

South Carolina Board of Pharmacy

Board Meeting

9:00 a.m., November 18, 2009

Synergy Business Park

110 Centerview Drive, Kingstree Building

Columbia, South Carolina

Wednesday, November 18, 2009, Room 108

1. Meeting Called to Order

Allen Toole, R.Ph., chairman, of Liberty, called the regular meeting of the SC Board of Pharmacy to order at 9:00 a.m. Other Board members participating in the meeting included: Bobby Bradham, R.Ph., vice chairman, of Charleston; David Banks, R.Ph., of Simpsonville; Dan Bushardt, R.Ph., of Lake City; Addison Livingston, R.Ph., of Swansea; Hugh Mobley, R.Ph., of Lancaster; Leo Richardson, PhD., of Columbia*; and Dock Henry Rose, R.Ph., of Greer.

Staff members participating during the meeting included: Lee Ann Bundrick, R.Ph., Administrator; Rosemary Boguski, R.Ph., Pharmacist Inspector; Marilyn Crouch, Program Assistant; Eddie Durant, R.Ph., Pharmacist Investigator; Larry Grant, R.Ph., Pharmacist Inspector; and Ernie Shuler, R.Ph., Pharmacist Inspector. LLR employees participating during the meeting included: Sharon Dantzler, Deputy General Counsel; Sandra Dickert, Administrative Assistant; and Pat Hanks, Assistant General Counsel.

Members of the public attending the meeting included: Shannon Amerson, Paulette Bentley, Sarah Braga, Pam Cain, Annette Cantrell, Carmelo Cinqueonce, Terry Clark, Ronnie Duncan, James Frazier, Chris McCoy, Katia Frazier, Russell Frick, Elizabeth Grayson, Cynthia Kirshy, Mike Lippner, Michelle Mayer, Lewis McKelvey, Joe Mullinax, Kelly O'Donoghue, Nessa Petrie, Christy Pettit, Tom Phillips, Tom Porter, Eric Ridings, Nicole Roach, Kenneth Rogers, Yasmine Shakebi, Frank Sheheen, Whitney Sparks, Kelly Smith, Robert Spires, Ed Vess, Rick Wilson, Julie Wrenn, and Jerry Wojcik.

Public Notice

Mr. Toole announced that this meeting was being held in accordance with Section 30-4-80 of the SC Freedom of Information Act by notice sent to The State Newspaper, Associated Press, WIS-TV, and all other requesting persons, organizations, or news media. In addition, notice was posted on the bulletin boards at the main entrances of the Kingstree Building.

MOTION

Mr. Bradham made a motion the Board not use the Granicus system until technical difficulties are corrected. Mr. Banks seconded the motion. Following a brief discussion the motion carried.

Pledge of Allegiance

All present recited the Pledge of Allegiance.

Invocation

Mr. Bushardt delivered the invocation.

2. Chairman's Remarks – Allen Toole, R.Ph.

Mr. Toole made no remarks at this time.

3. Introduction of Board Members and all other persons attending

The Board members, staff and members of the public attending the meeting introduced themselves.

4. Approval of Minutes for the September 16-17, 2009 Meeting

Mr. Mobley made a correction to page nine regarding the SC Association of Chain Drug Stores letter to Mr. Hook, chairman of the Board. He stated the Board indicated it had the same concerns following Mr. Phillips request to have the letter become part of the official record.

MOTION

Mr. Rose made a motion to approve the September 16-17, 2009 meeting minutes as amended. Mr. Mobley seconded the motion, which carried unanimously.

5. Approval of Reciprocity Interview Candidates for Licensure

MOTION

Mr. Banks made a motion to approve the reciprocity candidates for licensure. Mr. Livingston seconded the motion, which carried unanimously.

Mr. Mobley stated the licenses are no longer distinguishing the reciprocity licensees from the in-state licensees. Mrs. Bundrick stated she had spoken with Ms. Laura McDaniel from OLC in regard to this matter. She further stated Ms. McDaniel was pulling the same information from the report from the ReLAES system that has always been pulled and does not know why the distinction is not being captured.

MOTION

Mr. Bradham made a motion the Board continue the practice of noting the reciprocity licensees on the licenses signed by the Board as previously handled in the past and that reciprocity be noted on the licenses versus NABPLEX and MPJE examination. Mr. Rose seconded the motion, which carried unanimously

6. Administrator's Report - Lee Ann F. Bundrick, R.Ph.

Good Morning Mr. Chairman and members of the Board

- The next Board vacancy begins July 1, 2010 and ends June 30, 2016 for the Third Congressional District. Before December 1, 2009, a candidate interested in running for the vacancy must submit a biography and a petition bearing signatures of at least 15 pharmacists practicing in the Third District and be licensed and actively practicing pharmacy in South Carolina. To date, we have not received any information on possible candidates.
- As of this report we have approximately 2,664 active state-certified pharmacy technicians and 4,615 active registered pharmacy technicians. We have 6,585 active licensed pharmacists, 3,570 permitted facilities and three routing companies.
- The Pharmacist Inspectors have conducted 153 inspections since the last Board Meeting:
 - ◇ Pharmacy Permit Inspections 64
 - ◇ Non-Dispensing Drug Outlet Permit Inspections 65
 - ◇ EMP Permit Inspections 7
 - ◇ Medical Gas/DME Permit Inspections 17
- Of the 153 inspections, 35 new permits were issued.
- 3 Citations have been issued since the last Board Meeting

- 26 Reciprocity Interviews have been conducted since the last Board Meeting. 11 of the 26 reciprocity interviews have been done by Board staff.
- My staff and/or I have participated in the following meetings since the September meeting:
 - Mr. David Banks and I attended a program at South University School of Pharmacy on September 24, 2009.
 - Mr. Al Toole, Mr. David Banks and I attended a legislative meeting regarding the Pharmacy Technician Bill H3394 on September 29, 2009 at the SC Pharmacy Association with Rep Kit Spires and other interested parties
 - I attended the OBB Administrator's Meeting on September 30, 2009
 - Ms. Cle Sanders, Mr. Randy Bryant, Mr. Bruce Duke and I met on September 30, 2009 regarding E-prescribing concerns with licensed practitioners authorized to prescribe.
 - Mr. Wilbur Harling and I participated in the MPJE State Specific Law Review October 5,8,9,15, 2009.

We reviewed 4000 law questions for the MPJE exam.

- I was appointed to the NABP Task Force on Pharmacy Technician Education and Training and attended the Task Force October 6-7, 2009 in Chicago, IL
 - Ms. Cle Sanders, Mr. Hugh Mobley, and Mr. Bobby Bradham participated in a meeting with the SC Hospital Association and the SC Society of Health System Pharmacists on October 8, 2009 regarding Non Dispensing Drug Outlet Permits as it relates to hospital owned physician practices.
 - Mr. David Banks represented the Board during the on site visit with ACPE as it evaluated the Doctor of Pharmacy program at the Presbyterian College School of Pharmacy, October 13-15, 2009.
 - I attended the South Carolina Coalition for Older Adult Immunizations meeting on October 13, 2009.
 - Ms. Cle Sanders attended the SCSHSP Innovative Medication Use Technologies and Automation Conference on October 13, 2009.
 - Mr. Al Toole and I attended the MALTAGON Conference October 18-21 in Nashville, TN
 - Mr. Hugh Mobley and Ms. Rosemary Boguski attended the SCPhA Regional Rally in Columbia on October 20, 2009.
 - Telephone IRC meeting with Mr. C Turner on October 26, 2009.
 - Mr. Carmelo Cinqueonce, Mr. Robert Spires and I met on October 27, 2009 regarding pharmacy technician legislation.
 - Mr. Henry Rose and I attended at meeting with DHEC Bureau of Drug Control, Ms. Mary Ludlow, Mr. Jimmy Sain and Ms. Pam Whitmire regarding Hospice Issues and LTHC Issues on November 3, 2009
 - The Pharmacy Technology Committee met on November 12, 2009. Mr. Bobby Bradham was the Board member who participated in this meeting as well as Mr. Ernie Shuler, Mr. Larry Grant and myself as staff.
 - Mr. Bobby Bradham and I met on November 12, 2009, regarding SCDMH MOA.
 - Board of Pharmacy staff meeting on November 13, 2009.
 - Mr. Joe Newton is teaching the compounding labs at SC College of Pharmacy MUSC Campus on November 17, 18 and 19, 2009.
- Staff has attended agency, board staff, compliance staff and legal counsel meetings.
 - Mr. Larry Grant has met with CVS regarding electronic prescribing and visited several physician offices to discuss the use of rubber stamps signatures and the signing of e-prescribed prescriptions which are handed to the patients instead of being transmitted.

- Mr. Larry Grant and Mr. Joe Newton have worked with County Jails regarding how to handle prescription medications and be in compliance.
- The Board of Pharmacy has continued to serve as a site for pharmacy students on clinical rotations from SC College of Pharmacy. Ms. Lindsay Gilstrap from the MUSC Campus was on rotation with the BOP for the month of October. Ms. Whitney Sparks is here for the month of November. These students have worked on projects to research information requested by the Board. The projects included VAWD/pedigree requirements and ADS machines in LTHC and Hospice settings. Their research has been a valuable resource.
- The Office of Licensure and Compliance will be distributing the 10% random CE audits for the pharmacists next month.
- I have interviewed seven candidates for the Compounding Pharmacist FTE that is posted. I am in the process of finalizing the paperwork to be forwarded to HR.
- The deadline for the 4th Quarter Board of Pharmacy Newsletter to NABP is quickly approaching. If you have any suggestions for articles, please let me know. We have been sending these to you for your review and comments. If anyone is having problems receiving this information, please let me know.
- Handouts for your review that may be of interest to you include: A letter from Mr. Michael A. Podgurski from Rite Aid informing the Board that Rite Aid Corporation has received ASHP accreditation for the Rite Aid Technician Training Program retroactive to August 5, 2008; an anonymous complaint regarding shortage of pharmacy technician staff in chain pharmacies; a complimentary e-mail from Ms. Carol McDowell regarding Mr. Ernie Shuler's inspection of her facility and a letter to Ms. Dantzler from Mr. James Walker, Senior Vice President Regulatory & Workforce, with the South Carolina Hospital Association regarding Board policies and the SCHA's concerns.
- I would like to thank the Board for their continued support of me and the rest of the staff in the office. We always appreciate the encouragement and support you give us.

I will respectfully answer any questions you may have.

Leo Richardson, PhD., of Columbia, arrived for the meeting at 9:18 a.m.

7. Compliance and Inspectors Report

IRC Recommendations for dismissals and dismissals with non-disciplinary letters of concern, Proposed Agreement to Relinquish, Consent Agreements and Cease and Desist Orders

Agreement to Relinquish

- i. Case #: 2009-66
- ii. Case #: 2009-67
- iii. Case #: 2009-79
- iv. Case #: 2009-84
- v. Case #: 2009-85

These cases were presented for the Board's information.

Consent Agreements

- i. Case #: 2008-146
- ii. Case #: 2009-2
- iii. Case #: 2009-23

MOTION

Mr. Rose made a motion the Board accept the consent agreements. Mr. Banks seconded the motion, which carried unanimously.

Cease and Desist

- i. Case #2009-76

Mrs. Bundrick presented the members with a cease and desist order which was issued on Tuesday, November 17, 2009.

IRC Report / Resolution Guidelines Report

Resolution Guidelines Report

Mrs. Bundrick the members with the resolution guidelines report, which contained eight cases for dismissals with letter of caution.

Dismissals with Letter of Caution

MOTION

Mr. Banks made a motion the Board approve the eight cases for dismissal with a letter of caution. Mr. Rose seconded the motion, which carried unanimously.

IRC Report October 26, 2009

The Board reviewed the October 26, 2009 IRC report which contained one formal complaint.

MOTION

Mr. Banks moved to approve the IRC report. Mr. Bushardt seconded the motion, which carried unanimously.

A. Request Modification of Order – Russell Frick, R.Ph.

On September 25, 2005 Mr. Frick entered into a consent agreement with the Board when it was found that Mr. Frick practiced pharmacy on one occasion while under the influence of alcohol. He was licensed to practice pharmacy at the time of the incident. Mr. Frick voluntarily surrendered his license to practice pharmacy on November 1, 2004 and admitted to diverting a quantity of a Schedule IV controlled substance without a prescription or authorization from a physician from the pharmacy in which he was employed. Mr. Frick's license was reinstated and according to the terms of the consent agreement, which included but was not limited to, his license being immediately placed on five years of probation during which time he must enter into a five year contract with the Recovering Professionals Program (RPP) and that he shall not serve as a pharmacist-in-charge (PIC) or a permit holder during the five year probation.

In a letter to the Board dated October 3, 2009 Mr. Frick states that he recently completed his five year agreement with RPP and that he is respectfully seeking the Board's approval to be released from the consent agreement. The letter notes that he surrendered his license on November 1, 2004 and that the consent agreement was dated September 25, 2005.

The Board also received a letter from Maureece Jones of RPP supporting Mr. Frick's request to be released from the consent agreement.

Russell Frick and Frank Sheheen appeared before the Board at this time. Mr. Frick stated he has successfully completed his five year contract with RPP. He noted it was brought to his attention during his exit interview with RPP that his time with the consent agreement did not coincide and is asking that his license be reinstated.

Mr. Sheheen stated Mr. Frick has been in compliance with his RPP contract.

Mr. Toole informed Mr. Frick the Board would take his testimony under advisement and render a decision later in the meeting.

B. Request Release from Order – James Frazier, R.Ph.

On November 17, 2004 Mr. Frazier entered into a consent agreement with the Board after it was found that he consumed alcohol on multiple occasions while working as a pharmacist. Mr. Frick's license was reinstated and according to the terms of the consent, which included but was not limited to, his license being immediately placed on probation for five years during which time he must enter into a five year agreement with RPP and that he shall not serve as PIC or permit holder during the five year probation period.

On September 28, 2009 the Board received a letter from Mr. Frazier stating he has completed the five years of probation and is seeking the Board's approval to be released from the consent agreement.

The Board received a letter dated October 13, 2009 from Chris McCoy of RPP supporting Mr. Frazier's request to be released from his consent agreement.

Mr. Frazier appeared before the Board at this time. Mr. Frazier thanked the Board for allowing him to participate in RPP. He feels he has been successful in the program. He is requesting release from the consent order.

Mr. Chris McCoy, of RPP, stated Mr. Frazier has been in full compliance with his RPP contract.

Mr. Toole informed Mr. Frazier the Board would take his testimony under advisement and render a decision later in the meeting.

C. Request Reinstatement – Elizabeth Grayson, R.Ph.

In April 2000 Ms. Grayson entered into a consent agreement with the Board after it was found she unlawfully dispensed quantities of various prescription drugs by fraud, misrepresentation or deception. Ms. Grayson's license was suspended which was stayed and her license was immediately placed in probation for 30 months. According to the terms of the consent agreement Ms. Grayson could not serve as a PIC or permit holder. On July 26, 2001 an Order of Temporary Suspension was issued against Ms. Grayson. In a document from the County of Pickens Ms. Grayson was convicted of plead guilty to obtaining goods under false pretenses following an arrest in January 2002. She was sentenced to one year imprisonment, suspended with probation for 18 months and had to complete 12 months with RPP. An affidavit from the County of Pickens shows Ms. Grayson received early termination of probation after satisfactory fulfillment of the conditions of the probation.

Ms. Grayson and Ms. Paulette Bentley, of RPP, appeared before the Board at this time. Ms. Grayson stated she is asking the Board's approval of reinstatement of her license. She further stated she underwent intensive recovery following the surrender of her license. She believes she is now a different person.

Ms. Bentley stated Ms. Grayson has been in compliance with her RPP contract.

Mrs. Dantzler stated the statute states an individual who has not actively practiced pharmacy in another state for three years or more must demonstrate at least one thousand hours of practice under the on-site supervision of a South Carolina licensed pharmacist, successful passage of

the MPJE, and submittal of proof of completion of sixty hours of acceptable continuing education. She noted a provisional license would be issued should the Board approve Ms. Grayson's license reinstatement request.

Ms. Grayson stated she has submitted a license reinstatement application, is ready to submit an intern application, and has taken 85 hours of continuing education courses, of which 22 hours were live. She noted most of the continuing education hours were completed within the last two years.

Mr. Toole informed Ms. Grayson the Board would take her testimony under advisement and render a decision later in the meeting.

D. Request Reinstatement – Cynthia Kirshy, PhT.

Cynthia Kirshy appeared before the Board on January 20, 2005 as a result of information received by a pharmacy investigator that Ms. Kirshy had been arrested in 2003 for the unlawful possession of cocaine and DUI and again in October 2004 for another DUI. She successfully completed the PTI program for the cocaine charge. However, she admitted to the investigator and to the Board during the hearing that she had submitted two fraudulent registration applications because she had answered no to the question asking if she any pending legal actions against. Ms. Kirshy's registration was temporarily suspended in October 2004 and on November 9, 2004 she requested a hearing before the Board. The Board denied her request for registration reinstatement during the January 20, 2005 hearing. On November 9, 2009 the Board received a request from Ms. Kirshy requesting an appearance during this meeting to seek the Board's approval for reinstatement of her registration.

Cynthia Kirshy appeared before the Board on January 20, 2005 after information was received that she had been arrested in 2003 for unlawful possession of cocaine and DUI and had been arrested in October 2004 for DUI. She admitted during the hearing that she answered no to the question asking if she had any pending legal action against her in her initial application received by the Board on December 19, 2003 and again lied on her answer to that question on her renewal application dated June 28, 2004. In a final order dated February 14, 2005 the Board Ms. Kirshy's request for reinstatement of her pharmacy technician registration

Ms. Kirshy appeared before the Board at this time. Ms. Kirshy stated she would like to request the reinstatement of her pharmacy technician registration. She further stated CVS has stood by her since she last appeared before the Board. She has worked her way up from cashier to store manager during the past three years. In 2003 she went through a recovery process, which included AA. Her desire is to stay as store manager; however, she would like to have a pharmacy technician registration to fill prescriptions when needed. A pharmacy technician registration is not a requirement for a management position with CVS; however, the company strongly encourages having a registration.

Ms. Sonia Haley, R.Ph., of CVS, spoke on Ms. Kirshy's behalf.

Mr. Toole informed Ms. Kirshy the Board would take her testimony under advisement and render a decision later in the meeting.

E. Request Modification of Order – Kenneth Rogers, R.Ph.

On September 8, 2008 Kenneth Rogers entered into a consent agreement with the Board after which he failed to adhere to controlled substance regulations as required by the practice act while he was the pharmacist in charge (PIC) at Apothecare Compounding Pharmacy. The consent agreement suspended Mr. Rogers license, which was stayed and placed his license in

probationary status for three years, required him to pay a \$5,000.00 fine, and that he not engage in the compounding of sterile or non-sterile drugs during his probation.

Kenneth Rogers appeared before the Board at this time. Mr. Rogers stated he is asking for a modification to the consent agreement. He further stated he would like to be able to compound Tamiflu Suspension, Magic Mouthwash, and to combine things that are readily available. He does not want to be labeled as a compounding pharmacy at this time.

Mr. Toole informed Mr. Rogers the Board would take his testimony under advisement and render a decision later in the meeting.

8. Old Business

F. Attorney General's Opinion – Hugh Mobley, R.Ph., Bobby Bradham, R.Ph.

Executive Session

MOTION

Mr. Mobley made a motion the Board enter executive session to seek legal advice. Mr. Banks seconded the motion, which carried unanimously.

Return to Public Session

MOTION

Mr. Banks made a motion the Board return to public session. Mr. Mobley seconded the motion, which carried unanimously

Mr. Toole noted for the record that no official action was taken during executive session

MOTION

Mr. Banks made a motion the Board turn the Granicus equipment on to allow the meeting to be broadcast publicly or to allow the meeting to be broadcast at a later time. Mr. Bradham seconded the motion, which carried unanimously.

Request Modification of Order – Russell Frick

MOTION

Mr. Banks made a motion the Board that Mr. Frick's request for modification of the order. Mr. Bradham seconded the motion, which carried unanimously.

Request Release from Order – James Frazier

MOTION

Mr. Rose made a motion that the Board approve Mr. Frazier's request to be released from his order. Mr. Bradham seconded the motion, which carried unanimously.

Request Reinstatement – Elizabeth Grayson

MOTION

Mr. Livingston made a motion that the Board allow Ms. Grayson to proceed with the process of having her license reinstated. Mr. Banks seconded the motion, which carried unanimously.

Request Reinstatement – Cynthia Kirshy, PhT.

MOTION

Dr. Richardson made a motion that the Board grant Ms. Kirshy's request for reinstatement. Mr. Rose seconded the motion, which carried unanimously.

Request Modification of Order – Kenneth Rogers, R.Ph.

MOTION

Mr. Mobley made a motion that the Board deny Mr. Rogers' request for modification of the order. Mr. Livingston seconded the motion, which carried with a majority vote. Mr. Banks voted nay.

G. Request Approval of Non-Resident Pharmacy Application – Cantrell Drug Company

During the September 16, 2009 meeting James McCarley appeared before the Board on behalf of Cantrell Drug Company, which is seeking licensure as a non-resident pharmacy. During the meeting with Mr. Cantrell the Board had questions as to whether it should issue the company a pharmacy permit or a manufacturer permit and if the company is violating any controlled substance laws since the company has form 222 records and deals with Schedule II drugs. Mr. Durant had spoken with Mr. Wilbur Harling of the SC Department of Health and Environmental Control (SCDHEC), Bureau of Drug Control who stated as long as the company is not doing business within the boundaries of South Carolina the company does not have to become registered with DHEC.

The Board voted to have Mr. McCarley work through DHEC and DEA on outlining what he is doing and if it legal with those entities.

On September 27, 2009 Mr. Durant sent an e-mail to Steve Bethel of Cantrell Drug Company seeking a copy of the current DEA registration for Cantrell Drug Company and a copy of an executed DEA 222 form and accompanying prescription order demonstrating the type activity Cantrell Drug Company is engaged with physicians.

Mr. Eddie Durant stated Cantrell Drug Company appeared during the September 2009 meeting requesting the Board's approval for a non-resident wholesale permit. He noted the company entered an administrative settlement with DEA. He noted Cantrell and Mr. McCarley does quite a bit of compounding and uses narcotics during the process. He further stated DEA does recognize a transfer between a pharmacy and a physician, but the physician can only transfer the product with a DEA Form 222. He spoke with DEA who stated Cantrell Drug Company is in total compliance with their laws. He also stated Arkansas inspects the company as a pharmacy.

Mrs. Bundrick stated she spoke to an assistant executive with Arkansas during the MALTAGON conference who stated to the best of his knowledge Cantrell Drug is run top notch and that the company has a state of the art compounding facility. She went on to say most other states are requiring both permits.

MOTION

Mr. Mobley made a motion the Board issue Cantrell Drug Company a non-resident wholesale permit and a non-resident pharmacy permit. Mr. Livingston seconded the motion, which carried unanimously.

H. Oxygen Policy and Procedure #131

Mrs. Bundrick stated the Board made a motion during the September 2009 meeting in regards to oxygen now that it requires a prescription instead of a CMN. She further stated the Board asked that an article regarding this matter be placed in the newsletter. She went on to say when she began drafting the article she reviewed the previous policy and procedure she found the revised policy and procedure is in direct conflict with what the Board has recommended. She discussed the matter with Mr. Mobley and they determined not to insert an article in the newsletter and to bring the matter back before the Board.

Ms. Boguski stated there is miscommunication in regard to what is required, a prescription or a CMN, on the inspection sheet. She further stated the inspectors have been moving forward with

stating a prescription since oxygen is a legend drug. She went on to say the facilities that are part of a corporation usually have a prescription which is used. She noted some of the other providers may be using CMNs because the physician may insert 99+ years. She said since oxygen is a legend drug there is a two year limit. She said there have been several questions of what constitutes a prescription, does it have to be in the prescription format, with e-prescribing coming into play and chronic medical records there are several grey areas. She suggested an article on the policy and procedure be placed in the newsletter and that it be sent to all medical gas providers.

Policy and Procedure #131 states:

An order, whether verbal or written, for oxygen therapy provided by a facility, which the Board of Pharmacy has jurisdiction over, should be maintained in a readily retrievable manner on the site permitted. The order should contain at minimum (1) full name and address of the patient (2) date of issuance (3) name, address, telephone number and degree classification of the prescriber (4) person issuing order and order contents, duration of use, duration and method of administration. A current order, which reflects the patient's therapy, should be maintained in a readily retrievable manner on the site permitted until the time which the prescriber discontinues the therapy.

In addition, facilities should maintain records which account for contents, lot numbers, and name of the patients to whom oxygen is dispensed as directed by the FDA.

The following language is new.

Only a practitioner's prescription can be used to order oxygen. A CMN (certificate of medical necessity) can no longer be considered a prescription. A practitioner's prescription should contain the standard information but limited to the flow rate and the length of therapy.

Manufacturers shall assume the responsibility of providing lot numbers and expiration dates on oxygen tanks. The expiration date must be clear, separate from the lot number, and not coded

All oxygen tanks must have proof of hydrostatic testing. Documentation of hydrostatic testing is required by the manufacturer and will follow GMPs set forth by the FDA.

Discussion on this matter ensued and included, but was not limited to, the expiration date on the tank, having an article in the newsletter and mailed to all medical gas legend devices, and what constitutes a prescription.

Mr. Mobley stated the committee would need to add if it is going to stand as a prescription and all of the components of a prescription be available in documentation. He feels it needs to be two separate policies and procedures.

MOTION

Mr. Mobley made a motion the Board refer this policy and procedure to the Pharmacy Practice Committee. Mr. Banks seconded the motion, which carried with a majority vote. Mr. Rose voted nay.

I. MALTAGON Report – Al Toole, R.Ph.

Mr. Toole briefed the Board regarding the MALTAGON meeting. He noted there was good discussion on all of the topics and that the states have a lot of common issues.

J. Pharmacy Technician Legislation

Mrs. Bundrick stated Representative Kit Spires could not be present for the meeting but asked that Board review a bill regarding pharmacy technician education.

Mr. Cinquence stated the association's board would not be opposed to the components contained in the legislation, although the Board has not yet voted on the draft.

Mr. Robert Spires stated the Society of Health System Pharmacists would also support the legislation.

Mrs. Bundrick noted the bill would grandfather registered technicians now without requiring those individuals to take the exam; however, the bill would not make the registered technicians state certified. She also stated the bill would not require the pharmacy technicians be high school graduates.

Mr. Mobley suggested the Pharmacy Technician Committee review the bill and have representatives from the Pharmacy Association, the Society of Health System Pharmacists and the Chain Drug Store Association involved in the discussion

Mr. Bradham expressed concerns with PIC determining the duties of the pharmacy technicians. He further stated the practice act specifies what the certified pharmacy technician's duties versus registered pharmacy technicians. He asked if that language is now being changed.

MOTION

Mr. Rose made a motion the Board approve the modified language. Mr. Bushardt seconded the motion, which failed. Dr. Richardson, Mr. Rose and Mr. Bushardt voted in favor of the motion. Mr. Bradham, Mr. Banks, Mr. Mobley and Mr. Livingston voted nay.

9. New Business

A. Request Approval of Pharmacy Technician Registration Application – Matthew Caudle

On August 10, 2009 the Board received a pharmacy technician registration application from Matthew Caudle. Mr. Caudle answered yes to the question asking, 'Have you ever been convicted of any criminal or civil charges (other than a minor traffic ticket)? Is there any legal action pending against you or are you currently on probation for any charges or legal action?' Mr. Caudle was arrested and charged on two separate occasions for DWI. Both incidents occurred in North Carolina. He has completed the requirements involved with these two charges and has completed half of the 12 month unsupervised probation from the second DWI conviction.

Matthew Caudle did not appear during this meeting and the Board took no action on his application.

B. Request Approval of Pharmacy Technician Registration Application – Eric Clamp

The Board received a pharmacy technician registration application dated August 29, 2009 from Eric Clamp. Mr. Clamp answered yes to the question asking, 'Have you ever been convicted of any criminal or civil charges (other than a minor traffic ticket)? Is there any legal action pending against you or are you currently on probation for any charges or legal action?' In December 2000 Mr. Clamp was arrested for simple possession of marijuana, which was a misdemeanor offense and was convicted of the offense in July 2001. In March 2005 he was arrested for a misdemeanor offense of public disorderly conduct and the unlawful carrying of a weapon.

Mr. Clamp appeared before the Board at this time. Mr. Clamp was charged and convicted of possession of marijuana. He was charged with disorderly conduct and unlawful carrying of a
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weapon on March 5, 2005. He noted the unlawful weapon charge was dropped and he plead guilty to disorderly conduct. He noted the law enforcement officer did not ask him any questions and he does not know what part of his behavior was disorderly. He currently works as an assistant manager with Walgreens.

MOTION

Mr. Banks made a motion the Board approve Mr. Clamp's pharmacy technician registration application. Mr. Rose seconded the motion, which carried unanimously.

C. Request Approval of Non-Resident Pharmacy Application – America's Best Care Plus, Inc, Ronnie Duncan

On August 28, 2009 the Board received a non-resident pharmacy permit application from America's Best Care Plus, Inc. The application reflects a yes answer to the question asking, 'To the best of your knowledge, has the applicant ever had a permit disciplined, denied, refused or revoked for violations of any pharmacy laws or drug laws in South Carolina or any other state?' America's Best Care Plus entered into a consent agreement with the Louisiana Board of Pharmacy after it was found the company dispensed prescription drugs between January 1, 2005 and May 9, 2005 to Louisiana residents without being properly permitted. The Louisiana Board of Pharmacy issued a letter of warning to America's Best Care Plus and also ordered the company pay a \$5,000.00 fine and a reimbursement expense of \$250.00.

Mr. Ronnie Duncan appeared before the Board at this time. Mr. Duncan stated the pharmacy is a respiratory care pharmacy which ships supplies to patients. He further stated Colorado has begun a prescription monitoring program which requires the company to report to the Board twice a month any controlled substances shipped. At the time the company had one pharmacist who would attempt to register but had problems with the registration. The company does not ship controlled substances; however, the company was fined \$5,000.00 for not submitting reports in a timely manner.

MOTION

Mr. Banks made a motion the Board approve America's Best Care Plus' non-resident pharmacy application. Mr. Mobley seconded the motion, which carried unanimously.

D. Change Date of March 17, 2010 Board Meeting to March 24, 2010 – Dock H Rose, R.Ph.

MOTION

Mr. Rose made a motion the Board change the March 2010 meeting date to March 24, 2010. Mr. Bradham seconded the motion. Mr. Rose stated he and Mr. Bradham will be attending the national ACPE meeting, which is scheduled for the week of March 17, 2010. Mr. Bradham stated the ACPE meets once every ten years. The motion carried unanimously.

E. Hospice Pharmacy Providers – Tom Porter, R.Ph.

Mr. Porter stated he has taken a pharmacy consultant position with Harmony Hospice Care. He further stated that with hospice care being 24 hour service every day of the week the company has sought out 24 hour pharmacies. He has been reviewing invoices he contacted some of the pharmacies regarding some of the charges that were incurred. He noted the cost of medication charged by the pharmacies concerns him and other individuals. He briefed the Board on prices for some of the medications the company has purchased. He said the written contract states it would adjust part of the claim if they thought it was necessary. He is unsure if the Board could draft an article for the newsletter regarding predatory pricing. He noted the contract contains a clause stating it can be dissolved with 30 day notice based on AWP. He also stated the individual discharged the contract the day he spoke with her regarding the prices.

Mr. Porter stated he was making this presentation as information to the Board.

Mr. Rose stated Cherie Crowley appeared before the Board in June 2009 during which time she spoke about how the pharmacy practice act lacks giving long term care facilities and hospice settings the dispensing machines. He went on to say Ms. Crowley had noted the dispensing machines are in seven facilities, one nursing home and six hospice settings. He said she had stated if could not do something by the first of the year (2010) she would pull all of those DEA licenses, which would close all of the machines. He had suggested the Board could require in-patient hospice settings that would like to have medication dispensing machines to have a non-dispensing permit and a consultant pharmacist who would be charged with developing a policy and procedure in regard to refilling the machines and maintaining the integrity of the machines with drug loss. He said there are approximately 17 states that have automatic dispensing machines in such facilities. He has received the regulations from those states and feels the Board should develop an emergency regulation regarding this matter. He went on to say most of the regulations require the consulting pharmacist to load the legend drugs into the machine or have a sealed unit delivered from the pharmacy providing service to the hospice setting. He went on to say he and Mrs. Bundrick met with Mr. Harling regarding this matter.

Discussion on this matter ensued and included, but was not limited to, the referral to Section 40-43-86(Q), which gives the Board authority since drug dispensing machines must be under the control of a licensed pharmacist, if the in-patient hospice settings submit applications now and are in line the Board could grant those permits based on the statute, and DHEC's Bureau of Drug Control's requirements for an emergency box in nursing home facilities.

MOTION

Mr. Rose made a motion the Board require in-patient hospice settings and long term care facilities to have a non-dispensing pharmacy permit and a consulting pharmacist. Mr. Mobley seconded the motion, which carried unanimously.

10. LUNCH

The Board recessed for lunch at 12:40 p.m. and returned to public session at 2:00 p.m.

Return to Public Session

11. New Business (Continued)

A. Request Approval of Non-Resident Wholesale/Distributor/Manufacturer Application – Baxter Healthcare Corp., Jerzy Wojcik

In September 2009 the Board received a non-resident wholesale/distributor and/or manufacturer application from Baxter Healthcare Corporation. The application reflects a yes answer to the question asking, 'To the best of your knowledge, has the applicant(s) ever had a permit disciplined, denied, refused, or revoked for violations of any pharmacy laws, drug laws in South Carolina or any other state?' and 'Have you ever violated the drug laws, rules, statutes and/or regulations of South Carolina, or any other state or country or the United States?' The Alabama Board of Pharmacy found the Buford, Georgia facility was in violation of a statute by continuing distribution operations during the time between when the valid license expired and when the expired license was renewed. The company renewed the license, entered into a consent agreement and paid the applicable fine. The Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the Hammond, Louisiana facility operated by the company's third party logistics provider and found the facility violated a law that requires a licensee to maintain copies of current licenses for its customers who are authorized to obtain and possess legend drugs and devices. The company obtained customer licenses, entered into a consent agreement and paid the applicable fine. The Missouri Board of Pharmacy issued a restricted drug distributor license to the facility located in Memphis Tennessee. The Board found the facility violated a law because the facility shipped legend drugs and/or medical devices into the

state without being properly licensed. The proper license was obtained, a probationary period was successfully completed on October 21, 2007 and the restriction placed on the license was removed.

Mr. Jerzy Wojcik appeared before the Board at this time. Mr. Wojcik stated the Memphis, Tennessee distribution location was distributing to Missouri without being properly licensed. The company was issued a provisional license, during which time the company demonstrated compliance with Missouri's regulations during that time, after which Missouri lifted the provision. He further stated the violation resulted from the company's misinterpretation of Louisiana's licensure requirement regarding customer licensing. The Board required the hard copies be maintained at the facility location. He noted the license renewal was missed by approximately two months with the Alabama Board of Pharmacy. In early 2009 all state licensing was transitioned from one area to another with the corporation. There are four facilities currently undergoing the VAWD process.

MOTION

Mr. Banks made a motion the Board approve Baxter Healthcare's non-resident wholesale/distributor/manufacture application. Mr. Bushardt seconded the motion, which carried unanimously.

B. Request Approval of Non-Resident Wholesale/Distributor/Manufacturer Application – Teva Pharmaceuticals USA, Inc., Kelly O'Donoghue

In October 2009 the Board received a non-resident wholesale/distributor and/or manufacturer application from Teva Pharmaceuticals USA, Inc. The application reflects a yes answer to the question asking, 'To the best of your knowledge, has the applicant(s) ever had a permit disciplined, denied, refused, or revoked for violations of any pharmacy laws, drug laws in South Carolina or any other state? 'Have you ever had an application for a drug distributor permit, pharmacy or pharmacist license, permit or certificate or a technician license or registration, denied, refused or revoked in South Carolina or any other state or country?', 'Have you ever had disciplinary action taken against you, or a pharmacy or drug distributor facility you owned, or a pharmacy or drug distributor facility where you were employed, by the Board of Pharmacy (or its equivalent) in South Carolina or any other state or country?' and 'Have you ever violated the drug laws, rules, statutes and/or regulations of South Carolina, or any other state or country or the United States?' In February 2009 the Colorado Board of Pharmacy initially denied Teva's application as an out of state wholesaler for its distribution facility in North Wales, Pennsylvania as a result of a lapsed license and ordered the company should cease and desist further shipments until the matter was resolved. The company entered into a stipulation with the Colorado Board of Pharmacy acknowledging its improper shipment on December 11, 2008 and paid a \$5,000.00 fine.

Kelly O'Donoghue appeared before the Board. Ms. O'Donoghue stated in February 2009 Teva Pharmaceuticals was disciplined in Colorado for failure to hold an out of state wholesale license during which time Teva was currently moving the VAWD accreditation. She noted Teva is now VAWD accredited.

MOTION

Mr. Rose made a motion the Board approve Teva Pharmaceuticals USAs non-resident wholesale/distributor/manufacture application. Mr. Bushardt seconded the motion, which carried unanimously.

C. Request Approval of Pharmacy Technician Registration Application – Annette Cantrell

On June 18, 2009 the Board received a pharmacy technician registration application from Annette Cantrell. Ms. Cantrell answered yes to the question asking, 'Have you ever been convicted of any criminal or civil charges (other than a minor traffic ticket)? Is there any legal action pending against you or are you currently on probation for any charges or legal action?' Ms. Cantrell was involved in a vehicle accident in 1993 when a vehicle failed to yield right of way. A passenger of the other vehicle was intoxicated and not wearing a seat belt and fell from the vehicle. Since the passenger was not the driver the evidence of intoxication was inadmissible and Ms. Cantrell was offered a plea bargain of involuntary manslaughter. She did not take the offer and went through two trials. Following the second trial in June 1995 she was convicted of reckless homicide. She was sentenced as a youthful offender to 90 days in the Shock Boot Camp.

Ms. Cantrell appeared before the Board at this time. Ms. Cantrell stated she was involved in a vehicle accident in 1993 in which an individual was killed. She was convicted of a felony during a second trial. She noted the first trial ended in a mistrial.

MOTION

Mr. Banks made a motion the Board accept Annette Cantrell's pharmacy technician registration application. Mr. Rose seconded the motion, which carried unanimously.

D. Request Approval of Pharmacy Technician Registration Application – Nicole Roach

On October 21, 2009 the Board received a pharmacy technician registration application from Nicole Roach. Ms. Roach answered yes to the question asking, 'Have you ever been convicted of any criminal or civil charges (other than a minor traffic ticket)? Is there any legal action pending against you or are you currently on probation for any charges or legal action?' In 2001 Ms. Roach was convicted of third degree burglary. She did not commit the crime, although she took the blame for a boyfriend at the time. She now regrets the decision and blames the decision on youthful foolishness.

Nicole Roach appeared before the Board. Ms. Roach stated she was convicted a third degree burglary when she was 17 years old. She has not been in trouble since that time. She is now a stay at home mother. She went on to say the boyfriend was 10 years older than her. She was actually at home at the time of the crime, which happened at 2:00 a.m.

MOTION

Mr. Mobley made a motion the Board approve Nichole Roach's pharmacy technician application. Mr. Banks seconded the motion, which carried unanimously

E. Immunization and Out-patient Formulary – Hugh Mobley, R.Ph.

Mr. Mobley stated he received an email from Kelly Crowley in reference to immunizations and outpatient formulary. He read Ms. Crowley's e-mail:

'I submitted a request to the Board of Pharmacy a couple of months ago requesting permission to have a formulary within our retail/outpatient pharmacies on the MUSC campus that would work as our inpatient formulary does, i.e., P & T committee review and approval of what drug could have automatic substitution. I have not heard back from the Board and wondered of the status of my request. I am attaching the letter for reference.

Also, I would like to implement pharmacist vaccine administration at our outpatient pharmacies on campus. We have researched the materials needed according to the CDC website and would like to put together our own training program and competency guidelines. We have sent four pharmacists to the APhA training program but it is rather expensive and the only official

program I can find. I would like to train another seven pharmacists to make our program successful. We would NOT be conducting a walk in clinic as we are a closed network for our PHS pricing. We would only administer upon receipt of a prescription from one of our (MUSC) physicians. Is there a way for us to have the four that attended the APhA program train the others and use information from the CDC site?

At one time I was given the direction to gather data and put together a program and then was told that the Board can't approve such programs.

The ACPE will only do continuing education programs, not certification programs. I am attaching the training materials we put together. I would appreciate any guidance you could give.'

Mr. Mobley stated there are two issues: 1) internal training of pharmacists outside of the APhA training and 2) whether or not they could have therapeutic substitution within the retail pharmacy.

Mr. Mobley is unaware, outpatient wise, of any existing situation where the Board has allowed therapeutic substitution. Mr. Rose stated the FDA prohibits therapeutic substitution nationally in regard to outpatient facilities.

Mr. Mobley stated Policy & Procedure #0138 discusses pharmacist administration of immunizations. The policy and procedure states the pharmacists must attend a CDC approved training program.

Mr. Mobley stated it would probably be inappropriate for the Board to approve this request during this meeting based on the environment.

F. Electronic Mailbag – Bobby Bradham, R.Ph.

Mr. Bradham stated the Board previously voted to accept the ICPT ExCPT examination in addition to the PTCB examination. The members received a letter from NABP dated October 30, 2009 regarding the ICPT ownership change. The letter states owners of the examination and program have been sold and that NABP have contacted the new owners asking if they were going to continue with the same program and keep it up to date. The letter also reiterates the new owners have not responded to NABP as to whether or not it will keep the program up to date which places the program in jeopardy through the NABP. He believes NABP had not given its blessing to the program and believes it may be in order, since the new owners do not see the importance of keeping the program up to date for the Board to review this issue and remove the examination from the Board's approved examinations until such time the new owners respond to the Board's parent organization's request.

MOTION

Mr. Bradham made a motion effective January 1, 2010 the Board remove the ICPT exam from the approved list until such time as they adequately address the concerns of NABP. Mr. Rose seconded the motion. Mr. Bradham stated he had noted concerns that the program was not psychometrically equivalent with PTCB and never provided data that the program was equivalent. He further stated PTCB now offers the exam 365 days a year, like the NAPLEX. Mr. Rose questioned Mrs. Bundrick if the PTCB exam has been approved by NABP. Mrs. Bundrick replied affirmatively. She further stated ICPT will not go through the blueprint for the psychometrically sound accreditation. Mr. Banks asked if candidates who had previously scheduled their exams with a test date after January 1, 2010 would be acceptable.

The motion carried unanimously.

The Board asked that an article regarding this decision be placed in the Association's *Small Doses*.

G. Request Approval of Non-Resident Wholesale/Distributor/Manufacturer - Xttrium Laboratories, Inc. – Mike Lippner, VP of Finance

On August 5, 2009 the Board received a non-resident wholesale/distributor and/or manufacturer application from Xttrium Laboratories, Inc. The application reflects yes answers to the questions asking, 'To the best of your knowledge, has the applicant(s) ever had a permit disciplined, denied, refused, or revoked for violations of any pharmacy laws, drug laws in South Carolina or any other state?' and 'Have you ever had an application for a drug distributor permit, pharmacy or pharmacist license, permit or certificate or a technician license or registration denied, refused or revoked in South Carolina or any other state or country?' During an inspection of the facility by the Missouri Department of Health and Human Services, Public Health Service, Food and Drug Inspection in 2004 several observations were noted in regard to the facility. The company entered into a Settlement Agreement with the Illinois Board of Pharmacy.

Mike Lippner appeared before the Board at this time. Mr. Lippner stated the Missouri Board of Pharmacy disciplined the company for late renewal. He further stated the Missouri Board of Pharmacy asked the company for a copy of the inspection reports. He noted the Illinois Board of Pharmacy does not conduct inspections so the company, in an attempt to comply with Missouri's request, submitted a 483 letter from the FDA the company had received at that time. The company was placed on probation in 2007, which expires in July 2010.

The company's primary business is the manufacture of hand soap for surgical settings. Per an oral agreement the company has manufactured oral rinse products for retailers for the past five years.

MOTION

Mr. Banks made a motion the Board approve Xttrium Laboratories' non-resident wholesale/distributor/manufacturer application. Mr. Rose seconded the motion, which carried unanimously.

D. Request Approval of Intern Hours – Nessa Petrie

In a letter to the Board dated November 12, 2009 Nessa Petrie states she has passed the NAPLEX AND MPJE exams and has been waiting to be licensed by LLR. The letter states there seems to be a problem with the validity of her intern hours. Ms. Petrie's letters explains the problems she has encountered while attempting to become licensed as a pharmacist.

Nessa Petrie appeared before the Board at this time. She explained what all she had done to become licensed. During her explanation she stated she had mailed documentation by certified letter, however, she did not request return receipt.

Staff researched the license database and discovered a \$100 fee was sent in on October 1, 2009 and deposited on October 5, 2009. Mrs. Bundrick stated a \$50 fee was mailed in on December 11, 2008 and deposited on December 15, 2008.

MOTION

Mr. Banks stated in light of some of the strong concerns the Board has had with the current system of keeping up with intern certificates, getting the certificates out to interns in a timely manner and record keeping, he moved the Board grant Nessa Petrie a license. Dr. Richardson seconded the motion, which carried unanimously.

E. Request Approval of Pharmacy Technician Registration Application – Katia Frazier

On August 6, 2009 the Board received a pharmacy technician registration application from Katia Frazier. Ms. Frazier answered yes to the question asking, 'Have you ever been convicted of any criminal or civil charges (other than a minor traffic ticket)? Is there any legal action pending against you or are you currently on probation for any charges or legal action?' Ms. Frazier's criminal history report reflects she was arrested and convicted of breach of trust in 2008.

Katia Frazier appeared before the Board at this time. Ms. Frazier had entered into a rental agreement on a rental car. Her ex-boyfriend does not have a driver's license and was driving the car when it had to be towed. She was charged with breach of trust since the ex-boyfriend's name was not on the rental agreement. She is currently employed as a cashier with Walgreen's.

MOTION

Mr. Banks made a motion the Board approve Katia Frazier's pharmacy technician registration application. Mr. Rose seconded the motion, which carried unanimously.

12. Committees

A. Pharmacy Technician – David Banks, R.Ph., Al Toole, R.Ph., Dan Bushardt, R.Ph.

This committee had no report.

B. Compounding – Hugh Mobley, R.Ph., Bobby Bradham, R.Ph., Addison Livingston, R.Ph.

The committee has not met since the last Board meeting.

Mr. Rose stated it has come to his attention a lot of pharmacists are compounding powders without a powder hood. He asked if there is a way the inspector could do something so those individuals could not compound without a hood. Mr. Mobley stated the committee had discussed in one of the meetings that inspectors make a presentation and that did come up. He noted the committee did discuss the matter as a possible hazard. He went on to say the Board probably needs to take a position and send it out in the newsletter. He said according to <795> USP is expecting containment. He will discuss this matter during the next committee meeting.

C. Legislative – Al Toole, R.Ph., Bobby Bradham, R.Ph., Dr. Richardson, Hugh Mobley, R.Ph.

Mr. Toole stated the Legislative Committee has not met since the last meeting, but he hopes to have a meeting in December.

Mr. Cinqueonce stated not much is happening legislatively. He further stated there are two primary pieces of legislation, the PBM transparency and pharmacists administering immunizations are both still before the legislature. He hopes the bill regarding pharmacists administering immunizations will advance. He has been meeting with legislators attempting to get support; however, he feels it will be difficult. He hopes the PBM language which is before the US Congress will assist in obtaining support from state legislators. He went on to say there is a host of other matters to contend with such as the pharmacy technician education, and AWP rollback

Mrs. Bundrick stated she emailed the members a bill, H-4216, which was introduced on November 17, 2009. She also presented the members with a copy of the bill during the meeting. She noted this bill deals with a provisional law that would allow a properly trained

community residential care facility staff member to administer medication injections for diabetes, osteoporosis, and conditions associated with anaphylactic reactions.

MOTION

Mr. Rose made a motion the Board oppose bill H-4216. Mr. Mobley seconded the motion, which carried unanimously.

- D. Nuclear Pharmacy – Dock H. Rose, R.Ph., Bobby Bradham, R.Ph. Hugh Mobley, R.Ph.

This committee had no report.

- E. Pharmacy Practice – Dock H. Rose, R.Ph., David Banks, R.Ph., Hugh Mobley, R.Ph.

This committee had no report.

- F. Pharmacy Technology – Bobby Bradham, R.Ph., Dan Bushardt, R.Ph., David Banks, R.Ph.

The Committee met on November 12, 2009 and developed proposed Policy and Procedure #147. The committee is bringing the proposed policy to the Board for discussion and a vote.

Remote Medication Order Processing

(1) Definitions,

(a) "Remote Medication Order Processing" includes any of the following activities performed from a remote location:

1. Receiving, interpreting, or clarifying medication orders.
2. Entering or transferring medication order data.
3. Performing prospective drug use review.
4. Obtaining substitution authorizations.
5. Interpreting and acting on clinical data.
6. Performing therapeutic interventions.
7. Providing drug information
8. Authorizing the release of a medication for administration.

(2) General Requirements.

(a) An entity may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

1. The pharmacist may be employed or contracted by the entity.
 - a. The pharmacist must be a SC licensed pharmacist.
 - b. The entity must have a written agreement or contract with the pharmacist. The written agreement or contract shall:
 1. Outline the services to be provided.
 2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements.
 3. Require that the parties adopt a policies and procedures manual.
 4. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has

sufficient patient information necessary for prospective drug use review and approval of medication orders.

2. The pharmacist may be employed by a contractor of the entity to provide remote medication order processing in South Carolina
 - a. The pharmacist must be a SC licensed pharmacist.
 - b. The entity must have a written agreement or contract with the pharmacist. The written agreement or contract shall:
 1. Outline the services to be provided.
 2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements.
 3. Require that the parties adopt a policies and procedures manual.
 4. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

3. The pharmacist may be employed by a contractor of the entity to provide remote medication order processing outside of South Carolina.
 - a. The entity must have a written agreement of contract with the contractor employing the pharmacist. The written agreement or contract shall:
 1. Require the contractor to have a South Carolina pharmacy permit.
 2. Require the Pharmacist-in-Charge of the contractor to be a South Carolina licensed pharmacist.
 3. Outline the services to be provided.
 4. Delineate the responsibilities of each party including compliance with federal and state law and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements.
 5. Require that the parties adopt a policies and procedures manual.
 6. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

 - b. The entity must have a South Carolina pharmacy permit.

(3) Policy and Procedures. A policy and procedure manual shall:

- (a) Be accessible to each party involved in remote medication order processing.
- (b) Be available for inspection by the Board or an authorized agent of the Department.
- (c) Outline the responsibilities of each party involved in remote medication order processing.
- (d) If the pharmacist is not employed by the entity, then include a current list of the name, address, telephone number, and license number of each pharmacist involved in remote medication order processing.
- (e) Include policies and procedures for:

1. Protecting the confidentiality and integrity of patient information by accessing secure networks.
2. Ensuring that a pharmacist performing prospective drug use review has access to appropriate drug information resources.
3. Ensuring that medical and nursing staff understand how to contact a pharmacist.
4. Maintaining records to identify the name, initials, or identification code of each person who performs a processing function for a medication order.
5. Complying with federal and state laws and regulations.
6. Operating or participating in a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
7. Reviewing the written policies and procedures and documenting the review every year.

(4) Records.

- (a) The entity involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name.
- (b) The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a processing function for a medication order.
- (c) The record shall be readily retrievable for at least the past two (2) years.
- (d) The record shall be available for inspection by the Board or an authorized agent of the Department.

Mr. Bradham stated point #1 discusses pharmacists who may be employed or contracted by the entity, point #2 discusses the pharmacists who may be employed by a contractor of the entity to provide remote medication order processing in South Carolina and point #3 discusses pharmacists who may be employed by a contractor of the entity to provide remote medication order processing outside of South Carolina. It's similar to a Florida document. The committee moved the Board adopt the proposed policy. Since the motion came from committee no second was needed.

Mr. Bradham addressed the letter from the SC Hospital Association regarding the Board developing policies and procedures, in particular Policy and Procedure #137, which discusses sterile product compounding facilities. He further stated the issue the Board has going the regulatory route in dealing with technology. If the Board goes the regulatory route in his 35 years of dealing with pharmacy legislation, with as much research as what has been done on the proposed Policy and Procedure #147, decided to go through the regulatory route the Board rather than as a proposed policy, the Board would do well in getting it passed the next three years. By then a lot of the technology involved in remote order processing will have been refined, changed, and hopefully improved. The Board would not be able to do a lot of what the Board is able to do if the Board attempts to go through the regulatory route. He would like to do away with the policies and procedures and go through the regulatory process, however, Ms. Dantzler has mentioned on several occasions, of the 50 states South Carolina probably has one of the most cumbersome routes as far as being able to enact legislation by regulation. There are good reasons for that and bad reasons as well. He noted regulations must be tied back to a section of the statute.

The motion carried unanimously.

G. Recovering Professional Program – Dr. Richardson

This committee had no report

H. Medication Integrity Committee – Dan Bushardt, R.Ph., Al Toole, R.Ph., Addison Livingston, R.Ph.

This committee had no report.

13. Discussion Topics

A. List of Requirements for Intern Information Packets – Dan Bushardt, R.Ph.

Mr. Bushardt stated he just wanted to ensure a list of requirements is mailed with the intern certificates.

Mrs. Crouch provided the members with information mailed to the pharmacy interns from the Office of Licensure and Compliance.

MOTION

Mr. Bushardt made a motion to send the required information in the pharmacy intern packets when mailed to the interns. Mr. Banks seconded the motion, which carried unanimously.

14. Public Comments

Mr. Banks stated he visited the Presbyterian College School of Pharmacy campus, which is going through the accreditation process. He further stated he guessed the Board member was there to see how thorough the accreditation process is. He commended the college for their hard work, time and effort in being prepared for the process.

15. Adjournment

MOTION

There being no further business to be brought before the Board at this time, Mr. Rose made a motion the meeting be adjourned. Mr. Bushardt seconded the motion, which carried unanimously.

The November 18, 2009 meeting of the SC Board of Pharmacy adjourned at 3:47 p.m.