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

ALASKA STATE BOARD OF PHARMACY

MINUTES OF TELECONFERENCE MEETING
August 26, 2011

These final minutes were prepared by the staff of the Division of Corporations, Business and Professional Licensing. They have not been reviewed or approved by the Board.

By authority of AS 08.01.070(1) and in compliance with the provision of AS 44.62, Article 6, a teleconference meeting of the Board of Pharmacy was held on August 26, 2011to discuss regulations and other board business.

Call to Order/Roll Call

The meeting was called to order by Dick Holm at 1:03 pm. Those present constituting a quorum of the board, were:

Richard (Dick) Holm, RPh., Chair
Christopher Kim, RPh., Secretary
Lori DeVito, RPh
Anne Gruening

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

Brian Howes, Investigator and PDMP Program Manager
Jun Maiquis, Regulations Specialist
Mary Kay Vellucci, Licensing Examiner
Brenda Donohue, Licensing Examiner, Dental and Veterinary Boards

Telephonic participation from Attorney General's Office:

Dan Branch, AG

Agenda Item 1 **Review of Agenda**

Chair Holm stated there have been questions and apparent confusion over the changes allowed to CS II prescriptions. Recent DEA correspondence inadvertently omitted the section regarding allowable changes to CS II prescriptions, which resulted in contradictory information being given to pharmacists. The DEA advised pharmacists to abide by state regs until clarification was provided by the DEA in a future rule making.

Since then, the DEA published a rule making letter via the NABP Electronic News which was recently forwarded to the board members.

Ms. Vellucci informed the members the new regulations regarding changes to CS II prescriptions, 30 day disciplinary reporting, reinstatement of a lapsed pharmacist license and remote pharmacies will go into effect on September 17, 2011

Agenda Item 1 **PDMP Regulations**

The members were provided with copies of the regulations they approved at the May, 2011 meeting and revised regulations from the Department of Law.

Mr. Holm stated the following sections were approved at the May meeting and then deleted in Law due to lack of statutory authority.

12 AAC 52.877 Unsolicited patient profiles
12 AAC 52.879 Statistical profiles
12 AAC 52.895 Evaluation, data analysis and reporting

The members then reviewed the individual sections of the revised regulations.

12 AAC 52.855 Registration and access requirements for controlled substance prescription database: Mr. Holm brought item (d), to the attention of the members. It addresses the method by which profiles will be routed to the pharmacist or practitioner. Mr. Howes clarified this item pertains only to those who have not registered. Practitioners who have registered will be able to get patient profiles immediately online. The option to fax was deleted from (d) when this point was clarified. The following changes were made

(c) A licensed pharmacist and licensed practitioner "not" registered under this section....
(d) all profiles generated by the board "under subsection (c) shall be mailed certified mail".... delete "if mailed."

12 AAC 52.860 Conditions for access to and use of database: Mr. Branch noted the language was changed to include the HIPPA provisions of the CFR. No changes were made.

12 AAC 52.865 Requirements for dispensers: Mr. Branch stated research was done on the software ASAP Standard for Prescription-Monitoring Programs 2007 Version 004.1, mentioned in item (b). It is

available at no cost to the practitioner or prescriber. This regulation allows a dispenser to submit data either through this software or by an internet portal provided by the board. Both are forms of electronic data submission. To submit data in paper, the members were referred to 12 AAC 52.870 Waiver of electronic submission requirement by dispenser.

Discussion occurred about the entities that submit data, given the pharmacies and the pharmacists have separate NPI numbers. Item (a) refers to the NPI number of the pharmacy because, according to Mr. Howes, the data information was keyed back to the pharmacy. Mr. Branch stated the statute reads "each pharmacist and each pharmacist in charge shall submit to the board." The implication is the pharmacist in charge will submit data for each pharmacist. Mr. Howes noted the original prescription will identify which pharmacist issued it. The conclusion was the actual data submission must be done according to the NPI number of the pharmacy, as stated in the language before them. However, when submitting an individual profile request, the pharmacist's NPI number will be used, not the facility's. This will occur because the pharmacist will log in as him/herself, using his/her NPI number, and request the profile under that user name.

Discussion then occurred regarding how PDMP information would be managed at various facilities and in various settings. Mr. Branch stated HIPPA laws govern the confidentiality of the profile information within a given facility and/or among colleagues. Mr. Howes added the board can only control who is granted access to the database and create regulations regarding its safe and confidential use. It cannot control how PDMP information is managed within individual facilities.

No changes were made to this section.

12 AAC 52.870 Waiver of electronic submission requirement by dispenser. Mr. Branch clarified if a facility is granted a waiver under this section, they must still submit data in paper format. The purpose is to accommodate those who cannot meet the requirement electronically. The Program Manager will determine if the licensee meets the criteria to submit data by paper. The members agreed to add "and shall inform the Program Manager within thirty days if the basis for the waiver to electronic reporting no longer exists." Mr. Howes stated he will add a certifying statement to the Request for Waiver from Electronic Submission.

The statute states you have to report controlled substances. If a facility doesn't have a DEA license but they are dispensing

controlled substances, they must complete a Request for Waiver from Electronic Reporting and submit paper reports.

Mr. Holm stated a waiver from reporting at all, including a waiver from zero reporting, could only be done if a facility dispenses no controlled substances. In that case, Mr. Howes would acquire a signed notarized statement to that effect. The document would need to include a statement indicating the facility would register and begin reporting immediately if they begin to dispense controlled substances. This would eliminate monthly zero reporting at facilities that do not dispense any controlled substances. Mr. Branch added this suggestion is consistent with statute. He suggested, and the members agreed to add:

12 AAC 52.865 (e) Licensed pharmacists that are not required to report under AS 17.30.200 shall submit a sworn statement at the end of each calendar year certifying that the pharmacist has not dispensed any controlled substances listed in that subsection during the previous twelve months, and does not intend to dispense the controlled substances listed in that subsection.

Item (3) was changed as follows:

(3) the dispenser will dispense less than 10 prescriptions of controlled substances per month.

Mr. Howes asked if a two or three day supply of controlled substances dispensed from an emergency must be reported. Mr. Holm said yes. Mr. Branch stated the statutes require it and because of that, the question is not on the table for consideration.

12 AAC 52.875 Solicited requests for information from non-registered persons: Mr. Branch stated the only substantial change to this adds appropriate language for an emancipated minor.

Item (c) was reworded to be consistent with 12 AAC 52.855 (d).

Mr. Holm asked Mr. Branch if statistical profiles were now precluded. He replied it may be a matter of clearly defining the type of "statistical profile" for release. The board, in executive session, however, is privy to all statistical information.

12 AAC 52.880 Reports: The members agreed no changes to the revisions were indicated in this section, 12 AAC 52.885 Storage of Information or 12 AAC 52.890 Termination of access; grounds for discipline.

Advisory Board: Mr. Branch said the members have the authority to add an Advisory Committee via resolution but the board cannot have people from the private sector (public members) on the committee due to the limits of statute and confidentiality. The board cannot delegate a substantive degree of its work to the Advisory Committee because the governor and the legislature designated the decision making role to the Board of Pharmacy members. A regulation is not needed to create the Advisory Committee. The board will discuss this further at the September meeting. Mr. Branch will create a draft resolution for the meeting September 15-16.

12 AAC 52.995 (a) (34) "dispenser" definition was changed to add "pharmacist" to its content.

The members were polled to determine their consent with the changes to the regulations discussed today:

DeVito Aye; Kim Aye; Gruening Aye; Holm Aye.

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

Resolved to approve the regulations as amended and recorded .

The meeting was adjourned at 2:40 pm.

Respectfully Submitted:

_____
Mary Kay Vellucci,
Licensing Examiner

Approved:

_____
Dick Holm, Chair
Alaska Board of Pharmacy

Date: _____