will do intakes and admissions on some of those days or other days as described by law. Mr. Ruscella stated that in other states the physician only has to see the patient within 48 to 72 hours live or come in, sign the charts and the licensed nurses at the clinic can do the initial physicals and examinations and so forth and initiate treatment. It differs state by state by what the time frame is that the doctor has to see the patient live, it usually is within 48 hours.

Ms. Cummins and Ms. Lower addressed the board with all of the federal requirements and who from their perspective is ultimately culpable.

Mr. Holm addressed the board that CRC Opioid Treatment Facility does fall under the requirements of a drug room. The board's main concern is the health and safety of the citizens of Alaska and Mr. Holm believes that there needs to be oversight that can be controlled from within the state.

Ms. Giessel recommended some time off the conference call for discussion and then decide how to proceed after the discussion. Ms. Giessel then made a motion

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

> **RESOLVED to amend the agenda from 10:15 a.m. to 10:45 a.m. to allow for a discussion period to discuss the licensing of Opioid Treatment Programs where the board can discuss this.**

Mr. Burns then asked the impact of the motion and asked if the board would be going into Executive Session. Ms. Giessel then advised that the board could do that and made the motion

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

> **RESOLVED In accordance with the provisions of Alaska Statute 44.62.310(c), Ms. Giessel moved to go into executive session for the purpose of discussing the licensing of the opioid treatment facilities. The board, licensing examiner, AAG Araujo, and Investigators Kennedy and Howes to remain during session.**

Off the record at 10:15 a.m.
Back on the record at 10:32. a.m.

The board determined that a drug room license will be required for any non-physician practice sight. A physician's office does not require a drug room license. All other clinic and operating facilities will be required to register, and they will need to obtain a drug room license for the upcoming licensing period and licensing will need to be in place by July 1, 2014. Ms. Bellino will send a letter to all interested parties.

The board then formally introduced themselves to AAG Araujo and took the opportunity to ask and briefly discuss the letter received from the FDA Commissioner and how that harkens back to the "high risk" pharmacy. A copy of the FDA letter was given to AAG Araujo for further review and advisement.

The board recapped the OTP discussion and Ms. Bellino will send a draft of the letter to the board for review before being sent to all interested parties.

Agenda Item 4 Charles Ward, Paralegal –

Charles Ward discussed continuing education audits and consent agreements with the board.

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

> **RESOLVED In accordance with the provisions of Alaska Statute 44.62.310(c)(1), Mr. Holm motioned to go into executive session for the purpose of discussion regarding Continuing Educations matters board, staff and paralegal to remain.**

Off the record at 10:45 a.m.
Back on the Record at 11:00 a.m.

Break:
Off the record at 11:01 a.m.
Back on the record at 11:14 a.m.

The board decided to review the Pharmacist to Technician Ratio regulation before Agenda Item #5 Office business. The board reviewed other states regulations' regarding Pharmacist to Technician ratio's and it varies, from where the regulation is placed to the ratio quantity. The board is entertaining instituting a 1 to 4 pharmacist to technician ratio and after much discussion and debate the board decided to table this topic to next board meeting in April so the two other board members who are not in attendance can be present and involved in the discussion.

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

RESOLVED to move table agenda item Pharmacist to Technician Ratio to the next board meeting on April 3rd, 2014.

Agenda Item 5 Office Business –

The board signed Travel Authorizations, Wall Certificates and reconfirmed the April meeting will be split. Friday April 4th the BOP meeting will be at the Anchorage Hilton. Ms. Bellino advised the board that Josh Bolin from NABP will be presenting on the VPP program that Friday after public comment.

This meeting is Richard Holm's last board meeting. His two terms have concluded and a new board member will begin their term on March 1, 2014 and will be present for meeting in April.

The board thanked Mr. Holm for his service and all of his hard work over the last eight years. Mr. Holm thanked the board and stated he enjoyed his time on the board and worked hard to serve and protect public safety for the citizens of Alaska. Mr. Holm wished the board continued success in doing the same.

The board adjourned at 12:00 p.m.

Respectfully Submitted:

Donna Bellino

Donna Bellino
Licensing Examiner

Approved:

Dirk White, R. PH., Chair
Date: 4-3-14