COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor (804) 367-4456 (Tel)
Richmond, Virginia 23230 (804) 527-4472(Fax)

Tentative Agenda of Meeting

June 10, 2009

9:00AM

TOPIC	PAGE(S)
Call to Order: David C. Kozera, Chairman	
• Welcome and Introductions	
• Reading of emergency evacuation script	
• Approval of Agenda	
• Approval of previous Board meeting minutes: • March 11, 2009 Board meeting, general business • March 11, 2009 Formal hearings, panel • March 19, 2009 Telephone Conference Call • March 26, 2009 Telephone Conference Call • March 31, 2009 Special Conference Committee • May 8, 2009 Telephone Conference Call • May 12, 2009 Board meeting, summary suspension • May 12, 2009 Formal hearings, panel	1-26 **(attachments to 3/11 minutes available on the Board's web site)**
Public Hearing: Proposed regulations on changing expiration dates	27-32
Call for public comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.	
DHP Report: Sandra Whitley Ryals, Director	
Election of Chairman and Vice Chairman 7/1/2009-6/30/2010	
Legislation: Scotti Russell	
• Approve scheduling bill for 2010	33-42
• Review legislative proposal by Office of Community Integration for People with Disabilities-no action needed	43-46
Regulations: Scotti Russell	
• Update on regulation processes	47
• Adopt proposed regulations on drug donation programs	48-57
• Petition for Rulemaking	58-70
Update on Action Items: Scotti Russell	

• Medical Equipment Suppliers written vs. verbal order update	
Miscellaneous:	
• Review request for ADA accommodations	Separate handout
• Delegate approval of certain ADA accommodations to staff	71-74
• Review Revenue and expenditure analysis	75
Reports:	
• Report on Board of Health Professions-Jennifer H. Edwards	
Consideration of consent orders (if any)	
Adjourn	

***The Board will have a working lunch at approximately 12 noon.**

****A panel of the Board will convene to hold formal hearings after the adjournment of the Board meeting.**

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 11, 2009
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15AM.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
John O. Beckner
Willie Brown
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

MEMBERS ABSENT: Gerard Dabney

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Sandra Whitley Ryals, Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant

QUORUM: With 9 members present, a quorum was established.

APPROVAL OF AGENDA: The amended agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for December 10, 2008; December 17, 2008; January 7, 2009; January 13, 2009;, and February 17, 2009. With no changes to the minutes, the minutes were approved as presented.

DHP DIRECTOR'S REPORT Ms. Ryals provided an update on the performance measures for DHP and specifically the Board of Pharmacy as measured for the second quarter of FY2009, October 1, 2009 through December 31, 2008. She reviewed with the Board the data in the agenda package showing 80% clearance rate of cases closed over cases received (goal at or over 100%); 10% cases open that are over 250 business days (goal at or under 25%); and 97% cases closed within 250 business days (goal at or over 90%). She also remarked that the licensing statistics for customer satisfaction were 96% and licenses

issued within 30 days were at 100%. She thanked the Board and staff for their efforts to streamline processes, move old cases and meet the agency's goals.

Ms. Reiniers-Day added the following information concerning the disciplinary caseload for the Board of Pharmacy:

The Board closed 120 cases since the last meeting on December 10, 2008 through March 9, 2009. Currently, there are 69 cases at the investigation level; 17 cases at the probable cause level; 9 cases with administrative proceedings; 7 cases scheduled for informal conferences; 2 cases scheduled for formal hearings and 14 cases in the pending closure stage.
Additionally, Ms. Reiniers-Day thanked Leo Ross and John Beckner for their coming in one afternoon for case presentation which assisted in the closure of 51 cases that particular week.

Ms. Ryals reported on the four agency bills passed in the 2009 session.

- HB1852 Confidentiality of investigations-clarifies requirements related to disclosure of investigative information by investigators to further the investigation.
- HB2405 Workforce Data-allows the Department to release certain information for the purpose of research related to determining workforce shortages.
- HB2211 Prescription Monitoring Program-removes the requirement for prescribers to obtain written signed consent to query the database and allows transfer of information to other state PMPs.
- HB2407 Health Practitioners Intervention Program-there were several changes to make the program strictly a monitoring program to conform to the mission of DHP. She stated that the Department has extended the agreement with VCU HealthSystems to continue administering the program with changes. Case managers are no longer attending informal conferences on a routine basis. Monitoring for certain categories of persons, including those with expired, revoked, suspended, or inactive licenses or those for whom Virginia is the secondary monitor, will no longer be covered by agency funding. The Board of Pharmacy may have approximately six persons currently covered by the program who are in those categories. These will all be reviewed on a case by case basis. There are about 150 persons total for the agency who may be affected.

PUBLIC COMMENTS: There were no public comments.

LEGISLATION UPDATE: Ms. Yeatts reviewed with the Board a summary of legislation passed that the agency was tracking for the 2009 session.

REGULATION UPDATE:

Ms. Yeatts reviewed the status of regulation processes in progress as provided in the summary in the agenda package.

ADOPTION OF FINAL REGULATIONS FROM PERIODIC REVIEW AND RESPONSE TO PUBLIC COMMENT

The Board reviewed all comments received during the public comment period, discussed the need for changes to the proposed regulations, and made the following changes to the proposed regulations.

Motion:

The Board voted unanimously to further change the proposed language in section 180 B, last sentence, related to security systems upgrades after a breaking with loss of drugs, by replacing the term "immediately" to "within 14 days". (motion by Yi, second by Brown)

Motion:

The Board voted unanimously to further clarify the new requirements for perpetual inventory by deleting the phrase "and drugs on hand" from the definition for "perpetual inventory" in section 10, and changing the term "every 30 days" in the first sentence of new language in section 240 A1, to "monthly" to be consistent with the second sentence in that same subsection. (motion by Abernathy, second by Beckner)

Motion:

The Board voted unanimously to further clarify section 270 E by changing the phrase "other means" in the first sentence to "by other means including by professional judgment". (motion by Beckner, second by Ross)

Motion:

The Board voted unanimously to amend section 110 E to conform this subsection to the proposed changes in 110 D by removing the phrase "and taking the required inventory". (motion by Beckner, second by Brown)

Motion:

The Board voted unanimously to further amend section 580 to provide for consistency with new provisions in law enacted by the 2009 General Assembly by removing language referring only to drugs for euthanasia, and merely cross-referencing the authority in § 54.1-3423 of the Code of Virginia, and clarifying that "animal shelters" are also included. (motion by Ison, second by Stredler)

Motion:

The Board voted unanimously to adopt the response to public comment as drafted by staff and amended by the Board (Attachment 1), and adopt as final regulations the proposed regulations as published and amended by the Board (Attachment 2). (Motion by Ross, second by Beckner.)

ADOPTION OF EXEMPT REGULATIONS RELATED TO ADDRESS OF RECORD

Ms. Yeatts explained that all Boards in the department were in the position of having to change regulations related to address of record as a result of SB 1282, which allows an individual licensee of the department to request that the address of record with the Boards not be public by providing another address for public disclosure.

Motion:

The Board voted unanimously to adopt the draft exempt regulations related to address of record as presented with the address of record section for pharmacist being removed from section 80 and placed into its own section (Attachment 3). (Motion by Abernathy, second by Ross)

ADOPTION OF NEW GUIDANCE DOCUMENT 110-41 RELATED TO CHANGES TO A SCHEDULE II PRESCRIPTION

Ms. Russell reviewed with the Board the DEA history of allowing a pharmacist to make certain changes to a Schedule II prescription after verbal consultation with the prescriber; DEA's recent publication in the Federal Register that rescinded the previous allowances; and DEA's current FAQ on its website that acknowledges the conflicting advice and allows pharmacists to follow state law or policy until such time as DEA can address the issue in regulation. Because Virginia does not have specific law or regulation relating to this issue, and because DEA's guidance allows for pharmacists to use state issued policy, Ms. Russell suggested that the Board adopt a guidance document establishing policy to provide some protection for pharmacists. The Board reviewed the draft guidance document in the agenda package that reiterates DEA's previous allowances.

Motion:

The Board voted unanimously to adopt Guidance Document 110-41 as presented. (Motion by Beckner, second by Ross)

ADOPTION OF NEW PROCEDURES FOR HANDLING CASES INVOLVING CE DEFICIENCIES

Ms. Russell explained to the Board that each year the Board has a number of cases involving CE deficiencies that tend to be less important than other disciplinary cases, and as such have not been treated as a priority. From random audits, auditing persons who had previously been granted an extension, and from those persons who renew their license, yet check "no" that they do not have their CE, the number of cases piles up and contributes to a backlog. Ms. Russell presented in the agenda package a sample one-page consent agreement that staff would like to begin using in order to expedite these cases. Persons who do not agree with the terms have the opportunity to request an informal conference. Persons who do agree will sign the form and return it with the specified monetary penalty and proof of late CE compliance. There was discussion that this is a departure from current handling of CE cases involving the issuance of a CCA for first time non-compliance. Ms. Russell stated that even with the CCA's, these

cases took up a lot of staff time including APD time that could be better spent on more complicated or serious cases. The new procedure would not require APD involvement. The new procedure also contemplates a standard deficiency for each year that there is CE missing, regardless of how many hours. Either a person meets CE requirements, or they do not. This approach will also save time in processing the documents related to these cases.

Ms. Russell asked that in addition to the use of the CE deficiency letter process, that the Board review and approve new Guidance Document 110-42 and amend Guidance Document 110-9 removing previous guidance on sanctions in CE cases. The new guidance document sets a standard penalty of $250 per year for a pharmacist who does not meet CE requirements and $50 a year for a pharmacy technician who does not meet CE requirements. Because the Board only audits two years at a time, the maximum penalty for a pharmacist would be $500 and the maximum for a pharmacy technician would be $100. There was discussion as to whether this was too high a penalty for pharmacy technicians, however, this is consistent with other standard sanctions for pharmacy technicians practicing without being registered or with an expired registration.

Ms. Russell also stated that staff would develop new internal processes for expediting the cases in which the person either does not respond at all or responds requesting an informal conference, by possibly scheduling all of these cases before an agency subordinate on one day. She also stated that the Department is developing standards for conducting the random audits, and that the sample size would be related to what constitutes a statistically valid sample rather than an arbitrary number, such as 2% which the Board has previously been using.

Motion:

The Board voted unanimously to adopt the new process using the letter for CE deficiency, the new Guidance Document 110-42, and the amendments to Guidance Document 110-9 as presented in the agenda package. (Motion by Beckner, second by Brown)

SMARTRX DISPOSAL LINK FOR WEBSITE

Ms. Russell stated that it is standard policy to allow links on the Board's website to other government agencies, or government issued documents, but not to non-government links unless specifically reviewed and approved. Because there is a great deal of interest by consumers related to safe disposal of unwanted medications, and because there are no approved take-back programs in Virginia currently, staff is requesting that a link be added to the website to an APhA-sponsored website that includes recommendations for consumer disposal. APhA developed the

recommendations in consultation with PhRMA and the U.S. Department of Fish and Wildlife Services. Additionally, there will be a link to the recommendations for disposal by the White House Office of National Drug Control Policy. Both recommendations are similar.

Motion:

The Board voted unanimously to approve the addition of the link to SmartRx Disposal on its webpage. (Motion by Abernathy, second by Ross)

ORAL ORDERS TO MEDICAL EQUIPMENT SUPPLIERS

Ms. Russell stated that the Board has received calls asking whether it is lawful for personnel for a medical equipment supplier (MES) to take oral orders. Ms. Russell stated that this is not specifically addressed in statute, but that there were certain provisions that may relate to this issue. Mr. Casway advised that the Board could interpret its own statutes, but could not grant the authority for accepting an oral order if it does not exist. Ms. Russell stated that while the accepting of an oral prescription is an act restricted to pharmacists, so is the certification of accuracy of the completed prescription. The permit for a medical equipment supplier is a specific "carve-out" of the practice of pharmacy in which the General Assembly has determined that it is safe for medical devices, oxygen, and dialysis solutions to be dispensed to consumers by persons holding a permit from the Board of Pharmacy, but with no requirement for there to be a pharmacist to perform the dispensing, or certify the accuracy prior to dispensing. The statute says the dispensing may be done by a MES pursuant to a "lawful order" of a practitioner, but that term is not defined. The term "prescription" may be written or oral. Ms. Abernathy expressed concern that there could be a negative impact on patient health if a MES were not able to at least initially dispense pursuant to an oral order, such as in the case of patients being discharged from a hospital, when written orders may not be received timely enough.

Action Item:

Ms. Russell stated that if the Board concurs, she will do more research prior to the June meeting as to what is required by a MES in order to receive reimbursement, and that staff will draft a guidance document if necessary to address this. The Board agreed by consensus to continue this until the June meeting. There was no action taken by the Board at this time.

REQUEST FROM HOME CHOICE PARTNERS FOR DELIVERY OF IDPN SOLUTIONS TO DIALYSIS CENTERS

The Board reviewed a request from Home Choice Partners, an infusion pharmacy, to be allowed to deliver parenteral nutrition solutions to patients directly to the dialysis centers where they will be infused via dialysis by nurses. Home Choice stated that many of these patients are not mobile and rely on assisted transportation to get to dialysis, and that transporting of these large, heavy

solutions is very difficult. In addition, the solutions are very fragile and subject to contamination and degradation if not stored in an appropriate environment and under required temperature controls. The dialysis centers will be set up with the appropriate equipment to properly store the solutions.

Motion:

The Board voted unanimously to approve the request by Home Choice Partners to allow delivery of the solutions directly to the dialysis centers provided the centers obtain a controlled substances registration for alternate delivery, and the registration shall be limited to alternate delivery of these IDPN solutions. (Motion by Yi, second by Ross)

RESPONSE TO DEA ADVANCED NOTICE OF PROPOSED RULEMAKING FOR DISPOSAL OF CONTROLLED SUBSTANCES BY CONSUMERS AND LONG TERM CARE FACILITIES

Ms. Russell discussed with the Board the request for comment from DEA related to its notice of proposed rulemaking related to drug disposal programs for consumers. Ms. Russell provided a draft response in the agenda package for the Board to consider. The draft included factual responses to specific questions from DEA to regulatory authorities. Ms. Russell also suggested that the Board may want to comment that consumers should be allowed to return unwanted controlled substances to pharmacies or send them to returns distributors under controlled conditions as specified by DEA for reverse distributors, or Board regulation for pharmacies.

Ms. Russell also provided the Board in the agenda package with language in the 2009 budget bill that requires the Board of Pharmacy, in consultation with state police, to report in November 2009 to the money committees of the General Assembly with a recommendation for a statewide drug disposal program and any potential sources of revenue to fund such a program. Ms. Russell stated that recommendations for a program had already been provided in 2008, but that changes may need to be made if DEA initiates rulemaking to remove the requirement for law enforcement involvement which significantly increases costs of a program. Additionally, she provided a copy of a bill introduced in the U.S. House of Representatives to allow state "take-back" programs without the requirement for law enforcement involvement, which, if passed, would also necessitate the need for changes to the previous recommendation.

Motion:

The Board voted unanimously to send the response to DEA as included in the agenda package. (Motion by Beckner, second by Yi)

BOARD OF HEALTH PROFESSIONS

Ms. Edwards reported that the Board of Health Professions met once since the last Board meeting. She stated that the Board was studying emerging professions, specifically at this time, the need to

regulate surgical technologists and assistants. She also announced that she had been appointed to the regulatory research committee.

ADJOURN: With all business concluded, the meeting adjourned at 12:30 p.m.

Elizabeth Scott Russell
Executive Director

David C. Kozera, Board Chairman

Date

DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Wednesday, March 11, 2009
Second Floor
Board Room 4

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 1:10 p.m.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT:
Gill Abernathy
John O. Beckner
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Brandon K. Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General

QUORUM: With seven members of the Board present, a quorum to constitute a panel was established.

BRIDGETT S. BASSETT
Registration # 0230-011357

A formal hearing was held in the matter of Bridgett Bassett following the summary suspension of her pharmacy technician registration on September 22, 2008, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Wayne Halblieb, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Mr. Kozera and Mr. Ross informed Ms. Bassett that they are employed with CVS/pharmacy. However, they both stated that they never worked with or supervised Ms. Bassett and would be able to make a fair and impartial decision in this matter. There were no objections from Ms. Bassett or the remaining board members.

Douglas Rogers, CVS Regional Loss Prevention Supervisor, testified by telephone on behalf of the Commonwealth, and Scott Arnott, DHP Pharmacy Inspector, appeared and testified on behalf of the Commonwealth.

Ms. Bassett testified on her own behalf.

Closed Meeting:

Upon a motion by Mr. Beckner and duly seconded by Mr. Ross, the Panel voted 7-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(27) of the Code of Virginia for the purpose to reach a decision in the matter of Bridgett S. Bassett. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Panel re-convened in open meeting.

Decision:

Upon a motion by Mr. Yi and duly seconded by Mr. Beckner the Panel voted 7-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halblieb and amended by the Panel and read by Mr. Casway.

Upon a motion by Mr. Yi and duly seconded by Mr. Ross the Panel voted 7-0, that Ms. Bassett's registration be continued on suspension and that she may petition for the reinstatement of her registration upon successful completion of the Rappahannock Area Regional Drug Treatment Court Program.

DEDRA R. MICHAELIS
Registration # 0230-004646

A formal hearing was held in the matter of Dedra R. Michaelis following the summary suspension of her pharmacy technician registration on February 19, 2009, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Michaelis was not present at the hearing. The Panel proceeded in Ms. Michaelis' absence as the Notice of Formal Hearing dated February 19, 2009, was mailed to Ms. Michaelis' legal address of record, both regular and certified mail. Mr. Kozera ruled that adequate notice was provided to Ms. Michaelis and the hearing proceeded in her absence.

William Clay Garrett, Assistant Attorney General, prosecuted the case with the assistance of Mr. Egan.

DECISION: Upon a motion by Mr. Yi and duly seconded by Mr. Beckner the Panel voted 7-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett. Further, he moved that Ms. Michaelis' right to renew her registration be revoked.

ADJOURN: With all business concluded, the meeting adjourned at 4:05 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chairman

Date

DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, March 19, 2009

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

Orders/Consent Orders referred to in these minutes are available upon request

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy was held at 8:35 a.m., on March 19, 2009, to consider the summary suspension of the registrations of Cateama R. Jean-Baptiste and Tara Davis, to practice as pharmacy technicians in the Commonwealth of Virginia .

PRESIDING: Michael E. Stredler, Vice Chairman

MEMBERS PRESENT:
Gill Abernathy
John Beckner
Willie Brown
Bobby Ison
Brandon Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
William Clay Garrett, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension case. The Board members stated that they would not have been able to attend.

With six members participating and four members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider these matters.

CATEAMA R. JEAN-BAPTISTE
Registration Number 0230-008323

Mr. Garrett presented a summary of the evidence in this case.

Decision: Upon a motion by Mr. Beckner, and duly seconded by Mr. Brown, the Board unanimously voted that with the evidence presented, the practice as a pharmacy technician by Cateama R. Jean-Baptiste poses a substantial danger to the public; and therefore, that the registration of Cateama R. Jean-Baptiste to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Jean-Baptiste for the revocation of her registration in lieu of a hearing.

TARA DAVIS
Registration Number 0230-012876

Mr. Garrett presented a summary of the evidence in this case.

Decision: Upon a motion by Mr. Yi, and duly seconded by Mr. Beckner the Board unanimously voted that with the evidence presented, the practice as a pharmacy technician by Tara Davis poses a substantial danger to the public; and therefore, that the registration of Tara Davis to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Davis for the revocation of her registration in lieu of a hearing.

ADJOURN: With all business concluded, the conference call adjourned at 8:48a.m.

Elizabeth M. Revere
Disciplinary Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Michael E. Stredler, Vice Chairman

Date

DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, March 26, 2009

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

Orders/Consent Orders referred to in these minutes are available upon request

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy was held at 8:40 a.m., on March 26, 2009, to consider the summary suspension of the license of A. Carl Leuckert, III, to practice as a pharmacist in the Commonwealth of Virginia.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
John O. Beckner
Willie Brown
Leo H. Ross
Brandon K. Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
Wayne Halbleib, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension case. The Board members stated that they would not have been able to attend.

With six members participating and four members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider these matters.

A. CARL LUECKERT, III
License Number 0202-004705

Mr. Halbleib presented a summary of the evidence in this case.

Decision: Upon a motion by Mr. Yi, and duly seconded by Mr. Brown, the Board unanimously voted that with the evidence presented, the practice as a pharmacist by A. Carl Lueckert, III, poses a substantial danger to the public; and therefore, that the license of A. Carl Lueckert, III, to practice as a pharmacist be summarily suspended; and that a Consent Order be offered to Mr. Lueckert for the indefinite suspension of his license in lieu of a hearing.

ADJOURN: With all business concluded, the conference call adjourned at 9:00 a.m.

Elizabeth M. Revere
Disciplinary Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chairman

Date

DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, March 31, 2009
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 10:00 a.m.

PRESIDING: David C. Kozera, Committee Chairman

MEMBERS PRESENT: Brandon K. Yi

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist

RICHARD B. RICE, JR.
License Number 0202-011551

Richard B. Rice, Jr., appeared with Murray J. Janus, his attorney, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the January 17, 2009, Notice.

William Clay Garrett, Assistant Attorney General, was present for this hearing.

Closed Meeting: Upon a motion by Mr. Yi and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A.(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Richard B. Rice, Jr. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting.

Decision: Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reprimand Mr. Rice and impose a monetary penalty of

One Thousand Dollars ($1,000) and subject his license to certain terms and conditions.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Rice, unless a written request to the Board for a formal hearing on the allegations made against her is received from Mr. Rice within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

MARVIN W. SANDERS
License Number 0202-001364

Marvin W. Sanders appeared with Denise Sanders, his wife, to discuss his petition for reinstatement of his pharmacist license and to review allegations that he may have violated portions of the Board's laws and regulations as stated in the February 24, 2009, Notice.

Closed Meeting:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code, for the purpose of deliberation to reach a decision in the matter of Marvin W. Sanders. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to approve Mr. Sanders' application for reinstatement of his pharmacist license with terms and conditions.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Sanders, unless a written request to the Board for a formal hearing on the allegations made against him is received from Mr. Sanders within such time. If service of the Order is made by mail, three (3) additional days shall

be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN: With all business concluded, the meeting adjourned at 7:35 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chairman

Date

DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Friday, May 8, 2009

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

Orders/Consent Orders referred to in these minutes are available upon request

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy was held at 8:30 a.m., on May 8, 2009, to consider the summary suspension of the registration of Brandi S. Meador to practice as a pharmacy technician in the Commonwealth of Virginia .

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT:
Gill Abernathy
John Beckner
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Michael E. Stredler
Brandon Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
William Clay Garrett, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension case. The Board members stated that they would not have been able to attend.

With eight members participating and two members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider these matters.

BRANDI S. MEADOR
Registration Number 0230-011641

Mr. Garrett presented a summary of the evidence in this case.

Decision:

Upon a motion by Mr. Yi, and duly seconded by Mr. Beckner, the Board unanimously voted that with the evidence presented, the practice as a pharmacy technician by Brandi S. Meador poses a substantial danger to the public; and therefore, that the registration of Brandi S. Meador to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Meador for the indefinite suspension of her registration in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 8:43a.m.

Elizabeth M. Revere
Disciplinary Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chairman

Date

DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF THE BOARD OF PHARMACY

Tuesday, May 12, 2009
Second Floor
Training Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER:	A meeting of the Board of Pharmacy ("Board") was called to order at 10:15 a.m.
PRESIDING:	David C. Kozera, Chairman
MEMBERS PRESENT:	John O. Beckner Jennifer H. Edwards Bobby Ison Leo H. Ross Brandon K. Yi
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Elizabeth M. Revere, Disciplinary Program Specialist Howard Casway, Senior Assistant Attorney General
QUORUM:	With six members of the Board present, a quorum was established.
Closed Meeting:	Upon a motion by Mr. Ison and duly seconded by Mr. Beckner, the Board unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Cathy Reiniers-Day, Howard Casway, and Elizabeth Revere attend the closed meeting.
DENNIS W. EPPERSON Registration #0230-006809	William Clay Garrett, Assistant Attorney General, presented a summary of the evidence in this case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened in open meeting.

Decision: Upon a motion by Mr. Yi, and duly seconded by Mr. Ross, the Board unanimously voted that with the evidence presented, the practice as a pharmacy technician by Dennis W. Epperson poses a substantial danger to the public; and therefore, that the registration of Dennis W. Epperson to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Mr. Epperson for the indefinite suspension of his registration in lieu of a hearing.

ADJOURN: With all business concluded, the meeting adjourned at 10:30 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chairman

Date

DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD OF PHARMACY

Tuesday, May 12, 2009
Second Floor
Training Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of the Board of Pharmacy ("Board") was called to order at 10:35 a.m.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT:
John O. Beckner
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Brandon K. Yi

STAFF PRESENT:
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General

QUORUM: With six members of the Board present a panel was established.

Mr. Kozera was recused from the following hearing therefore, Mr. Beckner proceeded as the Acting Chairman.

CATEAMA R. JEAN-BAPTISTE
Registration # 0230-008323

A formal hearing was held in the matter of Cateama R. Jean-Baptiste following the summary suspension of her pharmacy technician registration on March 31, 2009, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Jean-Baptiste was not present at the hearing. The Panel proceeded in Ms. Jean-Baptiste's absence as the Notice of Formal Hearing dated March 31, 2009, was mailed to Ms. Jean-Baptiste's legal address of record, both regular and certified mail. Mr. Beckner ruled that adequate notice was provided to Ms. Jean-Baptiste and the hearing proceeded in her absence.

Mr. Garrett, Assistant Attorney General, prosecuted the case with the assistance of Mr. Egan, DHP Adjudication Specialist.

John Struder, CVS Regional Loss Prevention Supervisor, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Ison and duly seconded by Mr. Ross, the Panel voted 5-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose to reach a decision in the matter of Cateama R. Jean-Baptiste. Additionally, he moved that Cathy Reiniers-Day and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Panel re-convened in open meeting.

Decision:

Upon a motion by Mr. Yi and duly seconded by Mr. Ross, the Panel voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett and amended by the Panel and read by Mr. Casway.

Upon a motion by Mr. Yi and duly seconded by Mr. Ross, the Panel voted 5-0 that Ms. Jean-Baptiste's registration be revoked.

PRESIDING:

David C. Kozera, Chairman

Mr. Ross was recused from the following hearing.

TARA Y. DAVIS
Registration # 0230-012876

A formal hearing was held in the matter of Tara Y. Davis following the summary suspension of her pharmacy technician registration on March 31, 2009, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Davis was not present at the hearing. The Panel proceeded in Ms. Davis' absence as the Notice of Formal Hearing dated March 31, 2009, was mailed to Ms. Davis' legal address of record, both regular and certified mail. Mr. Kozera ruled that adequate notice was provided to Ms. Davis and the hearing proceeded in her absence.

Mr. Garrett, prosecuted the case with the assistance of Mr. Egan.

John Struder, CVS Regional Loss Prevention Supervisor, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Ison and duly seconded by Mr. Beckner, the Panel voted 5-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose to reach a decision in the matter of Tara Y. Davis. Additionally, he moved that Cathy Reiniers-Day and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Panel re-convened in open meeting.

Decision:

Upon a motion by Mr. Yi and duly seconded by Ms. Edwards, the Panel voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett. Further, Mr. Yi moved that Ms. Davis' pharmacy technician registration be revoked.

Ms. Edwards departed at 11:45 a.m.

A. CARL LUECKERT, III
License #0202-005105

A formal hearing was held in the matter of A. Carl Lueckert, III, following the summary suspension of his pharmacist license on April 3, 2009, and to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Elizabeth Scott Russell, Executive Director, was present for this hearing.

Mr. Ison stated that he knew of Mr. Lueckert and that he would be able to make a fair and impartial decision in this matter. There were no objections from Mr. Lueckert or the remaining board members.

Wayne T. Halbleib, Assistant Attorney General, prosecuted the case with the assistance of Mr. Egan.

Richard Waddell, Walgreens Loss Prevention Supervisor; Gerald J. (MJ) Ibraham, Walgreens Pharmacy Manager; and Nan Dunaway, DHP Pharmacy Inspector, testified on behalf

of the Commonwealth.

Mr. Lueckert testified on his own behalf.

Closed Meeting: Upon a motion by Mr. Ison and duly seconded by Mr. Ross, the Panel voted 5-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose to reach a decision in the matter of A. Carl Lueckert, III. Additionally, he moved that Elizabeth Scott Russell, Cathy Reiniers-Day and Howard Casway attend the closed meeting.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Panel re-convened in open meeting.

Decision: Upon a motion by Mr. Yi and duly seconded by Mr. Ross, the Panel voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib and amended by the Panel. Further, Mr. Yi moved to revoke Mr. Lueckert's' pharmacist license.

ADJOURN: With all business concluded, the meeting adjourned at 2:30 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chairman

John O. Beckner, Acting Chairman

Date

Agenda Item: **Regulatory Item – Public Hearing**

Change in certain renewal dates

Staff Note: Included in your package is a copy of the proposed regulations which replace emergency regulations currently in effect

Action:

None required – regulations provided for public hearing

Project 1311 - Proposed

BOARD OF PHARMACY

Changes in renewal dates for pharmacies and permitted facilities

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Nonresident pharmacy	$270
9. Controlled substances registrations ~~(Between November 2, 2005, and December 31, 2006, the application fee for a controlled substance registration shall be $50)~~	$90
10. Robotic pharmacy system approval	$150
11. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	$250
12. Approval of a pharmacy technician training program	$150
13. Approval of a continuing education program	$100

D. Annual renewal fees.

1. Pharmacist active license – due December 31	$90
2. Pharmacist inactive license – due December 31	$45
3. Pharmacy technician registration – due December 31	$25
4. Pharmacy permit – due April 30	$270
5. Physician permit to practice pharmacy – due February 28	$270
6. Medical equipment supplier permit – due February 28	$180
7. Humane society permit – due February 28	$20
8. Nonresident pharmacy – due April 30	$270

9. Controlled substances registrations – due February 28 $90

10. Innovative program continued approval based on board order not to exceed $200 per approval period.

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy permit	$90
5. Physician permit to practice pharmacy	$90
6. Medical equipment supplier permit	$60
7. Humane society permit	$5
8. Nonresident pharmacy	$90
9. Controlled substances registrations	$30

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125

5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Nonresident pharmacy	$115
f. Controlled substances registration	$180

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35

~~I. For the annual renewal due on or before December 31, 2006, the following fees shall be imposed for a license, permit or registration:~~

~~1. Pharmacist active license~~	~~$50~~
~~2. Pharmacist inactive license~~	~~$25~~
~~3. Pharmacy technician registration~~	~~$15~~
~~4. Pharmacy permit~~	~~$210~~
~~5. Physician permit to practice pharmacy~~	~~$210~~
~~6. Medical equipment supplier permit~~	~~$140~~
~~7. Humane society permit~~	~~$20~~
~~8. Nonresident pharmacy~~	~~$210~~
~~9. Controlled substances registrations~~	~~$50~~

18VAC110-50-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial application fees.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor	$270
6. Controlled substances registration	$90

C. Annual renewal fees shall be due on February 28 of each year.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180

3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor	$270
6. Controlled substances registration	$90

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Nonrestricted manufacturer permit	$90
2. Restricted manufacturer permit	$60
3. Wholesale distributor license	$90
4. Warehouser permit	$90
5. Nonresident wholesale distributor	$90
6. Controlled substances registration	$30

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Nonrestricted manufacturer permit	$240
b. Restricted manufacturer permit	$210
c. Wholesale distributor license	$240
d. Warehouser permit	$240
e. Nonresident wholesale distributor	$240
f. Controlled substances registration	$180

F. Application for change or inspection fees.

1. Reinspection fee	$150
2. Inspection fee for change of location, structural changes, or security system changes	$150

3. Change of ownership fee $50

4. Change of responsible party $50

G. The fee for a returned check shall be $35.

~~H. For the annual renewal due on or before December 31, 2006, the following fees shall be imposed for a license or permit:~~

~~1. Nonrestricted manufacturer permit~~ ~~$210~~

~~2. Restricted manufacturer permit~~ ~~$140~~

~~3. Wholesale distributor license~~ ~~$210~~

~~4. Warehouser permit~~ ~~$210~~

~~5. Nonresident wholesale distributor~~ ~~$210~~

Agenda Item: Review and Approval of Legislative Proposal

Included in the agenda package:

1. Draft legislative proposal to reschedule tapentadol to Schedule II and lacosamide to Schedule V to provide conformity with DEA schedules
2. Copies of the federal register notices for final scheduling

Background:

Whenever DEA schedules or reschedules, by final action, a controlled substance, the Board initiates a legislative proposal for the upcoming General Assembly to take the same scheduling action. This allows for prosecution of unlawful possession/distribution of the substance under Virginia law, and for Schedule II-V substances, eliminates any confusion on the part of health care practitioners as to what laws or regulations to use when prescribing, administering, or dispensing these substances.

DEA this past year has scheduled two new substances. Tapentadol, Schedule II is new drug approved for marketing in the US by FDA in November 2008. It is indicated for the treatment of moderate-to-severe pain, and shares some of the same pharmacological effects and abuse potential of the other Schedule II opiates. Lacosamide is also a new drug approved by FDA for marketing (trade name Vimpat®), for adjunct treatment of partial onset seizures in patients with epilepsy 17 years old or older. The pharmacological effects of this drug share similarities with those of alprazolam and phenobarbital, but are more transient.

Action needed: Motion to approve.

Department of Health Professions
2010 Session of the General Assembly

DHP-PHA-#1

A bill to of the *Code of Virginia* to add tapentadol to Schedule II and lacosamide to Schedule V in conformity with recent federal scheduling changes.

Be in enacted by the General Assembly:

1. That §§ 54.1-3448 and 54.1-3454 of the *Code of Virginia* are amended and reenacted as follows:

§ 54.1-3448. Schedule II.

The controlled substances listed in this section are included in Schedule II:

1. Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone naltrexone and their respective salts, but including the following:

Raw opium;

Opium extracts;

Opium fluid extracts;

Powdered opium;

Granulated opium;

Tincture of opium;

Codeine;

Dihydroetorphine;

Ethylmorphine;

Etorphine hydrochloride;

Hydrocodone;

Hydromorphone;

Metopon;

Oripavine (3-O-demethylthebaine or 6,7,8,14-tetradehydro-4, 5-alpha-epoxy-6-methoxy-17-methylmorphinan-3-ol);

Morphine;

Oxycodone;

Oxymorphone;

Thebaine.

Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this subdivision, but not including the isoquinoline alkaloids of opium.

Opium poppy and poppy straw.

Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine; cocaine or any salt or isomer thereof.

Concentrate of poppy straw, the crude extract of poppy straw in either liquid, solid or powder form, which contains the phenanthrene alkaloids of the opium poppy.

2. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

Alfentanil;

Alphaprodine;

Anileridine;

Bezitramide;

Bulk dextropropoxyphene (nondosage forms);

Carfentanil;

Dihydrocodeine;

Diphenoxylate;

Fentanyl;

Isomethadone;

Levo-alphacetylmethadol (levo-alpha-acetylmethadol)

(levomethadyl acetate) (LAAM);

Levomethorphan;

Levorphanol;

Metazocine;

Methadone;

Methadone - Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

Moramide - Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylicacid;

Pethidine (other name: meperidine);

Pethidine - Intermediate - A, 4-cyano-1-methyl-4-phenylpiperidine;

Pethidine - Intermediate - B, ethyl-4-phenylpiperidine-4-carboxylate;

Pethidine - Intermediate - C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

Phenazocine;

Piminodine;

Racemethorphan;

Racemorphan;

Remifentanil;

Sufentanil;

Tapentadol.

3. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

Amphetamine, its salts, optical isomers, and salts of its optical isomers;

Phenmetrazine and its salts;

Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;

Methylphenidate;

Lisdexamfetamine, its salts, isomers, and salts of its isomers.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Amobarbital;

Glutethimide;

Secobarbital;

Pentobarbital;

Phencyclidine.

5. The following hallucinogenic substance:

Nabilone.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances which are immediate precursors to amphetamine and methamphetamine or phencyclidine:

Phenylacetone;

1-phenylcyclohexylamine;

1-piperidinocyclohexanecarbonitrile (other name: PCC).

§ 54.1-3454. Schedule V.

The controlled substances listed in this section are included in Schedule V:

1. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

The Board may except by regulation any compound, mixture or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter and such substances so excepted may be dispensed pursuant to § 54.1-3416.

2. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

Pyrovalerone.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide];

Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].