KANSAS STATE BOARD OF PHARMACY

MINUTES OF THE MEETING

March 9 & 10, 2004 AmeriSuites 6021 SW 6th Ave. Topeka, Kansas

Tuesday, March 9, 2004

MEMBERS PRESENT: Mike Hurst, RPh., President; Frank Whitchurch, RPh., Vice President; Merlin McFarland, RPh.; Jeff Thompson, RPh.; JoAnne Gilstrap, RPh.; Howard Paul, Public Member.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh.; Pharmacy Inspector; LaTonyua Rice, Pharm.D., Pharmacy Inspector; Tom Frazier, RPh., Pharmacy Inspector; Reyne Kenton, Compliance Officer, Melissa Martin, Compliance Officer; Randy Forbes General Counsel and Karen Hollon Administrative Officer.

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: Mike Hurst called the meeting to order at 9:00 a.m.

APPROVAL OF AGENDA: Howard Paul made a motion to amend the agenda to add discussion regarding K.S.A. 74-1609 relating to the budget. The motion was seconded to approve the agenda as amended (Paul/McFarland). Motion carried 5-0.

ACCEPTANCE OF THE MINUTES: A motion was made and seconded to approve the minutes from the December 2-3, 2004 meeting as amended (McFarland/Thompson). Motion carried 5-0.

PUBLIC HEARING FOR K.A.R. 68-7-20 SHARED SERVICES

The regular board meeting was adjourned and President Mike Hurst convened the public hearing regarding proposed regulation K.A.R. 68-7-10 on Shared Services. In accordance with Kansas law, a 60-day notice was given by publication in the Kansas Register on January 2, 2004. Randy Forbes reported that the Joint Committee on Administrative Rules and Regulations had met on February 18, 2004 and had no recommendations and no comments. Debra Billingsley said no communications had been received at the Board office regarding the proposed regulation. Mike Hurst asked if there were any public comments. Hearing none Mr. Hurst closed the Public Hearing and reconvened the Board meeting.

RECONVENE: The Board meeting reconvened at 9:05. Mr. Hurst accepted proposed regulation K.A.R. 68-7-10 as written. A roll-call vote was taken with all members voting Yea.

STACI L. SNIDER #13371: Staci Snider appeared pro se. Assistant Attorney General, Marty Snyder, represented the Board. Ms. Snyder advised the Board that the Respondent was charged with K.S.A. 65-1637 (a)(4) by substituting levothroid on a prescription written for Synthroid. Ms Snyder stated that a consent agreement was sent to the Respondent recommending a \$250 fine and a period of one-year probation. The Board heard both the Respondent and the Complainant. A motion was made and seconded to go into executive session to deliberate until 9:50 a.m. Those present in executive session were Tom Frazier, LaTonyua Rice, Debra Billingsley and Randy Forbes. (Whitchurch/Gilstrap). Motion carried (5-0).

RECONVENE: The Board meeting reconvened at 9:50 a.m. with all members present as previously stated.

MOTION: A motion was made and seconded to accept the consent agreement as written (Whitchurch/Paul). Motion carried (5-0).

MICHAEL D. McDANIEL #11364: Michael McDaniel appeared with his attorney, Gary Peters. Assistant Attorney General, Marty Snyder represented the Board. Ms. Snyder advised the Board that the Respondent was charged with violating K.S.A. 65-1637 (a) in that he had filled a "dispense as written" prescription for Amnesteem with Claravis. The Respondent was also charged with K.A.R. 68-7-12b for failure to file an incident report. Howard Paul recused himself from the hearing and did not participate in any discussion. Ms Snyder stated that a consent agreement was sent to the Respondent recommending a \$500 fine and one-year probation. The Respondent advised that Walgreens had taken aggressive remedial action by requiring the Respondent to take continuing education regarding drug substitution and that he had received an internal reprimand. A motion was made and seconded to go into executive session to deliberate until 10:25 a.m. Those present in executive session were Jim Kinderknecht, Debra Billingsley and Randy Forbes. (Whitchurch/Gilstrap) Motion carried (4-0)

RECONVENE: The Board meeting reconvened at 10:25 a.m. with all members present as previously stated.

MOTION: A motion was made and seconded to accept the stipulation as written and to accommodate Mr. McDaniel on the language in the newsletter reporting the violation. (Whitchurch/McFarland). Motion carried 4-0.

MARY KAY JANCICH #10638 and NANCY PROHASKA #10123: Mary Kay Jancich and Nancy Prohaska both appeared pro se. Assistant Attorney General Marty Snyder represented the Board. Ms. Snyder reported that these were companion cases and could be heard together. Jancich was charged with violating K.S.A. 65-1627(a)(6)&(8) and K.S.A. 65-1637(a) for filling a prescription that was not in strict conformity with the directions and a second charge of K.A.R. 68-7-12b(b) for failing to file an incident report. Prohaska, as Pharmacist-in-Charge was charged with K.A.R. 68-7-12b(b) for failing to file an incident report. Jancich was offered a consent agreement recommending a fine of

\$500.00, requiring continuing education on the topic of prevention of medication errors, and requiring notification to the Board as to what steps had been taken to prevent this particular type of error in the future. Prohaska was offered a consent agreement recommending a \$500.00 fine and requiring implementation of procedures to prevent prescription errors. A motion was made and seconded to accept the stipulations (McFarland/Paul). Motion carried 5-0.

APOTEK #8831: No one appeared on behalf of APOTEK Pharmacy. Assistant Attorney General Marty Snyder appeared on behalf of the Board. Ms. Snyder advised the Board that she was recommending a consent agreement be offered to APOTEK Pharmacy. A motion was made and seconded to accept the agreement as proposed (McFarland/ Whitchurch). Motion did not carry 2-3. A motion was made and seconded to go into executive session to deliberate until 11:20 a.m. Those included in Executive Session were Jim Kinderknecht, Tom Frazier, Randy Forbes and Debra Billingsley (McFarland/Whitchurch). Motion carried 5-0.

RECONVENE: The Board meeting reconvened at 11:20 a.m. with all members present as previously stated.

MOTION: A motion was made and seconded to revise the proposed Consent Agreement such that APOTEK is changed to Robert Nyquist since he is the owner and Pharmacist-In-Charge. In addition that the Respondent be offered to settle the matter by imposition of a \$500 fine, that Mr. Nyquist be required to take the Pharmacist-in-Charge Examination, and that he provide education to staff about the Controlled Substance Law and provide documentation to the Board Office that the PIC test and education were completed within 60 days of filing the Final Order. (Thompson/Howard). Motion carried 5-0.

RECESS: The Board recessed the meeting from 11:25 until 11:30.

DISCUSSION REGARDING K.S.A. 74-1609/Budget: Howard Paul requested information regarding the legality of K.A.R. 74-1609, specifically regarding whether the State could take more than twenty percent from the Pharmacy fee fund. The Board had voted in December to encumber \$700,000 for three specific projects. Debra Billingsley reported that the Governor's recommendation was to remove 1.1 million from the Pharmacy Fee Fund for the State general fund. The sweep would not take place until the end of Fiscal Year 2005. Ms. Billingsley advised the Board that she had requested that the Pharmacy Board's allocation be adjusted for 2005 by \$700,000. The Senate Ways and Means Committee rejected the Board's request. The House Appropriations Committee hadn't made a decision as of the date of the Board meeting but the Subcommittee did not appear to favor raising the Board's allocation. Ms. Billingsley stated fees might have to be raised to cover the allotted expenditures. The Board's Financial Analyst recommended raising the technician fee to the maximum \$25 to get some history. Should the Board find that it isn't necessary to collect that amount they could lower it the next year. The fee for pharmacist's renewals is currently at \$150 and the maximum permitted is \$200. That fee might need to be raised based on what action is taken by the legislature. Howard Paul suggested that the Board seek a legal opinion confirming that K.S.A. 75-1609 is current law and whether the State can take more than 20 percent from the Fee fund. A motion was made and seconded to have Randy Forbes write a letter to the Attorney General to request verification that K.S.A. 74-1609 is currently in place and unmodified and what the legality is of moving money from the fee fund to fund the State. (Paul/Thompson). Motion carried 5-0.

RECESS: The Board recessed at 12:00 p.m. for lunch.

RECONVENE: The Board reconvened at 1:00 p.m. with all members present as previously stated.

MICHAEL R. LINDER #11223: Michael Linder appeared with his attorney, Michael Francis. Randy Forbes, General Counsel, represented the Board. The Respondent requested reinstatement of his revoked license. The Board advised the Respondent that he held the burden of showing that he met all of the requirements of *Board of Healing Arts. v. Vakas.* After hearing testimony and being fully and duly advised a motion was made and seconded to close the session to discuss confidential information. The closed session included the Respondent, his attorney, the court reporter, Dr. Mary Carder, Randy Forbes, Debra Billingsley. (McFarland/Thompson) Motion carried 5-0.

RECONVENE: The Board meeting reconvened at 2:40 p.m. with all members present as previously stated.

A motion was made and seconded to deny Mr. Linder's application for reinstatement (Thompson/Howard). Motion carried 5-0. Randy Forbes was directed to draft an Order Denying Reinstatement.

PAMELA L. STODDART #11059: Pam Stoddart appeared with her attorney, Steve Schwarm. Randy Forbes, General Counsel, represented the Board. Mr. Forbes had recommended that the Board approve a Stipulation and Final Agency Order as a settlement to allegations regarding drug impairment. Ms. Stoddart asked for a modification to the Stipulation. Specifically she wanted to shorten the agreement to three years instead of five. Ms. Stoddart also asked to have a statement be removed from the document because it implied that she was lying. A motion was made and seconded to go into a closed session to discuss confidential information until 3:20 p.m. The closed session included the Respondent, her attorney, Dr. Mary Carder, Randy Forbes and Debra Billingsley (Paul/McFarland). Motion carried 5-0.

RECONVENE: The Board reconvened at 3:20 p.m.

MOTION: A motion was made to approve the final agency order as written. (McFarland/Thompson). After discussion a friendly amendment was made to replace all references of 60 months in the Stipulation to 48 months, but all other provisions would remain in effect (McFarland/Whitchurch). Motion carried 5-0.

COREY V. PENNER #12658: Corey Penner appeared pro se regarding his request that the Board modify a Final Agency Action entered into on December 19, 2002. Mr. Penner asked that the Board lift the restriction that he never work alone. The request was to permit him to work alone on two Saturdays and holidays in a month for four-hour shifts so long as he did not perform outpatient dispensing and did not meet with or care for outpatients. This change would only apply to his employment at Prairie View Hospital. A motion was made to go into a closed session until 3:55 p.m. for the purpose of discussing confidential information. Those included in the closed session included the Respondent, Dr. Mary Carder, Randy Forbes and Debra Billingsley (Thompson/McFarland). Motion carried 5-0.

RECONVENE: The Board meeting reconvened at 3:55 p.m.

MOTION: A motion was made and seconded to modify the Board December 2002 Final Order such that it permits Mr. Penner to work two Saturdays and holidays in a month at Prairie View Hospital for four hour shifts so long as he did not perform outpatient dispensing and did not meet with or care for outpatients (Whitchurch/Gilstrap). Motion carried 4-1. Jeff Thompson opposed the motion.

RANDALL R. FILE #9670: Randy File did not appear but requested that the Board amend his Consent Agreement and Order entered into on November 18, 1999 to waive any additional fine he owes the Board of Pharmacy. Dr. Mary Carder spoke in favor of the modification. A motion was made and seconded to go into executive session to deliberate until 4:20 p.m. Those included in the Executive Session included Randy Forbes and Debra Billingsley (Whitchurch/McFarland). Motion carried 5-0.

RECONVENE: The Board meeting reconvened at 4:20 p.m.

MOTION: A motion was made and seconded to offer a modification to postpone payments for a period of three months however, during that time the money to CIPP needs to be paid 100 percent. The maturity date of the Board fine would be extended to March 2005. (Paul/Whitchurch). Motion carried 5-0.

PHARMACY TECHNICIAN REGULATIONS: Dr. Mary Carder requested clarification as to whether pharmacy technicians would be included in the CIPP contract. The Board determined that due to budgetary problems the Board wait a year before taking any action requiring technicians to be included in the CIPP agreement.

COMPOUNDING REGULATIONS: The Board had a general discussion regarding Draft 14 of the proposed compounding regulations. Jeff Thompson will work on another draft and the corrected version will be put in regulation format and submitted for approval to the Department of Administration.

ADJOURNMENT: The Board adjourned until 8:00 a.m., March 10, 2004.

Wednesday, March 10, 2004

MEMBERS PRESENT: Mike Hurst, RPh., President; Frank Whitchurch, RPh., Vice President; Merlin McFarland, RPh.; Jeff Thompson, RPh.; JoAnne Gilstrap, RPh.; Howard Paul, Public Member.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh.; Pharmacy Inspector; LaTonyua Rice, Pharm.D., Pharmacy Inspector; Tom Frazier, RPh., Pharmacy Inspector; Reyne Kenton, Compliance Officer, Melissa Martin, Compliance Officer; Randy Forbes General Counsel and Karen Hollon Administrative Officer.

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: Mike Hurst called the meeting to order at 8:00 a.m.

INVESTIGATIVE REPORTS: Frank Whitchurch gave his report and discussed with the Board the investigations that have taken place since the December Board Meeting. Mr. Whitchurch provided a list of the pharmacists that are currently on probation and whether they were in compliance. Mr. Whitchurch and Mr. Hurst complimented Ms. Billingsley, Jim Kinderknecht and the inspectors on their work.

CONTINUING EDUCATION AUDIT: Mike Hurst expressed concern to the Board about how continuing education is audited and suggested changing the audit procedure. A motion was made and seconded to change the procedure to ask pharmacists to list their continuing education when they renew their license and then the office will notify a percentage of the pharmacists at a later date that they are being audited. The pharmacist will then be required to submit documentation of his reported hours. (Whitchurch/Gilstrap). Motion carried 5-0.

PHARMACY TECHNICIANS: Debra Billingsley discussed with the Board raising the fee for technician registration based on a recommendation of the Board's financial analyst. A motion was made and seconded to raise the fee for pharmacy technician registration from \$10 to \$25 (McFarland/Thompson). Motion carried 4-1. Howard Paul opposed the motion. The Board will review all fees in June.

BOARD MEMBER REPORTS:

Jeff Thompson stated he had been receiving calls regarding the compounding regulations.

Merlin McFarland encouraged the Board to think about offering a rebate or refund to those technicians that become certified or goes through a junior college program. Mr. McFarland discussed with the Board the legality of prescriptions being delivered to a drop location so long as the patient signed a form directing delivery to a particular address. The Board's counsel stated that this would not be in compliance with the Pharmacy Act. Merlin McFarland and Frank Whitchurch agreed to serve on a task force

regarding telepharmacy and to explore whether this would help those in small towns with delivery type problems.

JoAnne Gilstrap reported concerns regarding pharmacy technician registration and requested clarification as to when the technician could actually begin working. The Board determined that so long as the technician had mailed or faxed their completed registration to the Board that they could begin working. The Board further discussed that proof of a passing technician examination needs to be available to the inspectors at the pharmacy upon request. Ms. Gilstrap also requested clarification as to whether a PA and ARNP from another state should be required to have the practitioner's name on the RX along with their own when their practicing state does not require this. The Board concluded that they must follow Kansas law and have the physician's name on the RX along with their own. It was suggested that the Nursing Board be asked to put this in their newsletter. Ms. Gilstrap thanked Jeff Thompson for the work on the compounding regulations.

Frank Whitchurch passed around an NACDS's practice memo telling how to detect when a drug is counterfeit. Mr. Whitchurch reported on a pharmacy advertising problem that had been resolved. Mr. Whitchurch also discussed with the Board problems regarding a local physician who was having his staff sign his name to his prescriptions. Mr. Whitchurch personally talked to the physician. The Board recommended that if problems persisted that a referral should be forwarded to the Board of Healing Arts.

Reyne Kenton reported that a Canadian pharmacy in Elkhart called Maple Leaf Script is covering a 5-state-area. Maple Leaf advertises that they don't counsel and the ad advises patients to call their local pharmacist or physician for information regarding drug interactions. Merlin McFarland suggested that if a patient has a problem that the investigator obtain a sample of the drug.

LaTonyua Rice reported that Wichita is opening another Canadian drug store. Pharmacists have commented that patients are asking them to counsel or give information because they can't get that from the Canadian storefront. The pharmacists advised that they are refusing to counsel or give any information to confirm the prescription since they have no assurances that the drug is correct.

Tom Frazier reported of having a problem with seeing preprinted C-II prescriptions and that he had talked to the physicians and told them that these are not permitted. Mr. Frazier shared a flier that shows how much someone can save using a Canadian pharmacy.

RECESS: The Board recessed until 9:30 a.m.

RECONVENE: The Board meeting reconvened at 9:30 a.m. with all members present as previously stated.

Jim Kinderknecht stated he appreciated Frank Whitchurch coming to the office a day or two a month to do investigations. Mr. Kinderknecht informed the Board that he had been subpoenaed to testify in a trial in Emporia involving possession of a vegetative matter called Khot, an analog of a Schedule 1 drug. Mr. Kinderknecht was called to testify that in K.S.A. 65-4102 the Board should submit to the Speaker of the House and President of the Senate any requested changes in scheduling of the controlled substances. Mr. Kinderknecht said it has never been done. Mr. Kinderknecht suggested looking into maybe scheduling Khot as a schedule 1 drug. Mr. Kinderknecht has been attending the Bioterrorism Committee Meetings in Topeka and has a video that shows warehouses as big as football fields. He stated they are very organized including working with the expiration date. The Board of Pharmacy now owns the four cars used by the inspectors since the Governor did away with Motor Pool. The Board of Pharmacy will need to budget to buy new cars in a few years.

Randy Forbes reported that he had done some preliminary research and that the Board did have statutory authority to take action on Canadian pharmacies. He stated that the FDA is interested in helping Kansas provide investigative support. The Attorney General in Oklahoma got an injunction saying RX Depot could not function in the manner they were conducting business. FDA also suggested contacting the Canadian government because they were sometimes interested in preventing depletion of available drugs for Canadians. Mr. Forbes discussed with the Board the David Waxman Bill involving a very new grant to State and Federal government to stop importation. A motion was made and seconded to authorize Mr. Forbes to proceed in moving forward with the Canadian pharmacy situation. (Whitchurch/Gilstrap). Motion carried 5-0. Mr. Forbes discussed with the Board as to whether incident reports could be used in civil cases. Nine statutes provide that certain types of documents are privileged. Mr. Forbes stated that the Board of Pharmacy might wish to draft a short bill providing privilege to incident reports. A motion was made and seconded to accept the proposal to draft legislation to include incident reports as evidence that is privileged. (Whitchurch/Thompson). Motion carried 5-0. Mr. Forbes stated that K.S.A. 68-1-3a includes the limitation that a preceptor can supervise no more than two students. This proposed regulation is somewhere in the process at the Attorney General's Office. Mr. Forbes suggested that the Board shouldn't make reference to any investigative committee when it is really an investigative member meeting with staff. The designation "committee" implies more than one Board member and subjects them to Open Meetings requirements of providing notice to members of the public. Mr. Forbes suggested to the Board that the licensees that are being disciplined be required to sign a waiver or a stipulation prior to the Board discussing the specifics of their case. Otherwise a licensee may decide to have a full hearing and the Board will be precluded from hearing the matter. A recommendation was made to have the Assistant Attorney General get a signed waiver prior to discussions with the Board.

Debra Billingsley asked the Board about their policy regarding the reinstatement application from those whom have let their license lapse for over three years and have not been licensed in any other state during that time. The Board determined that Frank Whitchurch, as the investigation member could review those types of applications to determine whether there are competency issues. Ms. Billingsley informed the Board

regarding a call for candidates to be on the Council of Experts Committee with USP during 2005-2010 if anyone was interested. The National Institute of Child Development was also looking for interested candidates. Ms. Billingsley stated she went to NABP's office for training found it very informative and helpful. The NABP has put together a self- assessment test that will be available in December. It could be a useful tool for disciplinary cases if there are competency or skill issues.

Ms. Billingsley reported that she attended a CIPP meeting and the contract is coming up in June. Ms. Billingsley stated that Dr. Mary Carder had been helpful regarding CIPP issues and that Randy Forbes had been good to work with in providing legal assistance.

JoAnne Gilstrap asked about Senate Bill 468. This bill would require all licensing agencies to deny licensure to those who were delinquent in filing or paying their taxes. This bill had not been worked to Ms. Billingsley's knowledge. The Drug Repository Bill was still being discussed although it had not moved forward.

The Board recommended having a meeting at the KU School of Pharmacy. The suggested date was for the September meeting to be held in Lawrence if possible. The Board also noted that the winter meeting would be held on November 30th and December 1st.

APPROVAL OF NEW LICENSES, REGISTRATIONS AND CERTIFICATES: A motion was made and seconded to approve the new pharmacists licensed, new pharmacies registered and certificates for pharmacists licensed for 50 years. (Gilstrap/Whitchurch). Motion carried 5-0.

ADJOURNMENT: The Board adjourned the Board meeting at 10:30 to travel to Stormant-Vail Hospital to view their automated dispensing and pharmacy system.