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 October 6, 2010

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

By authority of AS 08.01.070(1) and in compliance with the provision of AS 44.62, Article 6, a teleconference meeting of the Board of Pharmacy was held on October 6, 2010. The purpose of the meeting was to discuss a regulation project and other board business.

The meeting was called to order by Mary Mundell at 9:00 am.

Those present constituting a quorum of the board, were:

Leah Handley, Public Member Steven Johnson, Pharmacist Christopher Kim, Pharmacist Mary Mundell, Pharmacist

Dick Holm, Dirk White and Anne Gruening were not present.

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

Mary Kay Vellucci, Licensing Examiner

Agenda Item 1 <u>Licensing</u>

Tabled Biennial Pharmacy Renewals were discussed at length and in detail during Executive Session at the September 23, 2010 board meeting. Afterwards, on the record motions were made regarding the actions to be taken on each license. In the case of denied licenses, the motions cited the statutes and regulations which were the basis of the denial. The specific occurrences at the facility which correlated to the violated statutes and regulations were inadvertently omitted from the record. The purpose of this teleconference was to provide that information on the record.

The board members were provided with copies of these motions for denial from the September 23, 2010 draft meeting minutes prior to the teleconference.

Aetna Specialty Pharmacy, LLC: The New Jersey Division of Medical Assistance administers New Jersey's Medicaid Program, which is a state and federal entitlement program. New Jersey denied Aetna Specialty Pharmacy's Medicaid application due to falsification of the Medicaid application because Aetna did not disclose the disciplinary action taken by the Florida Board of Pharmacy against pharmacist Rebecca Jo Mitchem for medication mismanagement. The New Jersey Medicaid denial did not prompt Aetna Specialty Pharmacy LLC to review their records to determine if this omission also occurred

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in other relevant applications and documents where this reporting is required. This disciplinary action was not disclosed to the Alaska Board of Pharmacy in Aetna's initial application dated 4/20/05, which was the first correspondence to the Alaska Board listing Ms. Mitchem as a pharmacist under their employ. Further, Aetna Specialty Pharmacy LLC did not disclose this previous infraction in any subsequent Biennial Out of State License Renewals, all of which list Ms. Mitchem as a pharmacist dispensing to Alaska consumers. The Alaska board regards this as a pattern of falsification and unprofessional conduct in the practice of pharmacy. It is contradictory to our mission to protect the public and therefore this renewal was denied. All board members agreed this content accurately captured the basis for denial of this license.

College Pharmacy:

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

RESOLVED to add the violation of *AS 08.80.261 (11): violation of state, federal laws and regulations related to drugs or pharmacies* to the cited violations of College Pharmacy.

College Pharmacy clearly violated state and federal laws when they illegally sold and distributed HGH, as they reported in their July 1, 2008 – June 30, 2010 Biennial Renewal with the State of Alaska. The illegal scheme generated nearly \$5 Billion in proceeds, most of which was planned to be retained for profits. Since that time, Colorado initiated a Stipulation and Order, which resulted in actions by four other state boards. The Alaska Board of Pharmacy would be remiss in its obligation to protect the health, safety & welfare of Alaska residents if we did not deny College Pharmacy's license. All board members agreed this content accurately captured the basis for denial of this license.

Franck's Compounding Lab: In a complaint filed by the FDA, Franck's Lab was charged with four counts of violating the Federal Food, Drug and Cosmetic Act regarding illegal preparation of compounded drugs which resulted in the death of 21 polo ponies. This was also an infraction of Florida statutes and caused the Indiana Board of Pharmacy to order a 90 day summary suspension based on the filing of federal charges. The Alaska Board is aware 1) an August, 2010 court hearing denied the FDAs motion for a preliminary injunction and 2) ultimately the Indiana Board of Pharmacy reinstated this license. We are also aware the Florida Board of Pharmacy described the precipitating event as a "misfill."The Alaska Board of Pharmacy, however, does not regard this so lightly given the extreme consequences of this compounding error. Further, we find licensing this facility would be contradictory to our primary mission to promote, preserve and protect the public health, safety and welfare of Alaskans. All board members agreed this content accurately captured the basis for denial of this license.

Prime Therapeutics: The following applies Out of State Pharmacy License Renewals #790 and #679 for two Prime Therapeutics facilities.

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

RESOLVED to delete the citation of Statue 08.80.157 (a) (1) from the original motion denying these licenses as it was misspoke. There is no such statute.

The out of state pharmacy renewal forms for these pharmacies, dated Jun 7, 2010, listed one violation that occurred during this renewal period with the Texas Board of Pharmacy. When the Alaska Licensing Examiner requested the Texas board documents from a self-described "new employee" at Prime, she received a list of violations by Prime Therapeutics involving six additional states and ten subsequent violations dating from December 2005 through the present. Of these violations, only one had been reported to the Alaska Board of Pharmacy as required. Furthermore, the investigator also determined Prime Therapeutics also did not furnish violation information, applications or renewals within the required time frame to the States of Hawaii, Connecticut and Oregon.

This, in addition to 1) the extensive Previous History of Complaints against Prime Therapeutics from the Texas Board of Pharmacy; 2) a significant medication error in the dispensing of Levothyroxine; 3) allegations of excessive recovery amounts from insurers and; 4) apparent profitable data errors in remittance forms, leads the Alaska Board of Pharmacy to deny these licenses in the best interest of the public. All board members agreed this content accurately captured the basis for denial of this license.

ExcelIRX: It was stated the following applied to Out of State Pharmacy License Renewals #698 for EXCELLRX PA DBA Hospice Pharmacia, # 930 for EXCELL RX and # 684 for ExCellRX Inc. The parent corporation for these facilities is Omnicare Inc. The denial of these licenses is based on Omnicare's violations of state and federal laws due to making payment to nursing home chains in return for referral of pharmaceutical business, providing pharmacist services to its customers below its rate and fair market value and accepting multiple forms of remuneration from a drug manufacturer to induce their sales. Omnicare submitted false claims to Medicaid that should have been submitted by and paid to a nursing home. Michigan also entered into a settlement with Omnicare based on false claims for its terminally ill Hospice patients. Michigan alleges Omnicare knew they were making false claims. For these reasons, the Alaska Board of Pharmacy denies the renewals of these facilities. All board members agreed this content accurately captured the basis for denial of this license.

Ms. Mundell stated she read through each of these items thoroughly to prepare for the September board meeting. Although she was not able to appear at the board meeting due to sudden illness, the discussion that occurred today addressed her exact concerns about these licenses and substantiated a group discussion did in fact occur. Her reason for tabling these decisions on the initial ballots was to allow for that discussion. She added "everybody came to the same conclusions" and described these decisions as "100%" accurate. Ms. Handley added these denials did not come about lightly. They were discussed and evaluated at length during Executive Session.

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PDMP: The board members received a copy of the draft minutes of the September 23rd meeting regarding the PDMP. It addressed the need for revisions in 12 AAC 52.875 Solicited Profile Requests. Mr. Howes revised this section and the revisions were distributed to the board prior to the teleconference. The revisions were reviewed. The word "or" needed to be added to at the end of 12 AAC 52.875 (c) (3) (A) to meet the intention of this revision. The revised text was read onto the record.

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

RESOLVED to accept 12 AAC 52.875 as amended.

The Universal Claim Form, which is to be used for "paper claims" was distributed to the board members immediately prior to the teleconference. This document was requested by Mr. Holm during the September meeting to illustrate the amount of time and paper work that will be required for paper claims.

The meeting was adjourned at 9:35.	
	Mary Kay Vellucci, Licensing Examine
	Approved:
	Dick Holm, Chair Alaska Board of Pharmacy
	Date: