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

ALASKA STATE BOARD OF PHARMACY

MINUTES OF MEETING
September 20-21, 2007

By authority of AS 08.01.070(2) and in compliance with the provision of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held on September 20-21, 2007, at the Atwood Building, 550 West 7th Ave., Suite 1270.

Call to Order/Roll Call

The meeting was called to order by Gary Givens, Chair, September 20, 2007 at 9:02 a.m. Those present constituting a quorum of the board, were:

Gary Givens, R. Ph.
Richard Holm, R. Ph.
Leona Oberts, Public Member
Mary Mundell, R. Ph.
Dirk White, R. Ph.

Cindy Bueler was not present at the meeting.

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

Sher Zinn, Licensing Examiner
Susan Winton, Investigator
Jun Maiquis, Regulation Specialist-via telephone
Gayle Horetski, Assistant Attorney General-via telephone
Brian Howes, Investigator

Visitors present:

Ken Truitt, SEARHC
Robert Young, R. Ph., SEARHC
John Wanek, AkPhA
Ted Leonard, Deputy Commissioner
Mark Davis
Hilary Martin, Sonosky Chambers law firm

Agenda Item 1 **Review of Agenda**

The board approved the agenda:

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

RESOLVED to approve the agenda as written.

Agenda Item 2 **Review of Minutes**

The board reviewed the minutes for the May 17-18, 2007 meeting and the July 10, 2007 teleconference. No changes were made.

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

RESOLVED to approve the minutes of the May 17-18, 2007 meeting as written.

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

RESOLVED to approve the minutes of the July 10, 2007 teleconference as written.

Agenda Item 3 **Ethics**

The board watched the ethics video. There were no ethics violations to report. Mr. Givens asked the board because he is a Commissioned Corp Officer, if he should recuse himself from the Public Health Service Commissioned Corp Officer discussion on Friday and the regulation discussion considering the board adopting the ten mile rule for remote pharmacies. He noted that after watching the ethics video, he had no personal or financial gain from either matter. He further stated he had spoke with an attorney and was advised that no ethics disclosure needed to be made because there was no personal or financial gain. Therefore, he did not feel he needed to recuse himself from the discussion. He stated that if the board felt he needed to abstain from the discussions, he would do so. He said the purpose of the board was to protect the public health, safety and welfare by regulation of the pharmacy profession. Therefore the board needed to be knowledgeable of issues concerning the board and its purpose.

Agenda item 4 **Goals and Objectives**

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

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

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

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

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

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

7. The board will continue their affiliation with NABP and send one board member to the District VII NABP meeting and two members to the annual NABP meeting. The Division's budget currently allows only one out-of-state travel per fiscal year; this is generally used for attendance at the District VII NABP meeting.

8. The board will continue to evaluate the need for regulations specific to facility activities (i.e.; retail pharmacies, drug rooms, institutional pharmacies, home infusion pharmacies, nuclear pharmacies, remote sites, sterile products, etc.).

9. The board will continue to evaluate regulations regarding the electronic transmission of prescriptions.

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

11. The board will assess and evaluate the growing public concern regarding abuse of prescription drugs.

The board reviewed the goals and objectives and made the following changes:

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

9. Delete

11. The board will assess and evaluate the growing public concern regarding abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs, and development of a prescription monitoring program.

The board decided to evaluate the intern jurisprudence questionnaire and asked Ms. Zinn to gather data from past exams for the board to review at the next meeting. The board discussed whether a pool of questions should be used as the MPJE has, or if three exams should be used alternately.

In regards to number 6 if the goals, the board asked Ms. Zinn to obtain a history of licensing actions against pharmacy technicians to determine if a pattern had evolved.

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

RESOLVED to approve the changes to the Goals and Objectives as noted.

Break-Off the record at 10:22 a.m.
On the record at 10:47 a.m.

Agenda Item 16 **Correspondence**

The board reviewed the NABP correspondence.

NABP-August 24, 2007-Suspension of the NAPLEX and Georgia MPJE Examinations-No action required.
NABP-August 22, 2007-E-news-No action required.
NABP-August 6, 2007-Materials Seized from Univ. of Georgia College of Pharmacy-No action required.
NABP-July 27, 2007-Implementation of Section 7002(b)-No action required.

The board reviewed the general correspondence.

Troutman Sanders LLP, Attorneys at Law-September 4, 2007-Response to NABP Seizure of materials-No action required.
Island Pharmacy-August 10, 2007-Notice of Theft or Loss-No action required.
DEA-July 31, 2007-Notice of Diversion Trends-Letter to be posted on the board website.
Whale Tail Pharmacy-July 23, 2007-Notice of Theft or Loss-No action required.

ACLU-June 18, 2007-Religious Refusals and Reproductive Rights-No action required.

Mr. Holm shared with the board a fax he had received at his pharmacy from an internet pharmacy that offered prescription medication without a prescription by completing an online questionnaire. He also handed out copies of a prescription obtained from the internet he had received from a patient along with a letter asking the customer for information regarding any problems the patient had with the pharmacies refusal to fill the prescription. Mr. Givens thought an article should be put in the newsletter regarding internet pharmacies and warning pharmacists of illegal prescriptions. Mr. Givens also asked who on the board would like to replace Cindy Bueler as the secretary for the board meeting since she was not able to attend the board meeting. Ms. Bueler asked Mr. Givens to appoint someone as secretary to gather needed information for the Board Newsletter and the Board Report for the Alaska Pharmacist Association. It was decided Ms. Zinn would make a copy of the meeting recording for Ms. Bueler to obtain the information for the newsletters.

Ms. Zinn suggested the board could put information on the website for the public regarding internet pharmacies. The board directed Ms. Zinn to put the letter from the DEA discussed in the correspondence on the website which was in regards to internet prescriptions and drug diversion. Mr. Givens noted that the issue of internet pharmacies would also be a good topic for the newsletter.

After discussion of the Reports of Theft or Loss in the general correspondence, the board decided to put the discussion of a regulation for a secure closed pharmacy on a future agenda.

Ms. Zinn distributed a letter to the board from Nancy Sanders, Executive Administrator for the Board of Nursing. The letter asked the board if a pharmacist would accept and fill an order written for medication, such as rabies vaccine or immune globulin, by a veterinarian. The medication would be intended for human consumption. The board opined that current regulations do not prohibit a pharmacist from accepting a prescription from a veterinarian for human consumption in an emergency. The pharmacist would recommend the patient be seen by a physician as soon as possible and verify the treatment was in line with appropriate medical care.

Agenda Item 5 **Prescription Monitoring Program**

Brian Howes, Senior Investigator, joined the meeting for a power point presentation concerning the division's proposed Prescription Monitoring Program. Mr. Howes stated the division was looking for support from the Board of Pharmacy in implementing a Prescription Monitoring Program for controlled substances. As of November 6, 2006, 33 states had enacted legislation which

required prescription monitoring programs. Twenty five were in active status and another eight were in the start up process. Another 15 states were in the process of proposing, preparing, or considering legislation, including Alaska. The

program had not been used to target possible subjects of an investigation but the data would be used after an official complaint had been received. The system could be programmed to trigger an alert in regard to blatant abuses and could be used to query "doctor shoppers".

Emergency Fire Alarm Drill-Off the record at 11:25
On the record at 11:55

The controlled substance prescription data system provides safeguards for the protection of patient confidentiality through statutes and regulations and access to information is already granted to State authorities and officials. The data does not generate a case but creates an uncomplicated path to the collection of information. Alaska Statutes allows investigative staff to "provide inspection, enforcement and investigative services to the boards and for the occupations listed in AS 08.01.010, regarding all licenses issued by or through the department". The average cost to start would be approximately $350,000 and annual costs range from $100,000 to nearly $1,000,000. The division had been awarded a grant from the Department of Justice, Harold Rogers Prescription Monitoring Program for planning of the program. There is an additional grant program called NASPER that can be used to enhance the program to share data among states.

Mr. Howes stated the division is pursuing legislation and he hoped it would be in place next year. He noted the pharmacy would not have to have specific software to report. Some chain stores already have software that could be used for a "data dump".

Mr. Howes stated he would be going to a conference in Albuquerque to obtain more information on the process of starting up a program and would share his findings with the board.

Mr. Givens thanked Mr. Howes and told him the board would discuss the letter of support later in the meeting.

Lunch Break-Off the record at 12:15 p.m.
On the record at 1:07 p.m.

Agenda Item 6 **Regulations**

Jun Maiquis, Regulations Specialist, and Gayle Horestski, Assistant AG joined the meeting via telephone.

Shared Pharmacy Services

The board reviewed the public comment received from Lis Houchen, NACDS, regarding the Shared Pharmacy Services proposed regulations. After considering the comments for 12 AAC 52.445(c)(1)(A) and (B), the board decided to make the following changes to the proposed regulations:

(c)Identification of pharmacies engaged in shared pharmacy services:
(1) before using shared pharmacy services provided by another pharmacy a pharmacy shall use an identifier on the prescription container to identify prescriptions filled at a shared services pharmacy, and shall:
(A) notify patients that their prescription order may be processed or filled by another pharmacy; and
(B) give the name of that pharmacy or if the pharmacy is part of a network of pharmacies may process or fill the prescription order, the patient shall be notified of this fact; such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy;

The following changes were made to 12 AAC 52.445(c)(2)(A), (d)(1) and (2):

(c) Identification of pharmacies engaged in shared pharmacy services:
(2)(A) the local, and if applicable, the toll-free telephone number of the requesting pharmacy or filing pharmacy; and

(d) A pharmacy engaged in shared pharmacy services shall meet the following requirements:
(1) maintain manual or electronic records identifying, individually for each order process, the name, initials, or identification code of the pharmacist(s) responsible for the final verification of dispensing, which includes order interpretation, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, or refill authorization functions performed at that pharmacy;
(2) maintain manual or electronic records identifying, individually for each order filled or dispensed, the name, initials, or identification code of the pharmacist(s) responsible for the final verification of dispensing, which includes filling, dispensing, and counseling functions performed at that pharmacy;

The following changes were made to 12 AAC 52.445(e)(3)(A) and (D):

(e) Each pharmacy providing or utilizing shared pharmacy services shall develop, implement, review, revise, and comply with joint policies and procedures for shared services. Each pharmacy is required to maintain only those portions of the joint policies and procedures that relate to that pharmacy's operations. The policies and procedures shall:

(3)(A) notifying patients that their prescription may be outsourced to another pharmacy for shared services and providing the name of that pharmacy, or alternatively, satisfying the identifier requirements of (c)(1) of this section;

(D) maintaining appropriate manual or electronic records to identify the name, initials, or identification code and specific activity or activities of the pharmacist(s) responsible for the final verification of dispensing;

After discussion of who would ultimately be responsible to ensure compliance with the requirements of this section, it was decided to add a new section. The new section would read, "(g) The pharmacist-in-charge of the requesting pharmacy must ensure compliance with the requirements under AS 08.80 and this section".

Telepharmacy Ten Mile Rule

The board discussed the changes to the telepharmacy regulations, which would require a remote pharmacy to be located not within 10 miles of a licensed pharmacy. Ms. Horetski noted that in accordance with State Statutes, "the practice of pharmacy is declared to be a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest that only qualified persons be permitted to engage in the practice of pharmacy, and to ensure the quality of drugs and related devices distributed in the state." She stated that throughout the legislative history of the board, there was no intent that regulations be drafted to further the economic interests of specific licensees or interests. Regulations should focus on practice standards, training, continuing education, investigation of violations and so forth. Regulations are focused on the public health and safety. The board should look at the effect of regulations and the cost to comply for small businesses and the public, but that is a separate issue.

Mr. Givens stated that it was a gray area in that if the board allowed a telepharmacy into an area, it could possibly change patient access in that community by shutting down brick and mortar pharmacies. How would economics cross over in that type of situation? Ms. Horetski noted that in certain situations, such as hospitals that need a certificate of need, the legislature had set the requirement in statute that the hospital must prove it is needed in that community before they may receive the certificate. She further stated there was nothing in the Board of Pharmacy statutes that would allow the board to make those types of judgments. Ms. Horetski further stated, "How was the board to know the effect of a remote pharmacy in a given location is going to be? It is really speculation. And to refuse to issue a license to a pharmacy or to change the regulations that would prevent the issuance of a remote pharmacy license based on some kind of speculation that it might hurt an established business is not directly focused on the public health and safety." Mr. Givens stated he had

been thinking about the issue since the last board meeting. He stated the discussion revolved around the issue that if the board did not have a ten mile rule, that would allow a telepharmacy or automation come into the community and compete with the brick and mortar pharmacies and jeopardize the pharmaceutical care in the community because of the economic impact. He further stated that the more he had thought about it, it would not be a sound reason. He noted he would like to change his stance and not put a ten mile rule

in the regulations. He would prefer the patient make the determination whether they want to have a technician or pharmacist for pharmacy needs.

Mr. White stated the situation that had come before the board was for a pharmacy that currently exists that had a pharmacist on staff. He stated it is hard to get pharmacists and a new option had opened up making it a financial advantage for them. He stated that would allow one group financial advantage over another group. He said he understood that if it was a new pharmacy, the board may be applying financial dictates, but that would not be the case for an existing pharmacy. Mr. Holm stated that he felt he was misquoted from a prior board meeting in the public comments submitted for the regulation. He stated that what he had said was, if a remote pharmacy came into a community, it could possibly force the closure of a fully staffed pharmacy. Therefore the public would not have access to quality care by not having a pharmacist in that community. He stated that his opinion was that a live pharmacist in the community was better service to the public than a telepharmacy. Ms. Mundell stated the ten mile rule was decided on because the board's intent for a telepharmacy was for an "underserved" community, a community that did not have access to pharmacy services. Mr. Holm stated when the board discussed the issue, they noted the purpose of the telepharmacy was to serve "underserved" communities, not to solve staffing issues. Ms. Mundell noted that another pharmacy had brought an application before the board for review and the intent for the telepharmacy was to eliminate staff issues, not because the community was underserved. Mr. Givens stated that the issue first came to the board when Safeway in Ketchikan submitted an application for a remote pharmacy. He stated he felt they should have granted the license because Island Pharmacy was not open on Sundays. The telepharmacy would have been able to provide services on Sundays. Mr. White noted that although the pharmacy is closed on Sunday, an emergency number is posted at the pharmacy so a patient may speak to a pharmacist at any time. Ms. Horetski said that people could get healthcare and pharmacy services from a variety of providers, including Native Health Providers and if they chose a telepharmacy where they did not have face to face contact with a pharmacist, it was not up to the board to determine it would be a bad choice for them. The concept that a remote pharmacy could come in and provide pharmacy access to a patient who could get their medication at less cost through them because their healthcare plan contract approved it, was not for the board to determine. She further stated it was not the role of the board to decide where the patient should go for healthcare. The board's role is to ensure there are minimum standards in

place to protect the public health and safety. Deciding where a patient goes for healthcare was not within the board's purview. Ms. Horetski stated that since the board's purpose was to serve an "underserved" community, she would urge the board to not adopt the ten mile rule, but draft language to define "underserved" and use size of the community, population, or whether the community was on a road system. She further suggested the board could adopt the Shared Pharmacy Services portion of the regulation project only, and then have the proposed definition go out for public comment.

Ms. Horetski noted that to defend the regulation, the board would have to have a defense other than economic reasons, such as the original intent of the regulation. It was noted by Mr. White that all of the public comment for the regulation came from the native healthcare facility in Klawock. Ms. Mundell noted that what the board was looking at was a type of government facility and the board would need to ascertain if the facility would serve non-beneficiaries, then it would fall under the purview of the board. Mr. Givens stated the board should do what was best for the state, not just one community. He further noted the reason for taking out the ten mile rule was to give better service to the community, and now the board wanted to take that away. If it was not good care, the board should repeal the regulation. Ms. Oberts noted that the intent was not to disallow free healthcare to the native population, or federal facilities.

Mr. Givens asked the board if they wanted to table the issue until after discussion with Paul Lyle, assistant AG, on Friday, or vote now. Mr. Holm stated he wanted to wait until the board received information from the other states that have the rule of mileage for remote pharmacies. Specifically, how their laws gave them the authority to restrict the remote pharmacy by miles.

After further discussion, it was noted the Board's position for wanting the ten mile rule was, they felt face to face contact with a pharmacist was better for the patient than contact with a pharmacy technician. If the patient did not have contact with a pharmacist because the community was too small for a full pharmacy, the next best care would be with a pharmacy technician. It was also noted for the record, the board did not institute the telepharmacy regulations to solve staffing issues, but to serve communities that were "underserved", meaning a community without a pharmacy staffed by a pharmacist.

The board decided to wait on a decision for the ten mile rule until after the discussion with Paul Lyle on Friday.

Mr. Maiquis would re-draft the Shared Pharmacy Services Regulations and send copies to the board for approval on Friday.

Wholesale Distributor Licensing

Ms. Horetski noted that Mr. Maiquis had given her a copy of the proposed wholesale distributor licensing regulations the board had drafted. Ms. Horetski said she was given the regulations to determine if the board had the statutory authority to license out-of-state wholesale distributors. She stated the pharmacy profession had been regulated since 1955 and changes had been made over the years. In 1992, existing statute 08.80.158 was added dealing with registration of pharmacies located outside the state of Alaska. The pharmacy statutes were substantially revised in 1996. That was when most of the current statutes for pharmacy came from that act and most of the regulations were adopted in 1998

to implement the 1996 statute changes. The board has the authority for licensing of pharmacists and pharmacies in state and out-of-state, and wholesale distributors which is found in 12.56.610. She stated the board had some authority for licensing of wholesale distributors. The statutory authority may be found in 08.80.005, 08.80.030(a)(4),(7), (10), 08.80.157 adopted in 1992 and not rewritten in 1996. In 1996, 08.80.158, registration of pharmacies located out of the state was added. She stated that their charge was to decide what the legislative intent was. The board only has the power given to it specifically by the legislature through statute. The issue was if the legislature granted the authority to the board to register or regulate wholesale distributors located outside of the state. She noted that the legislature gave clear authority to license out of state facilities in 08.80.158, but there was no provision for drug wholesale distributors located outside of the state. The statute giving authority to license wholesale distributors in 08.80.157 does not specifically state facilities located outside of the state. The definitions in 08.80.480(24) defines pharmacy which states “a pharmacy means a place in this state where drugs are dispensed…that is subject to licensure or registration under AS 08.80.157(b)”. That clearly shows the legislature knew how to delineate between inside the state and outside the state. She further stated that in 08.80.480(35) “wholesale” means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user. Ms. Horetski said the statutes clearly show the board has authority to license wholesale distributors inside the state, but the statutes do not show clear authority for licensure or registration for wholesale distributors outside of the state. Ms. Horetski noted the draft regulations given to her from Mr. Maiquis, was written by Josh Bolin from the NABP using the NAPB’s model rules for Wholesale Distributor Licensing. She further noted that since the time Mr. Bolin drafted the language, the NABP had adopted new model rules and a new Model Pharmacy Act in 2007. Ms. Horetski stated that she had conferred with Deb Behr and Steve Weaver from the Department of Law regarding the issue. They advised Ms. Horetski the board could do some “fine tuning” of the current wholesale distributor regulations, however there were several issues in the proposal that would require clear statutory authority the board does not have. Specifically the section that states the board must keep certain information confidential. Another was requiring employers to do background checks on their employees. She stated the board clearly does not have that authority. After looking at the language, the conclusion by the Department of Law was the board would have to obtain specific statutory authority for it.

Mr. Givens asked Ms. Horetski what the Board needed to do to get the authority. Ms. Horetski said the Board could submit a proposal for statutory change through the division director, Rick Urion. He would then send the proposal to the commissioner's office for approval, and from there it would go to the governor's office. If the concept was approved by the governor, it would either be forwarded to the Department of Law to be drafted and introduced as a bill from the governor, or once the language was drafted, the governor would give it to a "friendly" legislator for sponsorship. Either way the governor would have to

approve it for drafting by the Department of Law. Ms. Horetski further stated there was a one page form that should state the concept of the board's proposal, that should be completed by the board staff and given to the director for approval.

Ms. Oberts left the room at 3:00 p.m. and returned at 3:05 p.m.

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

> **RESOLVED to submit a proposal to the Governor for statutory authority for licensing of instate and out-of-state Wholesale Drug Distributors.**

Ms. Oberts was not in the room during the vote. Those voting yea on the motion included Mr. Holm, Mr. White, Ms. Mundell and Mr. Givens.

Break-Off the record at 3:08
On the record at 3:23

It was noted Nancy Davis would not be present at the meeting for the AkPhA Report

Substitution

The board reviewed the need for changing 12 AAC 52.510 to incorporate the use of electronic transmission of prescriptions. Currently the regulation required the prescribing practitioner to "hand write" on the prescription "brand medically necessary" or similar wording if the practitioner did not want a medication substituted. Since prescriptions may be sent electronically through the use of an electronic transmission system, the practitioner cannot "hand write" on the prescription.

The board decided to change 12 AAC 52.510(a)(1)to read, "The prescribing practitioner does not hand write or electronically note on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary" or similar wording.

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

RESOLVED to send the change to 12 AAC 52.510(1)(a) to the regulation specialist for drafting.

Agenda Item 16 Correspondence

The board continued to review the correspondence.

John Wanek, AkPhA President-September 18, 2007-Partnership for Prescription Assistance-For information only.

Agenda Item 8 Public Comment

Ms. Horetski, Assistant AG, was present during the public comment period via telephone.

Ken Truitt, General Council for Southeast Alaska Regional Health Consortium (SEARHC), Bob Young, PHS Commissioned Officer for SEARHC, and Hilary Martin from Sonosky Chambers law firm were present for public comment. Mr. Truitt started the public comment by noting he had previously been an Assistant AG for the division and was one of the board's attorney's while working for the state. He stated that approximately ten years ago, he had worked on the regulation package that was enacted in 1997. He stated that SEARHC had submitted an application for a facility license for Mt. Edgecumbe Hospital in Sitka and a remote pharmacy license for the Alicia Roberts Health Clinic in Klawock. He noted the regulation that was addressed earlier regarding a ten mile rule for remote pharmacies would have direct impact on the license application for Alicia Roberts Health Clinic. He noted it was a convergence of issues at the meeting that were very important to SEARHC. He stated that federal and state issues may be addressed by Paul Lyle on Friday. Mr. Truitt noted that SEARHC had submitted comment for the ten mile rule regulation that had gone out for public comment. He stated SEARHC was part of the Alaska Tribal Health Compact and the delivery of Indian healthcare in the State of Alaska was different than any other state in that every tribal group that wishes to operate under the Indian Self Determination Education and Assistance Act, comes together as one body and are signatories to the ATHC. In other states, each individual tribe contracts with the federal government for healthcare. In Alaska when it was determined that tribes and tribal groups did exist in the state, the Federal government recognized a list of 234 tribes. In Arizona there may be only four or five recognized tribes that occupy a large land mass. Congress decided the healthcare to the indigenous people of the country was falling short. The federal government was

not meeting the needs of the people through the system at that time. Since the act developed in 1973, tribes in Alaska had been able to enter into negotiations with the federal government and obtain a budget, take the money and run the program themselves. That does not happen on that scale anywhere else in the country. What they have found through inflation, the growing cost of healthcare far exceeds the funding of healthcare that was available. Annual inflation for healthcare was seventeen to eighteen percent, while the annual increase through the compact was one to two percent. SEARCH wants to deliver the highest healthcare that they can, and would like to do so through collaboration with others. One of the ways of evidence of that was through the application for Mt.

Edgecumbe Hospital as the central pharmacy and the remote pharmacy application for Alicia Roberts Health Clinic. One of the major issues was what authority the board had over tribal health providers. Even as tribal providers, they employ Public Health Service Commissioned Corp Officers. Does the board have authority to require licensure of the PHS Commissioned Corp Officers? The broader issues break down into smaller issues. It was an open legal question whether the board could require SEARHC or ANMC to have a state license, either as a facility or for pharmacists and technicians. Ms. Mundell asked Mr. Truitt if they were a federal facility and how would he define it. Do you find yourself strictly a tribal facility or since the federal government funds SEARCH and had managed in its own programs, are you or are you not "owned and operated by the federal government". Mr. Givens stated that it could be a very complex question since they do have federal authority to purchase off the prime vendor. They do have certain federal authority, such as being protected under the Federal Torts Claim Act. A direct hire physician who worked at ANMC would not have to purchase their own malpractice insurance, but would be covered under the Federal Torts Claim Act. Mr. Truitt said "after being in the state system, call it a hunch, I hope that I am wrong, but this is the part why Gayle is on line, we would love it if the state came down for the request that you put in from the Attorney General's office, the same way they came down with the Dental Board, which is for Dental Health Aide Therapists. The Dental Board does not have authority over the Dental Health Aide Therapists. That may not happen the way that we would like to see it. Which is to say, it's possible the state could come down the other way and say that tribal health facilities, ANMC, SEARCH are subject to state regulations. If it turns out to be the case, we don't know, I have my own hunches about that, then all the tribal health providers will be in a pretty awkward position. We would in my eyes, be out of compliance with state laws, but the final authority on that does not rest with Attorney Generals office. It could be just their opinion. The final authority, the final answer, without question is going to be the court system. And the only way to get that answer is to go through the court system, having litigation over that."

Ms. Oberts asked Mr. Truitt, "On that point, what would be the main concern for being in compliance with our state laws?" Mr. Truitt said, "I mentioned earlier, collaboration for our own reasons, whether or not we are forced as a matter of law, to comply with regulatory licensing provisions for pharmacy and practice of

pharmacy, we want to be licensed by the state. But without giving up any legal rights that we have, which is why we submitted applications for licensure. For our own internal purposes, maybe we don't find it particularly appealing to be at odds with the state, but if that's the way it is going work out, we would like to have our facilities licensed by the state and our direct hire pharmacists licensed by the state and alot of our Commissioned Corp Officers have state licenses." Ms. Mundell asked "And your pharmacy technicians as well?" Mr. Truitt responded, "Yeah". Mr. Givens stated he thought all of the pharmacy technicians were licensed. Mr. Truitt stated Mr. Young could answer that question and noted he thought all direct hire pharmacists were licensed. He stated he would like to

have Mt. Edgecumbe Hosptial Pharmacy as the central pharmacy licensed as well as the remote pharmacy. He also stated the board had a convergence of issues including the ten mile rule that if it becomes effective and the Attorney General opinion stated Native Healthcare Facilities must be licensed by the state, it would mean Alicia Roberts would be out of state compliance. That would mean a reduction in pharmacy services because there would be the question of whether they could have any kind of pharmacy services at Alicia Roberts. Staffing issues are directly related to whether they could provide pharmacy services at all to their beneficiaries on Prince of Whales Island. Mr. Truitt said, "HRSA (Health Resources and Services Administration) has defined that area as medically underserved and a lot of things go into that recognition. And some of those things are the economic health of the region, and it is a very economically challenged area as well. So if we are unable to offer pharmacy services on Prince of Whales at all, that means we would be back to what the chairman was talking about, mailing of pharmaceuticals, sitting on shelves, dispensed by health aides which don't have to be licensed by the state. So it would be a lower quality of care, it would be lesser patient safety without pharmacy services delivered by a licensed pharmacist, pharmacy tech. I am glad Gayle is on the line, because right now, we believe our applications meet all of the requirements of the regulations as they exist today. If the ten mile rule is adopted, it does not become effective after the Department of Law review, and it has been signed off by the Department of Law, then it's filed by the Lieutenant Governor. Then 30 days after it's signed it becomes effective. Our application is right before you today, and I believe you do not have the legal authority to withhold action on an application that is ready for action, ready for your action right here at this meeting with the regulations and laws as they currently exist." He stated that if Ms. Horetski advised the board to approve the licenses, and the board adopts the ten mile rule and it would go into effect in the future, in essence it would make the approved licenses "unlawful". He further stated, "We would just rather have you grant our application for licensure. We don't really want to be staring across a line in the sand at the state if and when it comes down from the Attorney Generals office delivering the opinion that tribal health consortiums be licensed. We would just rather be licensed."

Ms. Zinn asked Mr. Truitt what kind of healthcare Alicia Roberts currently has. Are they Nurse Practitioners or Physician Assistants? Mr. Truitt said that they

like to staff the clinic with physicians. Ms. Zinn further asked if the practitioner could dispense from their office. Mr. Truitt said that was a legal question. Ms. Mundell stated they have the authority to dispense medication to their patients from their office. Mr. Truitt further stated the turnover rate for physicians is very high and as of today he was not sure how many there were. They try to staff three or four physicians and physician assistants in the facility. If there is no one on staff, the management would bring in a locum physician. Mr. Givens asked how pharmacy services were currently being delivered at Alicia Roberts. Mr. Young, Director of Professional Services for SEARHC, stated they have had a telepharmacy system in place at Alicia Roberts since August 20th. The machines

that dispense the medication are large and bullet proof. The pharmacist in Sitka sits in an office in front of a computer screen with a camera on it. He can move the camera around and see anywhere inside the pharmacy and monitor the technician as the medication drops out of the machine. The order is scanned at the nurse's station right to the pharmacist in Sitka. It is then printed from the printer. The pharmacist puts it into the computer and then reviews the order. He then goes over to another computer where he tells the machine to drop the medication for the patient. The label prints at the clinic, the drug drops out of the machine, the technician barcodes and checks the drug, barcodes the label and her ID, and in the presence of the pharmacist, puts the label on the bottle and dispenses it to the patient. The technician then advises the patient that the pharmacist is available on the computer for counseling. The pharmacist in a closed room can then talk to the patient through the system. He stated it was not better than having a pharmacist right there but was "pretty darn close". He further stated that it was an experiment, if it works, they would look at putting it at other sites such as Angoon and Kake. He noted they serve a different population than the brick and mortar pharmacy serves. He said it was a quality program and did not think they were "short changing" the patient and the patient would still make the decision where they would go for pharmacy services. He stated the board said it was not their concern to solve staffing issues, but without the staff, it would be "underserved". Mr. Holm asked Mr. Young if a licensed technician would staff the remote pharmacy. Mr. Young said there was a licensed pharmacy technician currently at the facility. He said they operate as if they were licensed by the board. There would be nothing that would need to be changed if licensed. Mr. Holm stated that nothing they had shown them today would change his mind from putting in the ten mile rule. He said that was not what they really wanted to do but he did not see why the board could not issue an exemption since they would be serving their beneficiaries and then the ten mile rule would not apply. He said that he would like the board to be able to look at them on a case by case basis. Mr. Young responded by saying that Alicia Roberts is a HRSA facility but they have not been able to provide services for all of the HRSA patients they could. Ms. Oberts stated she would like the Department of Law to look into whether the board could consider an exemption for the ten mile rule before she would consider doing so.

Mr. Givens thanked Mr. Truitt and Mr. Young for speaking during public comment. He stated he had thought for example, if Mr. Holm could supply his compounding services to a place where that option was not available. For example in Fairbanks, where he could put a remote pharmacy in downtown Fairbanks and stock the compounded products that perhaps would not be available anywhere else in Fairbanks. He stated he was not thinking more of places such as Ketchikan or Alicia Roberts, but that anyone in the pharmacy industry could use the technology to provide the best care available to the patients anywhere in the state where they would not normally be available. He asked why would you need the ten mile rule and not allow that type of service available to everyone to give them the best care possible. He further stated he

thought the Department of Law would not allow them to have an exemption, but would counsel them to put the requirements for the licensing in the regulations.

The board recessed at 4:13 until Friday at 9:00 a.m.

Friday September 21, 2007

Call to Order/Roll Call

The meeting was called to oder by Gary Givens, Chair, September 21, 2007, at 9:04 a.m. Those present constituting a quorum of the board were:

Gary Givens, R. Ph.
Richard Holm, R. Ph.
Mary Mundell, R. Ph.
Leona Oberts
Dirk White, R. Ph.

Cindy Bueler was present at the meeting.

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

Sher Zinn, Licensing Examiner
Susan Winton, Investigator

Visitors present:

Bob Young, R. Ph., SEARHC
Ken Truitt, SEARHC
Hilary Martin, Sonosky Chambers law firm

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

RESOLVED to approve the agenda as written.

Agenda Item 10 **Division Updates**

The board reviewed the board's Annual Report and Expense Report. Ms. Zinn noted the expense report reflected a positive number and the board may not need to raise the licensing fees for the next renewal period.

Agenda item 16 **Correspondence**

The board continued to review the correspondence.

The board reviewed the e-mail inquiry from Elyse Tung. Ms. Tung asked the board if prescriptions for pain medication written for patients in Alaska by pharmacists who have prescriptive authority in the State of Washington, would be able to get their prescriptions filled in Alaska. Ms. Tung further stated that pharmacists with collaborative practice agreements are considered mid-level practitioners in the State of Washington. The board determined that since pharmacists in the State of Alaska do not have prescriptive authority, prescriptions written by Washington licensed pharmacists would not be allowed to be filled in the state. Mr. Givens stated the board should not change current regulations to allow for other states laws. Mr. Holm stated since the medication noted in the request was for scheduled drugs, it would also be a DEA issue. Mr. Mundell noted that a physician at Elmendorf may not write a prescription and have it filled unless they have their own DEA number. They may not use the facility DEA number. Mr. Givens asked if they could use the hospitals number with a suffix at the end. Ms. Mundell said no, that according to the last time she spoke with the DEA, the prescriber must have their own specific DEA number. Ms. Mundell suggested that should be a topic for the newsletter. Ms. Zinn stated the Medical Board regulations had changed for physician assistants. Physician assistants now have prescriptive authority to prescribe schedule II substances if the physician has given the physician assistant the authority, and perhaps the board could put the information in the newsletter to make pharmacies and pharmacists aware of the new regulation. Mr. Holm asked how the pharmacist was to know the physician assistant had the authority to prescribe schedule II controlled substances. Ms. Zinn noted the physician assistant must have a DEA registration showing the designation of schedule II substances.
Ms. Zinn would respond to the e-mail.

NABP-September 13, 2007-Reactivation of the NAPLEX and Georgia MPJE Examinations-No response required.

Agenda item11 **PHS Commissioned Officers**

Dirk White and Leona Oberts left the room at 9:28 a.m. and returned at 9:29 a.m.

Gayle Horetski and Paul Lyle, Jenna Conley Assistant Attorneys General, and Jun Maiquis, regulation specialist, joined the meeting via telephone to address the issue of Public Health Service Commissioned Officers. Mr. Lyle started the discussion by stating that state law cannot require a Public Health Service Commissioned Officer to be licensed by the state, which includes pharmacists, physicians and other health professionals. It was noted Mr. Lyle's e-mail to the board regarding PHS Commissioned Officers was included in the board packet. He stated federal law requires the practitioner to be licensed in one of the fifty states, but not necessarily the state in which they were located. As long as the Commissioned Officer was in good standing, the state cannot require the

pharmacist to be licensed in the state. If a PHS Officer was to be designated as the pharmacist-in-charge, under the duties described by federal law, the board cannot require the pharmacist to be licensed. He further stated that in the supremacy law in the constitution, federal law trumps state law. Ms. Oberts asked what a PHS Officer was allowed to do in the state in regards to the telepharmacy regulations. Mr. Lyle said he was not familiar with the program so could not answer that question. He said if the PHS Officer was in the state doing what state law allowed them to do, the state cannot require that officer to be licensed. Ms. Holm asked Mr. Lyle, that even though the state cannot require them to be licensed in their duties, can the state require them to be licensed if they provide services to non-beneficiaries? Mr. Lyle stated that would depend on the scope of their federal duties. He further stated that if a PHS Officer wanted to work in a pharmacy on weekends serving non-beneficiaries, they would need to be licensed by the state. If they are allowed by federal law, serving beneficiaries, they are authorized by federal law to serve a beneficiary class, regardless of who that beneficiary class is, they are within the scope of their federal duties. If the PHS Officer was not performing federal duties, such as moonlighting on weekends, it would then be private employment and they would be required to be licensed. Mr. Givens noted if a PHS Officer from ANMC wanted to work in the community on weekends, they would have to obtain permission from ANMC and be licensed by the state before they could work in the community. Mr. Lyle stated that would be his understanding. Mr. Holm said he would presume that if it applied to the pharmacist then it would apply to facility itself. Mr. Lyle said he was not speaking of the facilities. Mr. Givens said who the facility could serve was dictated by the agreement with IHS. If the facility such as in Barrow had a contract that stated they could serve non-beneficiaries, that would be allowed and be within the officers scope of work. If the contract stated the facility could serve beneficiaries and non-beneficiaries, they would still be within the federal scope of their duties, whether it is on an emergency basis or non-emergency basis. It would depend on what the funding agreement specifies. Mr. Holm stated that the question would then be who can make that agreement to serve non-beneficiaries when it would then become the responsibility of the board. He noted further the question would probably not be able to be answered at that time. Mr. Lyle said the state had no control over what the federal government stated was the responsibility of the federal employee any more than the board

could require the federal employee to be licensed. The federal government would decide what the scope of the federal employee's duties would be. Mr. Givens said the board's concern was if the facility treated native and American Indians, that is a specific population. He stated the board understands that because it would be under federal authority, but when the care would cross over to patients that are not beneficiaries, how then would the board protect the public safety and welfare? Mr. Holm stated that non-native Alaska citizens are the board's responsibility and how could that be superseded by federal law. Mr. Givens stated that it would usually be in a situation where no other healthcare services would be available. They would agree to provide services to non-beneficiaries. Then they would fall under the same umbrella as the native

beneficiaries. Mr. White asked how they could make that determination of a Public Health Service Officer, allowed to treat a non-beneficiary, when they would fall under the board's purview. Mr. Givens stated when they ask for the federal funding, they ask to be able to treat non-beneficiaries because they come in on boats, and into communities that have no other healthcare available. Then that would take it out of the purview of the board of pharmacy. Mr. Lyle stated again, you would go back to the scope of federal employment, regardless of any financial agreement. He said, "If the federal government determines that the scope of a Public Health Service Officer's employment or duties will include some subsidiary provision of services to non-Alaska natives or non-Indians, that scope of service determination is made by the federal government and the state has to respect that. We cannot tell the federal government what the scope of a federal officer's duties are. The federal government makes that determination. That is why congress has a specific statute that says that Public Health Service Officers can work in non-public health service agencies and clinics. That's within the scope of employment because congress says so. And the federal government determines, whether through congress or administratively, what the scope of its officers will be. This is quite common. It affects doctors, it affects lawyers in the military, lawyers in the Judge Advocate Generals Corp at Fort Wainwright here in Fairbanks, practice in the courts in the US Military, and with special permission can practice in federal court." Mr. White asked Mr. Lyle where the board could view the specific duties of the Public Health Service Officers. Mr. Lyle stated the federal government does not do everything by regulation and possibly they could be found in the personnel manuals. He said he had obtained one through the IHS. Personnel Instruction Four had the requirement of the office to be licensed "in a state", not necessarily in the state in which they were practicing. Mr. Lyle stated each tribal organization had its own funding agreement. The organization would negotiate with the federal government on what services and programs they would take over from the federal government, then the federal government negotiates an annual funding agreement. The money is then transferred to the tribes that would normally go to the Public Health Service. He said the contracts would be available from the IHS. Mr. Lyle stated he did not have all of the agreements, but would give the board all that he had. Mr. White asked where the supremacy clause was in the constitution. Mr. Lyle stated it was in Article VI, Clause II. Ms. Oberts asked Mr. Lyle, since SEARHC had voluntarily requested to be licensed, would they have to

comply with all state regulations, or could they pick and choose which ones they wanted to comply with? Mr. Lyle said that Mr. Truitt could probably answer the question. He stated he could not state what the intention was, but if someone wanted to be licensed voluntarily, the board should assume they would want to comply with all of the licensing requirements. Ms. Mundell asked in the case Mr. Givens had been speaking of earlier in the meeting, regarding a scenario in Barrow where the native clinic would be treating non-beneficiaries, would that facility if they were voluntarily license by the state, have to comply with all state regulations? Mr. Truitt responded by saying that would be determined on a case by case basis where each tribal organization had their own contract with the

federal government. They would argue that all duties of a Commissioned Corp Officer are within the scope of federal duties while employed by a tribal health facility. He said, "Whether that legal opinion, at the very end of the day turns out to be the correct one, is something that could only be decided in litigation. Sadly for you all, the law and the practice of law isn't as precise as the practice of pharmacy. So that question is not answered until a court of final review delivers an answer. Until that happens, it's a question that can be debated. "

Ms. Mundell asked Mr. Lyle if the Alaska licensed native facility was serving non-beneficiaries, would the pharmacy have to comply with all state regulations. Mr. Lyle responded by saying if the facility was voluntarily licensed by the state, they would be subject to state law, they must comply with state law. However, the Commissioned Officer would be a different issue. What they would be allowed to do would be controlled by federal law because federal law trumps state law. The federal government would control the federal employees not the facility. The facility would be licensed and require the employees to be licensed in the state as part of meeting regulations, except for the Public Health Commissioned Officers who would not be required to be licensed by the state because they would be under the federal laws as part of their scope of duties set out in the contract. He further stated the confusion maybe where the legislature had not provided an exception for Public Health Commissioned Officers in the pharmacy statutes as may be found in other licensing statutes such as the Medical Board for medical officers and physician assistants. It must be read into the pharmacy statutes under the supremacy clause. Mr. Holm asked if the pharmacist-in-charge of an Alaska license facility must be licensed by the State of Alaska. Mr. Lyle stated if the pharmacist was not a Public Health Commissioned officer, they must be licensed by the state. If the pharmacist-in-charge was a Public Health Service Commissioned Officer and working in the scope of his or her federal duties, they would not be required to be license by the State of Alaska. They may however choose to be licensed by the state. He further stated the facility must comply with the facility regulations, not the employee. The facility licensee would be responsible for ensuring the regulations for the facility have been met and would be subject to enforcement of those rules. A private pharmacy cannot employ a Public Health Commissioned Officer. In a national public health emergency, a Public Health Commissioned Officer may be sent into a private

pharmacy and would not be required to be licensed. Mr. Givens asked Mr. Lyle if he would address the opinion the board has requested from the Department of Law several years ago regarding licensing of native healthcare facilities. Mr. Lyle replied he was not prepared to address it at that point and did not know when the opinion would be completed. Ms. Oberts asked if a remote pharmacy license was issued for the Alicia Roberts Medical Clinic and later the ten mile rule took effect, would Alicia Roberts then have to comply with the new ten mile rule and again be licensed as a pharmacy. Mr. Lyle stated he was not an occupational lawyer and could not answer that question. Mr. Givens asked if a facility that had initially been licensed ten years ago could decide to not be under state regulations and go back to following federal law. Ms. Horetski answered that a

licensee could let their license lapse. Mr. Lyle stated that question would be whether they would be required to be licensed and he was not prepared to answer that question. Mr. Givens asked if a facility could surrender a license before the license had expired. Mr. Lyle stated any licensee could surrender a license, that it was not an issue.

Ms. Horetski noted the board had discussed Community Health Aides who had been trained in dispensing medication in native health clinics during the meeting the previous day. Ms. Horetski asked Mr. Lyle if he could summarize the Dental Health Aide Decision in respect to Community Health Aides. Mr. Lyle stated the decision in 2005 concluded the state could not require Dental Health Aides to be licensed by the state. The Indian Healthcare Improvement Act authorizes the creation of a Community Health Aide program in Alaska for paraprofessional Community Health Aides to be used in the provision of healthcare services if the beneficiaries were entitled to services under the Indian Healthcare Improvement Act. One section of the law, 25 USC 1616lb2B, requires the secretary to provide for training and development of a curriculum that provides instruction and practical experience in the provision of acute care, emergency care, health promotion, disease prevention and the efficient and effective management of clinic pharmacies, supplies, equipment and facilities. The rest of 1616 l establishes a federal regulatory board called the Community Health Aide Certification Board which develops the curriculum, recruits people to be trained under the program, licenses, evaluates and recertifies to ensure the provision of quality care. It is a federal licensing board that covers the Community Health Aide program in Alaska. If the Community Health Aide Board develops curriculum and trains community health aides, either a medical aide or if they develop a new program for pharmacy aides, and trains them in the efficient and effective management of clinic pharmacies, supplies, equipment and facilities, then those people licensed by the federal government while acting within the scope of their duties, could not be required to hold a state license. The reason would be a slightly different one under the supremacy clause. The Superior Court ruled on the Dental Health Aides. “Federal law preempts state law where it stands as an obstacle to the accomplishments of the purposes of the federal law.” The court found that requiring licensing of Dental Health Aides would stand

as an obstacle to the federal law. Therefore the state law had to give way. The same analysis and subsection would apply if Medical CHAP's (Community health Aide Program) or another classification of CHAP's were trained to run native health clinic pharmacies. They would have to be employed by a native health clinic. They could not work in another facility unless licensed by the state. As long as they were working within the scope of their federal duties, the state could not require licensure. He further stated he did not think at that time there was a pharmacy management program, but one may be developed in the future. If a pharmacy program was developed, the state could not require them to be licensed. Mr. Lyle clarified the federal Community Health Aide Board is a federal board and has a state employee from the Department of Health and Social Services assigned to the board. The board had created a new classification of

paraprofessionals licensed under federal law which are under federal law. Mr. Holm asked Mr. Lyle why the board would want to license a facility that the board would not have control of 50 percent of the facility. Mr. Lyle responded that the board would have 50 percent control and would not be liable under the federal tort law for federal employees. He further stated the federal supremacy clause is read into every state statute and is subject to the supremacy of the United States constitution and the laws passed by congress.

Mr. Givens thanked Mr. Lyle and Ms. Horetski for addressing the board on the matter.

Break-Off the record at 10:40 a.m.
On the record at 10:55 a.m.

Agenda Item 12 **Investigative Report**

Susan Winton, investigator, joined the meeting to give the investigative report. Ms. Winton outlined the open and closed cases, including investigations and complaints. There were 15 investigations, 13 complaints, two probations and 18 closed cases. Ms. Winton noted that in the last six months, 40 new matters were opened and 32 were closed. She further stated that was more than all of 2006. Ms. Winton stated there was not a specific violation or trend that she noticed.

Mr. Givens asked Ms. Winton if she could work on the 2005 through 2007 cases to see what kind of trends had developed for the investigations, specifically what kind of violations and how many were for pharmacy technicians or pharmacists. Ms. Winton said she would have a report for the board at its next meeting.

Agenda Item 13 **License Application Review**

The board reviewed the remote pharmacy application for Alicia Roberts Medical Center Pharmacy. Gayle Horetski, Assistant AG joined the meeting via telephone. Ms. Oberts asked Ms. Horetski if it would be appropriate to discuss

the ten mile rule regulation at the same time the board discussed the remote pharmacy application. Ms. Horetski stated the board could discuss anything they wanted too but advised against it. She further noted the board must review a license application based on regulations that were in effect at the time of review. The board may not delay licensure for the purpose of waiting for a change of a regulation. Mr. Givens asked Mr. Truitt if he would like to pursue licensure for the remote pharmacy in light of the earlier discussion with Mr. Lyle. Mr. Truitt stated it was SEARHC's intent to be fully compliant with state board laws and regulations. He stated direct hire pharmacists would be required to be licensed by the board but Public Health Service Commissioned Corp Officers would not be required to be licensed even though some already were. Mr. Holm asked if the board could also review the facility license for Mt. Edgecumbe Hospital Pharmacy before voting on the remote pharmacy application. Mt. Edgecumbe

Hospital Pharmacy would be licensed as the central pharmacy for the remote pharmacy application. Mt. Edgecumbe Hospital Pharmacy had not been previously licensed. Mr. Holm noted the pharmacist-in-charge for the remote pharmacy would be a Public Health Service employee. Since the board would not have purview over the PIC if any action against the PIC was deemed necessary, would the board want to grant a license to the pharmacy and not just allow the federal government to oversee the entire pharmacy. Ms. Horetski stated if there were some evidence showing a pharmacy was not operating in accordance with requirements of pharmacy operation, there would be provisions to suspend or revoke a pharmacy license. The action would be against the pharmacy owner, not the PIC. Ms. Horetski again stated the board cannot deny a license if the applicant meets the requirements set out in current regulations. Mr. White noted that he would vote to abstain until he had more information. Ms. Mundell noted on page two of the central pharmacy self-inspection report, the question asking if all interns, graduate or undergraduate, paid or unpaid, are currently licensed by the board, the answer was checked "no" and the comment in the comment sections stated "currently federal facility are not required, will apply now". She asked if the answer included interns and technicians, or only interns. Mr. Young responded by saying he was not 100 percent sure if all technicians were currently licensed. Ms. Mundell was concerned about the interns that would be working at the facility and if they would be licensed by the state. Mr. Young stated he believed all interns would be licensed. It was noted by Ms. Mundell on question ten that the response was "all technicians are currently licensed by the board". Mr. Givens noted at ANMC, unless the technician was a federal employee, all technicians must have a state license.

On a motion duly made by Ms. Oberts, seconded by Ms. Mundell and approved by roll call vote, it was

RESOLVED to approve the pharmacy license for Mt. Edgecumbe Hospital Pharmacy.

Roll call vote- Yeas- Ms. Oberts, Ms. Mundell, Mr. Holm, Mr. Givens. Abstention- Mr. White.

The board continued to discuss the remote pharmacy application for Alicia Roberts Medical Center Pharmacy. Mr. Holm asked if the pharmacist listed on the remote application, John Fulton, USPHS pharmacist, would be on-site at the remote pharmacy. Mr. Young stated Mr. Fulton would be the pharmacist at Mt. Edgecumbe Hospital that would be monitoring the telepharmacy equipment and processing the orders. It was note by Mr. Givens, the remote pharmacy application should be clarified to ask for the list of all on-site pharmacy employees.

On a motion duly made by Ms. Mundell, seconded by Ms. Oberts and approved by roll call vote, it was

RESOLVED to approve the remote pharmacy application for Alicia Roberts Medical Center.

Roll call vote- Yeas- Ms. Oberts, Ms. Mundell, Mr. Holm, Mr. Givens. Abstention- Mr. White.

Mr. Givens asked Ms. Horetski in light of the earlier discussion with Mr. Lyle, if the board should revisit an application for a Collaborative Practice Agreement submitted by SEARHC in Juneau which had a PHS Commissioned Officer as the collaborating pharmacist. The board discussed the issue at a previous meeting and decided it was not necessary for the parties to participate in a collaborative agreement with the board's approval since the board had no purview over the PHS employee. Ms. Horetski stated the board should send a letter to the applicant and ask if they would like to pursue the board's approval for the Collaborative Practice Agreement. It was noted by Ms. Zinn the physician was not a PHS employee but a physician licensed by the Medical Board and therefore the plan would need to be approved by the Medical Board. Ms. Horetski stated since the PHS officer was exempt from state licensure, the Medical Board should approve the application without regards to the pharmacist's state licensure status.

The board reviewed the remote pharmacy application for Safeway Pharmacy in Ketchikan. The board tabled the application from a previous meeting. Ms. Mundell stated she would like to have current information which included the list of the remote pharmacy employees and confirmation from Safeway they want to pursue the licensing of the remote pharmacy and review it at the next mail ballot. Ms. Horetski stated the board could obtain the information before the end of the meeting and therefore approve the application at the meeting. She further noted

it was in the best interest of all parties to not postpone the review of the application.

The board reviewed the applications for licensure for pharmacists, pharmacy technicians and collaborative practice agreements.

Ms. Mundell left the room at 11:45 and returned at 11:55.

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

> **RESOLVED to approve the collaborative practice agreements as read into the record.**

Collaborative Practice Agreements-

Safeway Pharmacy #0405, Lic. #383, Tammy Beaudreault, Candy Norris, ANP
Carrs #1812, Lic. #323, Shannon Hanson, Candy Norris, ANP
Carrs #1806, Lic. #317, Roberta Hull, Candy Norris, ANP
Carrs #1818, Lic. #328, Valentina Todd, Kimberly Anderson, ANP
Safeway #1832, Lic. #401, Teresa Heilig, Kimberly Anderson, ANP
Carrs #1808, Lic. #400, Susan Easley, Kimberly Anderson, ANP
Fred Meyer #071, Lic. #388, Charles Barnett, Leeann Mercier, ANP
Fred Meyer #158, Lic. #389, Michael Lessard, Leann Mercier, ANP
Fred Meyer #671, Lic. #406, Raymond Grogan, Leann Mercier, ANP
Fred Meyer #653, Lic. #392, Jamie West, Leeann Mercier, ANP
Fred Meyer #018, Lic. #387, Dawn Peet, Leann Mercier, ANP
Fred Meyer #668, Lic. #384, Julie Pritchard, Leann Mercier, ANP
Fred Meyer #011, Lic. #385, Kenneth Dazey, Leeann Mercier, ANP
Fred Meyer #656, Lic. #393, Uriah Clarkson, Leeann Mercier, ANP
Fred Meyer #224, Lic. #415, Kimberly West, Leann Mercier, ANP
Fred Meyer #017, Lic. #386, Douglas Morris Jr., Leann Mercier, ANP
Fred Meyer #485, Lic. #391, Jared Mattson, Leann Mercier, ANP

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

> **RESOLVED to approve the pharmacist and technician applications as read into the record.**

Pharmacists-

Joseph Caputo-pending MPJE passing score, verification from New Jersey
Lori Costa-pending Transcripts, MPJE passing score

Richard Evey-pending MPJE passing score
Dean Goroski-pending MPJE passing score
Michael Lee-pending NAPLEX and MPJE passing scores, verification of 1500 hours internship-one affidavit of moral character
Roberta Mueller-pending Transcripts, NABP passing score
Shauna Vickers-pending MPJE and NAPLEX passing scores
Quynhnga Weber-pending MPJE passing score, verification from California

Technicians-

Tonya Biles

The board continued the remote pharmacy application for Safeway in Ketchikan. Ms. Mundell noted that she could not locate Ron Miller regarding the remote pharmacy license application. Mr. Givens said it was the responsibility of the PIC to notify the board of updated information. Ms. Oberts noted that it brought up the issue for the need to define underserved community. Mr. Givens reiterated

the board must review an application based on the current regulations and if the application was complete, the board must vote on it. Mr. Holm asked if the pharmacy could hold a retail pharmacy and a remote pharmacy application at the same time. It was noted current regulations do not prohibit a facility to hold two licenses. Ms. Mundell said the purpose of the remote pharmacy application was strictly to solve staffing issues, not to serve an "underserved" community. Mr. Givens said he thought the board was not in agreement on what "underserved" was. He stated he would like to see technology used to its fullest extent and would not like to restrict pharmacists. Mr. White said he would not like to see Wal-Mart have a central pharmacy with satellite remote pharmacies all over the state. It was not the board's intent for remote pharmacy licensing.

On a motion duly made by Ms. Mundell, seconded by Mr. Holm, and approved by voice vote, it was

> **RESOLVED to table the remote pharmacy application for Safeway Pharmacy in Ketchikan until a current application with updated information has been received.**

Roll call vote- Yeas- Mr. Holm, Mr. White, Ms. Mundell, Ms. Oberts.
Nays- Mr. Givens.

It was noted the board would review the application at its next mail ballot upon receipt of the updated information.

Ms. Mundell stated she would look into other states reasons for instituting the mileage limit and the definition for remote pharmacy for the next meeting. The

board stated they would like to have Mark Bohrer at the meeting to help with the history of the telepharmacy regulation project.

The board discussed who could attend the Multi State Pharmacy Jurisprudence Question Writing meeting in Orlando in January. The board members decided to check their schedules for availability and contact Ms. Zinn by the deadline of October 9th.

Mr. White left the room at 12:50 and returned at 12:54.

Agenda Item 17 **Office Business**

Election of Officers.

Ms. Mundell was elected Board Chair, Mr. Holm was elected Vice-Chair, and Mr. White was elected Secretary.

The board set the tentative meeting dates for the 2008 calendar year as follows:

February 14-15, 2008
May 8-9, 2008
September 25-26, 2008

Agenda item 15 **Old Business**

The board discussed electronic prescribing since the new regulation had gone into effect. Mr. White noted he had received a few and asked the other board members if they had any problems with e-prescriptions. None of the other board members had received any e-prescriptions as of the board meeting.

Agenda Item 6 **Regulations**

The board reviewed the re-draft of the Shared Pharmacy Services regulations.

On a motion duly made by Mr. Holm, seconded by Ms. Mundell, and not approved by roll call vote, it was

> **RESOLVED to not adopt the Shared Pharmacy Services regulation, 12 AAC 52.445, and table the Ten Mile Rule regulation, 12 AAC 52.425(c) until the next board meeting.**

The motion failed.
Roll call vote- Nays- Ms. Mundell, Mr. White, Ms. Oberts, Mr. Holm, Mr. Givens.
Yeas- None

The board decided they wanted to discuss the regulations for the Shared Pharmacy Services further at a later meeting. The concern was adoption of the regulation without fully considering the consequences that may occur with the new regulation.

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

> **RESOLVED to table the Shared Pharmacy Services regulation, 12 AAC 52.334, and table the Ten Mile Rule regulation, 12 AAC 52.425(c) until the next board meeting.**

Mr. White stated he would talk to Lis Houchen from NACDS, regarding a definition for Shared Pharmacy Services for the next meeting. Ms. Mundell confirmed she would look into the definition for remote pharmacy and contact other state boards for their rules regarding the mileage limit for a remote pharmacy and report to the board at its next meeting.

Mr. Givens signed the adopted minutes. The board signed the wall certificates.

The meeting adjourned at 1:18 p.m.

Respectfully Submitted:

_____
Sher Zinn, Licensing Examiner

Approved:

_____
Mary Mundell, R. Ph., Chair
Alaska Board of Pharmacy

Date: _____