FINAL/APPROVED 9-13-05

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 7, 2005
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the Board of Pharmacy was called to order at 9:03 a.m.

PRESIDING: Mark A. Oley, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
Toni Aust
Michael J. Ayotte
John O. Beckner
Willie Brown
Michelle R. Easton
Bobby Ison
Diane M. Langhorst
Leo H. Ross

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Ralph A. Orr, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Donna M. Lee, Administrative Assistant

QUORUM: With ten members of the Board present, a quorum was established.

THANK YOU: Mr. Oley informed the Board that June 30, 2005 will end Mr. Ayotte's tenure as a Board member. He commended Mr. Ayotte for his eight years of public service and stated that he was an excellent Board member.

WELCOME: Mr. Oley welcomed Diane Langhorst as a new citizen Board member replacing Kim Anderson who resigned.

Mr. Oley introduced Catherine Campbell as an intern with the Attorney General's Office. He also introduced Noel Feminella and Woody Woodsworth as pharmacy interns with Lafayette Westwood Pharmacy.

APPROVAL OF AGENDA: Mr. Oley called for changes or corrections to the agenda. Hearing no changes, the agenda was approved as presented.

PUBLIC COMMENTS: No public comments were received at this time.

Ms. Reiniers-Day read the emergency evacuation procedure for Conference Room 2. She also reminded everyone to turn off cell phones during the meeting.

APPROVAL OF MINUTES:

Mr. Oley called for changes or corrections to the minutes of March 1, 2005. Hearing no changes, the minutes were approved as presented.

ELECTION OF OFFICERS:

Mr. Beckner nominated Leo Ross for the office of Chairman. There were no other nominations. The Board voted unanimously, to elect Leo Ross as Chairman for the term beginning July 1, 2005. Mr. Ross nominated John Beckner for the office of Vice-Chairman. There were no other nominations. The Board voted unanimously, to elect John Beckner as Vice-Chairman for the term beginning July 1, 2005.

PUBLIC HEARING ON PROPOSED REGULATIONS TO CHANGE REFILL LIMITATION ON SCHEDULE VI PRESCRIPTIONS FROM 2 YEARS TO A 1 YEAR DEFAULT:

A public hearing on proposed regulations to change refill limitation on Schedule VI prescriptions from two years to a one year default was held beginning at 9:20 a.m. There were no public comments made on the proposed regulations. Mr. Oley stated that written comments can be received through July 29, 2005, and that adoption of final regulations will be at the next Board meeting to be held on September 13, 2005.

OVERVIEW OF ONGOING REGULATION PROCESSES:

Ms. Yeatts reviewed with the Board the status of ongoing regulatory processes for the Board of Pharmacy.

ADOPTION OF NOIRA ON A PEDIGREE SYSTEM FOR WHOLESALE DISTRIBUTORS:

The Board reviewed a draft Notice of Intended Regulatory Action (NOIRA) to establish a pedigree system for prescription drugs as required by Chapter 777 of the 2005 Acts of Assembly (Agenda pgs. 13-18, Attachment 10). Mr. Ayotte moved, and the Board voted unanimously, to adopt and publish the NOIRA to promulgate regulations for a pedigree system for wholesale distributors. The Chair appointed Mr. Ayotte, Mr. Beckner and Mr. Ison to serve on a committee to work on drafting proposed regulations.

ADOPTION OF FINAL RULES ON OUTSOURCING, DISCUSSION AND RESPONSE TO PUBLIC COMMENT:

The Board reviewed public comment and draft responses on the proposed regulations for outsourcing prescription processing functions received from EPIC Pharmacies and NACDS (Agenda pgs 19-26, Attachment 10).

Alexander M. Macaulay addressed the Board on behalf of EPIC Pharmacies regarding 18VAC110-20-276(B)(2), and reiterated

that any central or remote pharmacy should comply with Virginia laws and regulations with respect to duties that are performed by pharmacists and pharmacy technicians so that there is a level of protection for patients in Virginia. He also stated that the Board should ensure in regulation that the ratio issue is addressed and that persons performing as technicians in a contract arrangement have the minimum competencies that Virginia requires.

Mr. Ayotte and Mr. Beckner expressed concerns about the technician ratio requirement in other states and whether it should meet the standards set by Virginia. The Board was advised by Mr. Casway that it has no statutory authority to impose requirements on out-of-state pharmacies, but the Board can require that the Virginia licensed pharmacy that contracts with an out-of-state pharmacy ensure that the out-of-state pharmacy meets certain requirements in order to be allowed to outsource its prescription processing.

Rebecca Snead, Virginia Pharmacist Association, informed the Board that she individually supported the changes proposed by EPIC Pharmacies and that Virginia patients expect reasonable compliance with the standards set forth in Virginia regulations.

After further discussion, Mr. Ison moved, and the Board voted unanimously, to adopt 18VAC110-20-276(B)(2) as amended. (Attachment 1) to incorporate the clarifications requested by EPIC.

18VAC110-20-276(B)(3) - The Board discussed the proposed changes by NACDS to remove the requirement for a Virginia licensed pharmacist to check the remote processing and allow any pharmacist to perform the final check. During discussion, the Board members expressed concern that without the requirement for a final check by a Virginia licensed pharmacist, the accountability to the public would be lost, and that the public has an expectation when going to a Virginia pharmacy that a pharmacist licensed in Virginia will be checking the dispensing for accuracy. Mr. Ison moved, and the Board voted unanimously, to keep the original proposed language and to not make the changes proposed by NACDS. (Attachment 1)

18VAC110-20-515(B)(2) – The Board discussed the proposed changes by EPIC Pharmacies, which are the same concerns as with 18VAC110-20-276(B)(2). Mr. Ison moved, and the Board voted unanimously, to adopt 18VAC110-20-515(B)(2) as amended. (Attachment 1)

18VAC110-20-515(B)(3) – The Board reviewed the proposed

changes by NACDS which are the same concerns as with 18VAC110-20-276(B)(2). Mr. Ison moved, and the Board voted unanimously, to reject the recommendation of NACDS for the reasons cited during the previous discussion and to adopt 18VAC110-20-515(B)(3) as amended. (Attachment 1)

ADOPTION OF EXEMPT CHANGES TO STERILE COMPOUNDING RULES:

The Board was advised that with passage of Chapter 200 of the 2005 Acts of Assembly, there are now regulations related to sterile compounding that will conflict with the statute. The Board reviewed draft exempt changes to the regulations repealing the section of regulations related to sterile compounding and several definitions only used in that section of regulations. Mr. Ison moved, and the Board voted unanimously, to adopt the exempt changes to the sterile compounding rules as drafted by staff (Attachment 2), and for staff to create a guidance document that provides direction for pharmacists as to where in USP to look for the standards.

APPOINTMENT OF A COMMITTEE TO REVIEW COLLABORATIVE PRACTICE REGULATIONS:

Ms. Russell advised the Board that it had adopted a notice of periodic review at the previous meeting and requested that a committee be established to review the regulations in conjunction with the Board of Medicine. Mr. Oley appointed himself, Jill Abernathy, and Rebecca Snead to serve on the Committee. He also recommended that Ralph Small be contacted and invited to serve on the Committee.

SANCTION REFERENCE POINTS PROGRAM DISCUSSION:

This matter was continued from the March 1, 2005 Board meeting so that the Board could further discuss the concerns that were expressed about the distribution of the worksheet to respondents (Agenda pgs. 27-28, Attachment 10). Neal Kauder, President, VisualResearch, Inc., and Karen Perrine, Deputy Executive Director with the Board of Medicine, explained to the Board how and when the worksheet is utilized for disciplinary cases by the Board of Medicine. Ms. Perrine informed the Board that it is a great training tool for new board members when making decisions at the informal conference level.

Closed Session:

Mr. Ross moved, and the Board voted unanimously, to enter into closed session pursuant to Section 2.2-3711(A(7) of the Code of Virginia for consultation with and the provision of legal advice by Howard Casway in the matter of the Sanction Reference Points Program. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Howard Casway, Ralph Orr, Donna Lee, Karen Perrine, Neal Kauder and Katherine Campbell attend the closed session because their presence was deemed necessary and would aid the Board in its consideration of this matter.

Reconvene:

Mr. Ross moved, and the Board voted unanimously, that only

public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

Mr. Beckner departed at 11:20 a.m. during the closed session.

Ms. Perrine answered questions posed by the Board pertaining to the effectiveness of the Sanction Reference worksheet since implementation by the Board of Medicine.

Mr. Kauder advised the Board that an evaluation of the Sanction Reference worksheet process will be presented at the Board of Medicine's November board meeting.

Mr. Ison moved, and the Board voted unanimously, that a decision in this matter be deferred for one year so that more data can be obtained from the Board of Medicine with respect to appeals from informal conference decisions, as well as other pertinent information the Board of Medicine may provide for review.

2006 LEGISLATIVE PROPOSALS:

Rescheduling Bill and DEA 222 – The Board was advised that DEA changed official orders for Schedule II drugs to allow for electronic orders; therefore, § 54.1-3414 and § 54.1-3415 are changed to reflect the new provision. Ms. Russell informed the Board that Zopiclone was also added under the list of Schedule IV drugs in § 54.1-3452.

Wholesale distributors criminal record requirement – Ms. Russell stated that in § 54.1-3435 the language was added to state that a national criminal record check will be required of all applicants for a wholesale distributor license.

Non-resident pharmacy inspection requirement – Ms. Russell informed the Board that § 54.1-3434.1 was changed to add the requirement that the inspection report shall be deemed current if conducted within the past five years; and that if an applicant was not able to meet the 5-year requirement, the Board may accept an inspection report by another entity that the Board has determined to be credible. Ms. Russell asked that the Board approve the proposal in concept, with the understanding that she and Mr. Casway would develop the actual language for the proposal.

Mr. Ayotte moved, and the Board voted unanimously, to approve the 2006 legislative proposals as presented by Ms. Russell with the understanding that the non-resident pharmacy proposal will be revised by Ms. Russell and Mr. Casway, but will not recognize any one specific entity as acceptable for conducting inspections.

(Attachment 3)

GUIDANCE DOCUMENT ON NON-RESIDENT PHARMACIES, REQUIREMENT FOR RECENT INSPECTION:

Ms. Russell reminded the Board that this matter was continued from the March 1, 2005, Board meeting where it was requested that a guidance document be drafted to define the term "recent" to reflect a time period of five years for an inspection report that is submitted with an application for a non-resident pharmacy permit. Ms. Russell also informed the Board that the guidance document is to assist the Board until such time as the statute can be changed.

Mr. Brown moved, and the Board voted unanimously, to adopt Guidance Document 110-38. (Attachment 4)

REVISION TO GUIDANCE DOCUMENT 110-09, CONFIDENTIAL CONSENT AGREEMENTS:

The Board was informed that currently, if a pharmacist-in-charge allows an unlicensed person to practice as a technician or if a pharmacy technician practices without being registered or enrolled in an approved training program, a CCA is offered for the first occurrence in each instance. Ms. Russell requested that the Board grant permission for a CCA to be offered in these types of cases without having to present the case to a Special Conference Committee for approval.

Mr. Ison moved, and the Board voted unanimously, to adopt Guidance Document 110-09 as amended. (Attachment 5)

PROPOSED BYLAWS AMENDMENTS:

Ms. Russell reviewed with the Board the proposed amendments to Article V of the Bylaws, primarily related to the delegation to staff the authority to convene telephone conference calls for the purpose of summary suspensions or settlements and the authority to make a determination of probable cause in certain circumstances. Mr. Ross moved, and the Board voted unanimously, to adopt the proposed bylaws as amended. (Attachment 6)

REQUEST BY DEPARTMENT OF HISTORIC RESOURCES, REFERENCE BRUCE'S DRUGSTORE:

Ms. Russell stated that this matter was previously before the Board in January of 2004 when the Town of Scottsville requested that the Board allow the pharmacy sign at Bruce's Drug Store to remain, even though the pharmacy closed. The pharmacy name was etched into the stained glass window and the building is considered a historic landmark. The Board notified the Town of Scottsville that it had no authority to waive § 54.1-3433, and that the sign would have to be removed. The Town of Scottsville agreed to cover the sign while they pursued legislative action to give the Board the authority to grant exemptions.

Ms. Russell further explained that the 2005 General Assembly amended § 54.1-3433 to provide the Board with the authority to grant exemptions provided the site is approved for such an

exemption by the Department of Historic Resources. Kathleen S. Kilpatrick, Director, Department of Historic Resources, submitted a letter stating that this building has been properly designated as a historic landmark, and the mayor of the Town of Scottsville requested an exemption under the new law (Agenda pgs. 43-48, Attachment 10).

Mr. Brown moved, and the Board voted unanimously, that effective July 1, 2005, the exemption shall be granted.

REQUEST BY FREE CLINIC OF CENTRAL VIRGINIA TO ALLOW VOLUNTEER WORK TO COUNT AS APPROVED CE:

The Board reviewed and discussed the request by Free Clinic of Central Virginia to allow volunteer work at a free clinic to count as approved continuing education for pharmacists (Agenda pg. 49, Attachment 10). There was a brief discussion of the fact that North Carolina allows this. Ms. Russell stated that the Board has previously declined to allow practical experience of any type to count as approved continuing education, because most pharmacists engage in practice daily, and still have to obtain additional continuing education. Ms. Abernathy moved, and the Board voted unanimously, to deny the request by Free Clinic of Central Virginia.

PHYSICIANS DISPENSING DURING CLINICAL TRIALS, CSRC VS. LICENSE TO SELL:

Ms. Russell informed the Board that physicians working in clinical trials do sometimes dispense medications, but they cannot meet the requirements to apply for a License for Practitioner of the Healing Arts to Sell Controlled Substances. She also stated that researchers apply for a Controlled Substance Registration Certificate. Ms. Russell requested that the Board grant approval for physicians dispensing during clinical trials only to be allowed to apply for a Controlled Substance Registration Certificate as a researcher instead of a license to sell.

Ms. Abernathy moved, and the Board voted unanimously, to accept the recommendation of Ms. Russell and to grant approval that physicians dispensing during clinical trials can be registered with a Controlled Substance Registration Certificate provided the dispensing is limited to the duration and scope of the clinical trial.

GUIDANCE ON DISPENSING ERROR CASES INVOLVING WRONG DRUG IN BAG OR WRONG BAG GIVEN TO PATIENT:

The Board was informed that there are disciplinary cases involving a prescription placed in a wrong bag or wrong bag given to a patient, however, the prescription was filled correctly by the pharmacist. Ms. Russell asked the Board for guidance as to who the case should be docketed against initially; the pharmacist-in-charge or the facility permit holder. It is currently being docketed against the pharmacist on duty at the time the bag is given out, but often that pharmacist had nothing to do with the dispensing of that prescription. In many cases this relates to a system problem rather

than an individual error.

Mr. Brown moved that the case should initially be docketed against the pharmacy permit if the wrong drug is placed in the bag or the wrong bag given to the patient.

Ms. Abernathy offered an amendment to the main motion that the case should initially be docketed against the pharmacist-in-charge in such instances.

The Chair ruled that the discussion would be on the main motion. After further discussion, the Board voted 6-3 that a case should initially be docketed against the pharmacy permit if the wrong drug is placed in the bag or the wrong bag given to the patient, with the understanding that it would be docketed against a specific pharmacy and not the corporation, as the system problem may be related to that specific pharmacy.

REPORT FROM THE BOARD OF HEALTH PROFESSIONS – MICHELLE EASTON:

Ms. Easton stated that the April 13, 2005 minutes from the Board of Health Professions were an accurate reflection of what occurred at the meeting.

EXECUTIVE DIRECTOR'S REPORT:

• REPORT ON NABP ANNUAL MEETING:

Ms. Russell stated that all resolutions, except one, were passed by NABP. She informed the Board that the resolutions are available on the NABP website, and that copies will be forwarded to each Board member once she receives a copy.

• SUMMARY SUSPENSION CONFERENCE CALLS:

Ms. Russell asked the Board to decide whether they would prefer to hold summary suspension telephone conference calls early in the morning or later in the evening when more Board members could be available by phone. She stated that recent efforts to convene a quorum during regular business hours have resulted in an unacceptable delay of action. She stated that an e-mail will be sent to Board members providing a date, time, and dial-in number for a summary suspension telephone conference call. She reminded the Board that it is very important that they respond when they receive the e-mail as to whether or not they can participate and reiterated the importance of a summary suspension telephone conference call.

The Board decided that they preferred to hold summary suspension telephone conference calls at 8:30 a.m.

• DRUG AND DEVICE

The Board was informed that notice will be posted on the Board's

MANUFACTURERS NO LONGER ACPE APPROVED PROVIDERS:

website so that pharmacists can be made aware of ACPE no longer accepting drug and device manufacturers as continuing education providers.

NEW BUSINESS:

Mr. Ayotte delivered a parting statement to the Board and staff as this is his last full Board meeting saying that his Board work has been an important part of his life for the past eight years. His comments also recognized and commended the members and staff for their work and dedication.

Donna Lee and Elaine Yeatts departed at 1:30 p.m. and Elizabeth M. Revere, Administrative Assistant, arrived.

FORMAL HEARINGS:

DEBORAH L. DODD, Pharmacy Technician Registration Number 0230-004698

A formal hearing was held in the matter of Deborah L. Dodd following the summary suspension of her pharmacy technician registration on March 3, 2005, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia. Ms. Dodd was not present at the hearing. The Board proceeded in Ms. Dodd's absence as the Notice of Formal Hearing dated March 3, 2005, was mailed to Ms. Dodd's legal address of record, both regular and certified mail, said receipt indicating received by Ms. Dodd. Mr. Oley ruled that adequate notice was provided to Ms. Dodd and the hearing proceeded in her absence. (Agenda pgs. 59-60, Attachment 10.)

Quorum:

With nine Board Members in attendance, a quorum was established.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Jane A. Smith, Adjudication Specialist.

Virginia Tworek, Pharmacy District Manager, Wal-Mart, testified on behalf of the Commonwealth.

Dr. Easton stated that in her work at Hampton University, she has a working relationship with the Wal-Mart in Hampton, but that she could make a fair and unbiased judgment in this matter. There were no objections made by any of the remaining board members.

Closed Session:

Mr. Ross moved, and the Board voted unanimously, to convene a closed meeting pursuant to Section 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Deborah L. Dodd. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell, Howard Casway and Catherine

Campbell attend the closed meeting because their presence in the closed meeting was deemed necessary and their presence would aid the Committee in its deliberations.

Reconvene: Mr. Ross moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision: Mr. Ayotte moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann, amended by the Board and read by Mr. Casway (Attachment 7).

Mr. Ayotte moved, and the Board voted unanimously, that the pharmacy technician registration of Deborah L. Dodd be revoked.

DANIEL M. VARALLI, Pharmacist
License Number 0202-006335

A hearing was held in the matter of Daniel M. Varalli to discuss his petition for reinstatement of his license that was mandatorily suspended on August 18, 2004, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy in Virginia. (Agenda pgs. 61-62, Attachment 10.)

Toni Aust was recused from this hearing.

Quorum: With eight Board Members in attendance, a quorum was established.

William C. Garrett, Assistant Attorney General, prosecuted the case with the assistance of Patricia L. Larimer, Adjudication Analyst. Mr. Varalli appeared with counsel, Mark T. Bowles.

Andria P. Christian, DHP Senior Investigator, testified on behalf of the Commonwealth.

Daniel M. Varalli testified on his own behalf.

Closed Session: Mr. Ross moved, and the Board voted unanimously, to enter into closed session pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Daniel M. Varalli. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell and Howard Casway attend the closed session because their presence was deemed necessary and would aid the Board in its deliberation.

Ms. Russell recused herself from the closed session.

Reconvene: Mr. Ross moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

Decision: Mr. Ayotte moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett, amended by the Board and read by Mr. Casway (Attachment 8).

Mr. Ayotte moved, and the Board voted 5 to 3 that Mr. Varalli's license be reinstated. The motion failed as 6 affirmative votes are necessary to reinstate Mr. Varalli's license subsequent to the mandatory suspension. Ms. Abernathy moved and the license of Mr. Varalli be continued on indefinite suspension for a period of not less than four months.

JAMES J. MIZNER, Pharmacist License Number 0202-006072

A hearing was held in the matter of James J. Mizner to discuss his petition for reinstatement of his license that was mandatorily suspended on December 21, 1998, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy in Virginia. (Agenda pgs. 63-64, Attachment 10)

Quorum: With nine Board Members in attendance, a quorum was established.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Jane A. Smith, Adjudication Specialist. Mr. Mizner appeared with Mary E. Shedlock, his wife.

Mr. Ayotte stated that he is employed by CVS/pharmacy and can make a fair and impartial judgment in this matter as he had never supervised Mr. Mizner. There were no objections made by any of the remaining board members.

Mr. Mizner and Ms. Shedlock testified on his behalf.

Closed Session: Mr. Ross moved, and the Board voted unanimously, to enter into closed session pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of James J. Mizner. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell and Howard Casway attend the closed session because their presence was deemed necessary and would aid the Board in its deliberation.

Reconvene: Mr. Ross moved, and the Board voted unanimously, that only

public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

Decision: Mr. Ayotte moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann, amended by the Board and read by Mr. Casway (Attachment 9).

Mr. Ayotte moved, and the Board voted unanimously, to reinstate Mr. Mizner's license on probation with terms and conditions as read by Mr. Casway (Attachment 9).

ADJOURN: With all business concluded, the meeting adjourned at 6:30 p.m.

Elizabeth Scott Russell
Executive Director

Donna M. Lee
Administrative Assistant

Cathy M. Reiniers-Day
Deputy Executive Director

Elizabeth M. Revere
Administrative Assistant

Mark A. Oley, Board Chairman

Date

BOARD OF PHARMACY
18VAC110-20-10 et seq.

FINAL REGULATIONS ON OUTSOURCING PRECRIPTION PROCESSING

18VAC110-20-276. Central or remote processing.

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;

2. Entering prescription and patient data into a data processing system;

3. Transferring prescription information;

4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;

5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;

6. Interpreting clinical data for prior authorization for dispensing;

7. Performing therapeutic interventions; or

8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;

2. Any central or remote pharmacy shall comply with Virginia law [and regulation] with respect to [requirements for supervision of pharmacy technicians and the] duties which are restricted to pharmacists and pharmacy technicians ~~must be directly supervised by a pharmacist~~[. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia];

3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and

4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;

2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;

3. Procedures for protecting the confidentiality and integrity of patient information;

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

5. Procedures for maintaining required records;

6. Procedures for complying with all applicable laws and regulations to include counseling;

7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and

8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.

2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing

certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.

A. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;

2. Entering prescription and patient data into a data processing system;

3. Transferring prescription information;

4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication;

5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order;

6. Interpreting or acting on clinical data;

7. Performing therapeutic interventions;

8. Providing drug information to the medical or nursing staff of the hospital or long term care facility; or

9. Authorizing the administration of the drug to the patient by appropriate hospital or long term care facility staff.

B. The primary pharmacy providing pharmacy services to a hospital or long term care facility may outsource certain order processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;

2. [~~Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist and the remote pharmacy shall comply with Virginia law with respect to duties which are restricted to pharmacists and supervision requirements for pharmacy technicians~~ Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia];

3. [~~A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor~~ Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist]; and

4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a prescription order.

C. A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;

2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;

3. Procedures for protecting the confidentiality and integrity of patient information;

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

5. Procedures for maintaining required records;

6. Procedures for complying with all applicable laws and regulations;

7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and

8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

D. A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.

1. The record shall be available by prescription order or by patient name.

2. 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 task involved in processing a prescription order and the location where the task was processed.

3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

E. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

Repeal of Part X. Compounding Sterile Pharmaceutical Products

Conforming Regulations to the Code of Virginia

Chapter 200 of the 2005 Acts of the Assembly

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

~~"Aseptic processing" means the technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing~~.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

~~"Class 100 environment" means an atmospheric environment which contains less than 100 particles, 0.5 microns in diameter, per cubic foot of air.~~

~~"Closed system transfer" means the movement of sterile products from one container to another in which the container-closure system and transfer devices remain intact throughout the entire transfer process, compromised only by the penetration of a sterile, pyrogen-free needle or cannula through a designated stopper or port to effect transfer, withdrawal, or delivery, to include the withdrawal of a sterile solution from an ampul in a class 100 environment.~~

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

~~"Cytotoxic drug" means a drug which has the capability of killing living cells.~~

"DEA" means the United States Drug Enforcement Administration.

"Electronic transmission prescription" is any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted from a practitioner authorized to prescribe directly to a pharmacy without interception or intervention from a third party, or from one pharmacy to another pharmacy.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs which have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

~~"Hermetic container" means a container that is impervious to air or any other gas under the ordinary or customary conditions of handling, shipment, storage, and distribution.~~

~~"Home infusion pharmacy" means a pharmacy which compounds solutions for direct parenteral administration to a patient in a private residence, long-term care facility or hospice setting.~~

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

~~"Light-resistant container" means a container that protects the contents from the effects of light by virtue of the specific properties of the material of which it is composed, including any coating applied to it. Alternatively, a clear and colorless or a translucent container may be made light resistant by means of an opaque covering, in which case the label of the container bears a statement that the opaque covering is needed until the contents have been used. Where a monograph directs protection from light, storage in a light-resistant container is intended.~~

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

~~"Open-system transfer" means the combining of products in a nonsealed reservoir before filling or when a solution passes through the atmosphere during a transfer operation.~~

"Permitted physician" means a physician who is licensed pursuant to §54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

“PIC" means the pharmacist-in-charge of a permitted pharmacy.

“Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for continuous monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§1471-1476), i.e., in testing such containers, that 85% of a

test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

~~"Sterile pharmaceutical product" means a dosage form free from living microorganisms.~~

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" is a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in §54.1-2982 of the Code of Virginia.

~~"Tight container" means a container that protects the contents from contamination by extraneous liquids, solids, or vapors, from loss of the drug, and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage, and distribution, and is capable of tight reclosure. Where a tight container is specified, it may be replaced by a hermetic container for a single~~

~~dose of a drug and physical tests to determine whether standards are met shall be as currently specified in United States Pharmacopeia-National Formulary.~~

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-321. Compounding.

The compounding of both sterile and non-sterile drug products shall be performed in accordance with USP-NF compounding standards and §54.1-3410.2 of the Code of Virginia.

~~Part X. Compounding Sterile Pharmaceutical Products~~ (Repealed)

18VAC110-20-411. ~~General requirements.~~ (Repealed)

~~Products intended for parenteral administration or ophthalmic instillation shall be compounded using aseptic processing and in accordance with §54.1-3410.2 of the Code of Virginia.~~

18VAC110-20-412. ~~Policy and procedure manual.~~ (Repealed)

~~A policy and procedure manual shall be prepared and maintained for the compounding, dispensing and delivery of sterile products that is consistent with USP-NF standards and guidance and shall include at least the following elements:~~

~~1. Personnel qualifications including initial and follow-up training and method of periodic reevaluation of qualifications and performance;~~

~~2. Scope of compounding performed at the pharmacy and proper procedures for compounding to include maintaining suitable environmental conditions in the compounding area, wearing appropriate garb to reduce particulate matter and contamination of work area, performing aseptic procedures.~~

~~3. Procedures for maintaining and monitoring proper operating conditions for all equipment used in sterile compounding;~~

~~4. Guidelines for patient or caretaker education if products are dispensed for home use to include instructions concerning proper storage, aseptic manipulation of the product, proper administration and use of devices if applicable, recognizing signs of instability or incompatibility, and procedures in case of an emergency with the product;~~

~~5. Guidelines for assignment of beyond-use dates for all compounded sterile products and justification for any date chosen which exceeds the standard set forth in this chapter;~~

~~6. Separate procedures for handling cytotoxic drugs, if applicable, to include protective apparel; disposal procedures consistent with applicable local, state, and federal requirements; procedures for handling spills; special packaging and labeling requirements, and delivery procedures to minimize risks of accidental spills;~~

~~7. If applicable, separate procedures for compounding sterile products using nonsterile components or open system transfer techniques and for end-product sterilization of these products.~~

18VAC110-20-413. ~~Physical and equipment requirements for pharmacies preparing sterile products.~~ (Repealed)

~~A. The sterile compounding area shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies used in aseptic processing.~~

~~B. The sterile compounding area where parenteral products are routinely prepared shall be isolated from other areas and other pharmacy functions.~~

~~C. Sterile compounding shall be performed within a laminar flow hood or other appropriate environmental control device capable of maintaining, during normal activity, at least Class 100 conditions in the work area where sterile compounding is performed. Compounding of cytotoxic preparations shall be performed in a vertical flow Class II biological safety cabinet.~~

~~D. A pharmacy preparing sterile products shall maintain supplies adequate for the aseptic preparation of sterile products including, but not limited to, the following:~~

~~1. Antimicrobial soap;~~

~~2. Hot and cold water supply easily accessible to the sterile compounding area for hand washing prior to aseptic compounding;~~

~~3. Appropriate apparel for personnel performing sterile compounding;~~

~~4. Suitable disposal containers for used needles, syringes, etc. and, if applicable, containers for cytotoxic waste and infectious wastes.~~

~~E. A pharmacy preparing sterile products shall have sufficient current reference materials related to sterile products consistent with the policy and procedure manual and with the types of products prepared.~~

~~F. The pharmacy preparing sterile products shall have equipment necessary for maintaining and monitoring required temperature storage conditions both in the pharmacy and during delivery to the patient, if applicable.~~

18VAC110-20-414. ~~Labeling requirements.~~ (Repealed)

~~A. In addition to other applicable labeling requirements for prescriptions as set forth in §54.1-3410 of the Code of Virginia and 18VAC110-20-260 B and 18VAC110-20-330, the label of a compounded sterile product shall include all active ingredient names, strengths, amounts, and concentrations, when applicable, and for IV infusion shall include the name of all solutions.~~

~~B. The label of a compounded parenteral sterile product shall include an appropriate beyond-use date and time, if applicable, and the required storage conditions to assure product integrity for that time period. Unless otherwise specified and justification provided in the policy and procedure manual, the expiration date for unpreserved sterile products prepared aseptically in a closed system for a single patient shall bear a maximum beyond-use date, including administration, as follows:~~

~~1. Twenty-eight hours if stored at controlled room temperature;~~

~~2. Seven days if stored under refrigeration; and~~

~~3. Thirty days if stored under freezing conditions.~~

~~C. The label of other compounded sterile products shall bear an appropriate beyond-use date, not to exceed 30 days from the date of preparation.~~

~~D. If the product is for home or other outpatient use, the label shall bear the prescribed administration regimen including rate and route of administration and any device specific instructions.~~

~~E. The label shall bear any appropriate auxiliary labeling, including precautions for cytotoxic drugs.~~

18VAC110-20-415. ~~Quality assurance.~~ (Repealed)

~~A. The PIC in a pharmacy compounding sterile products shall be responsible for maintaining and updating the policy and procedure manual as set forth in 18VAC110-20-411 in accordance with current acceptable standards, and for ensuring compliance with the policy and procedure manual.~~

~~B. All laminar flow hoods or other environmental control devices shall be certified according to accepted standards for operational efficiency by a qualified independent contractor initially, at least every six months and after relocation.~~

18VAC110-20-416. ~~Records for sterile compounding.~~ (Repealed)

~~In addition to other required records, the following additional records shall be maintained for sterile compounding:~~

~~1. Compounding records maintained on or with the original prescription, or in a log format which can be cross-referenced with the prescription, or in an automated data processing system which contains the same information required in a manual system and is capable of producing a hard copy printout of a two-year history of prescription compounding and dispensing upon request within 72 hours. In addition to prescription information, the record must include the following information:~~

~~a. Date of sterile compounding;~~

~~b. Beyond-use date assigned to the sterile product; and~~

~~c. Signature, initials, or electronic identification of pharmacist compounding, or of both the nonpharmacist compounding and pharmacist checking the compounding of the sterile product.~~

~~2. Record documenting certification of clean room or laminar flow hoods.~~

~~3. If sterile products are provided to a patient's residence, a record documenting training of the patient or caregiver, or both, in the proper storage and use of the product and any devices used to administer the devices.~~

Part ~~XI~~. X. Unit Dose Dispensing Systems

Part ~~XII~~. XI. Pharmacy Services to Hospitals

Part ~~XIII~~. XII. Pharmacy Services to Long-Term Care Facilities

Part ~~XIV~~. XIII. Other Institutions and Facilities

Part ~~XV.~~ XIV. Exempted Stimulant or Depressant Drugs and Chemical Preparations

Part ~~XVI~~. XV. Manufacturers, Wholesale Distributors, Warehousers, and Medical Equipment Suppliers

Part ~~XVII.~~ XVI. Controlled Substances Registration for Other Persons or Entities

§ 54.1-3414. Official orders for Schedule II drugs.

An official written order for any Schedule II drug shall be signed by the purchasing licensee or by his agent. The original shall be presented to the person who supplies the drug or drugs. If such person accepts the order, each party to the transaction shall preserve his copy of the order for two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter. It shall be deemed a compliance with this section if the parties to the transaction have complied with the federal laws respecting the requirements governing the use of order forms. Parties ordering Schedule II drugs electronically shall comply with all requirements of federal law and regulation governing such transactions.

§ 54.1-3415. Distribution of drugs in Schedules II through VI by manufacturers and wholesalers.

A. A permitted manufacturer or wholesaler may distribute Schedule II drugs to any of the following persons, but only on official written orders or pursuant to an electronic order in compliance with federal laws and regulations governing the electronic ordering of Schedule II drugs:

1. To a manufacturer or wholesaler who has been issued permits pursuant to this chapter;
2. To a licensed pharmacist, permitted pharmacy or a licensed practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine;
3. To a person who has been issued a controlled substance registration certificate pursuant to § 54.1-3422, if the certificate of such person authorizes such purchase;
4. On a special written order accompanied by a certificate of exemption, as required by the federal laws, to a person in the employ of the United States government or of any state, territorial, district, county, municipal, or insular government, purchasing, receiving or possessing drugs by reason of his official duties;
5. To a master of a ship or a person in charge of any aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft when not in port. However, such drugs shall be sold to a master of such ship or person in charge of such aircraft pursuant to a special order form approved by a commissioned medical officer or acting assistant surgeon of the United States Public Health Service; and
6. To a person in a foreign country in compliance with the provisions of the relevant federal laws.

B. A permitted manufacturer or wholesaler may distribute drugs classified in Schedule III through Schedule VI and devices to all persons listed in subsection A of this section without an official written order. However, this section shall not be construed to prohibit the distribution of a Schedule VI drug or device to any person who is otherwise authorized by law to administer, prescribe or dispense such drug or device.

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

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

Alprazolam;
Barbital;
Bromazepam;
Camazepam;

Chloral betaine;
Chloral hydrate;
Chlordiazepoxide;
Clobazam;
Clonazepam;
Clorazepate;
Clotiazepam;
Cloxazolam;
Delorazepam;
Diazepam;
Dichloralphenazone;
Estazolam;
Ethchlorvynol;
Ethinamate;
Ethyl loflazepate;
Fludiazepam;
Flunitrazepam;
Flurazepam;
Halazepam;
Haloxazolam;
Ketazolam;
Loprazolam;
Lorazepam;
Lormetazepam;
Mebutamate;
Medazepam;
Methohexital;
Meprobamate;
Methylphenobarbital;
Midazolam;
Nimetazapam;
Nitrazepam;
Nordiazepam;
Oxazepam;
Oxazolam;
Paraldehyde;
Petrichloral;
Phenobarbital;
Pinazepam;
Prazepam;
Quazepam;
Temazepam;
Tetrazepam;
Triazolam;
Zaleplon;
Zolpidem.
Zopiclone

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:
Fenfluramine.
3. 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 stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
Cathine (+)-norpseudoephedrine;
Diethylpropion;
Fencamfamin;
Fenproprex;
Mazindol;
Mefenorex;
Modafinil;
Phentermine;
Pemoline (including organometallic complexes and chelates thereof);
Pipradrol;
Sibutramine;
SPA (-)-1-dimethylamino-1, 2-diphenylethane.
4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:
Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxy butane);
Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:
Butorphanol (including its optical isomers);
Pentazocine.
6. 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 if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in this Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on or before January 1 of each year; notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board. **Prior to permitting an applicant to be licensed as a wholesale distributor, the board shall require the applicant to submit to fingerprinting and to provide personal descriptive information to be forwarded along with the applicant's fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation (FBI) for the purpose of obtaining national criminal history record information regarding such applicant. The applicant shall pay the cost of the fingerprinting or a criminal records check or both.**

The Central Criminal Records Exchange, upon receipt of an applicant's record or notification that no record exists, shall make a report to the Board, who must be a governmental entity. If an applicant is denied a licensee because of the information appearing in his criminal history record, the Board shall notify the applicant that information obtained from the Central Criminal Records Exchange contributed to such denial. The information shall not be disseminated except as provided for in this section.

The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public.

CHAPTER 115

An Act to amend and reenact §§ 54.1-3434.1 through 54.1-3434.4 of the Code of Virginia, relating to registration of nonresident pharmacies; summary proceedings.

[H 2538]

Approved March 20, 2005

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3434.1 through 54.1-3434.4 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside ~~this~~ *the* Commonwealth which ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into ~~this~~ *the* Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs or devices to residents of ~~this~~ *the* Commonwealth. A report containing this information shall be made on an annual basis and within ~~thirty~~ *30* days after any change of office, corporate officer, or principal pharmacist.

2. That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the ~~Commonwealth~~ *jurisdiction* in which it is licensed as well as with all requests for information made by the Board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a ~~valid unexpired~~ *current unrestricted* license, permit, *certificate,* or registration to conduct the pharmacy in compliance with the laws of the ~~state~~ *jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States,* in which it is a resident. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the ~~state~~ *jurisdiction* in which it is located. The inspection report shall be deemed current if conducted within the past five years. If the nonresident pharmacy has not been inspected by the resident state regulatory or licensing agency within the past five years, the Board may accept an inspection report by another entity that the Board has determined to be credible. (other documentation?)

3. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in ~~this~~ *the* Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

4. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of forty hours per week, provide a toll-free telephone service to

facilitate communication between patients in ~~this~~ *the* Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in ~~this~~ *the* Commonwealth.

C. The registration fee shall be the fee specified for pharmacies within Virginia.

D. A nonresident pharmacy shall only deliver controlled substances, that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

§ 54.1-3434.2. Permit to be issued.

~~No out-of-state pharmacy doing business in this Commonwealth which has not obtained a permit shall conduct the business of selling or distributing drugs in Virginia without registering as a nonresident pharmacy.~~ *The Board shall only register nonresident pharmacies that maintain a current unrestricted license, certificate, permit, or registration as a pharmacy in a jurisdiction within the United States, or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States.*

Applications for a nonresident pharmacy registration, under this section, shall be made on a form furnished by the Board. The Board may require such information as it deems is necessary to carry out the purpose of the section.

The permit or nonresident pharmacy registration shall be renewed annually on or before January 1 of each year.

§ 54.1-3434.3. Denial, revocation, suspension of registration, summary proceedings.

The Board may deny, revoke, or suspend a nonresident pharmacy registration for conduct which causes serious bodily or serious psychological injury to a resident of the Commonwealth ~~if the Board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to initiate an investigation within forty-five days of the referral~~.

The Board shall immediately suspend, without a hearing, the registration of any nonresident pharmacy upon receipt of documentation by the licensing agency in the jurisdiction where a nonresident pharmacy registered with the Board is located, that the nonresident pharmacy has had its license, certificate, permit, or registration as a pharmacy revoked or suspended by that agency and has not been reinstated, or if the Board has received notification from the licensing agency that the pharmacy in the resident state no longer holds a valid unexpired license, permit, certificate, or registration as a pharmacy. The Board shall provide written notice of the suspension to the nonresident pharmacy at the address of record on file with the Board and to the resident-state licensing agency. The nonresident pharmacy may apply for reinstatement of the registration only after it has been reinstated by and holds a current and unrestricted license, certificate, permit, or registration as a pharmacy from the licensing agency in the jurisdiction where it is located. Such nonresident pharmacy shall be entitled to a hearing not later than the next regular meeting of the Board after the expiration of 30 days from the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses to testify on its behalf.

The Board may summarily suspend the registration of any nonresident pharmacy without a hearing, simultaneously with the institution of proceedings for a hearing, if it finds that there is a substantial danger to the public health or safety that warrants such action. The Board may meet by telephone conference call when summarily suspending the registration if a good faith effort to assemble a quorum of the Board has failed and, in the judgment of a majority of the members of the Board, the continued dispensing by the nonresident pharmacy constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension. The Board may consider other information concerning possible violations of Virginia law at a hearing, if reasonable notice is given to such nonresident pharmacy of the information.

A nonresident pharmacy with a suspended registration shall not ship, mail, or deliver any Schedule II through VI drugs into the Commonwealth unless reinstated by the Board.

The Board may refer complaints concerning nonresident pharmacies to the regulatory or licensing agency in the jurisdiction where the pharmacy is located. The Board may take other disciplinary action against a nonresident pharmacy in accordance with §§ 54.1-2400 and 54.1-3316 following notice and the opportunity for a hearing.

§ 54.1-3434.4. Prohibited acts.

It is unlawful for any ~~nonresident pharmacy~~ *person or entity* which is not registered under this article to *(i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii)* advertise ~~its services in Virginia or~~ *the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. Further, it shall be unlawful* for any person who is a resident of Virginia to advertise the pharmacy services of a nonresident pharmacy which has not registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the pharmacy to ~~dispense prescriptions~~ *obtain controlled substances*.

Board of Pharmacy Guidance Document 110-38
Requirement for Non-resident Pharmacies to Submit Most Recent Inspection Form

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

...

As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

...

The Board interprets "recent" to mean a report of an inspection conducted within the past 5 years. A non-resident pharmacy that is not able to produce an inspection report upon application of an inspection conducted within the past 5 years by the regulatory or licensing agency will be denied registration until such time as such a report can be provided, and the non-resident pharmacy will be informed of the right to an informal conference. The informal conference committee may review documents and other evidence provided by the non-resident pharmacy offered to prove a legitimate pharmacy operation, and if the committee is satisfied that the evidence represents substantial compliance with the requirement, it may grant registration.

Guidance Document 110-09

CONFIDENTIAL CONSENT AGREEMENTS

The following recommendations for use of CCAs are in addition to the recommendations for use of CCAs incorporated in revised *Guidance Document 110-26 Inspection Violations-Suggested Sanctions* and revised *Guidance Document 110-19 Continuing Pharmacy Education Requirement Violations*.

- For matters involving a pharmacist who has practiced without a license for less than six months (December 31st through June 30th), a CCA should be offered.

- For a first occurrence involving a pharmacist-in-charge allowing unlicensed persons to practice as pharmacy technicians, a CCA should be offered.

- For a first occurrence involving a registered pharmacy technician who practiced without being properly registered with the board or enrolled in an approved pharmacy technician training program, a CCA should be offered.

- CCAs may be recommended on a case by case basis by a SCC/ IFC during probable cause review.

- In following with the Agency's recommendation, once a Notice has been mailed, CCAs are no longer available for that particular matter.

BYLAWS OF THE VIRGINIA BOARD OF PHARMACY

ARTICLE I: GENERAL

The organizational year for the Board shall be from July 1st through June 30th. At the last meeting before July 1, the Board shall elect from its members a Chair and a Vice Chair. The term of office shall be one year and shall begin on July 1. A person shall not serve as Chair or Vice Chair for more than two consecutive terms.

For purposes of these Bylaws, the Board schedules full board meetings four times a year, with the right to change the dates, schedule additional meetings as needed, or cancel any board meeting, with the exception that one meeting shall take place annually. Board members shall attend all board meetings in person, unless prevented by illness or similar unavoidable cause. A majority of the members of the Board shall constitute a quorum for the transaction of business. The current edition of *Robert's Rules of Order*, revised, shall apply unless overruled by law, regulation, or these bylaws, or when otherwise agreed.

ARTICLE II: OFFICERS OF THE BOARD

1. The officers of the Board shall be the Chair and the Vice-Chair

2. The Chair presides at all meetings and formal administrative hearings in accordance with parliamentary rules and the Administrative Process Act, and requires adherence of same on the part of the board members. The Chair shall appoint all committees unless otherwise ordered by the Board.

3. The Vice-Chair shall act as Chair in the absence of the Chair.

4. In the absence, or inability to serve, of both the Chair and Vice-Chair, the Chair shall appoint another board member to preside at the meeting and/or formal administrative hearing.

5. The Executive Director shall be the custodian of all Board records and all papers of value. She/he shall preserve a correct list of all applicants and licensees. She/he shall manage the correspondence of the Board and shall perform all such other duties as naturally pertain to this position.

ARTICLE III: ORDER OF BUSINESS MEETINGS

The order of business shall be as follows:

1. Call to order with statement made for the record of how many board members are present and that it constitutes a quorum.

2. Approval of Agenda

3. Public comment received

4. Approval of Minutes

5. The remainder of the agenda shall be established by the Executive Director in consultation with the Chair.

ARTICLE IV: COMMITTEES

A. There shall be the following standing committees:

Special Conference Committees
Examination Committee
Item Review Committee
Regulation Committee
Pilot Committees

1. Special Conference Committees. These committees shall consist of two board members who shall review information regarding alleged violations of the pharmacy laws and regulations and determine if probable cause exists to proceed with possible disciplinary action. The special conference committees shall meet as necessary to adjudicate cases in a timely manner in accordance with agency standards for case resolution. The Chair may designate board members as alternates on these committees in the event one of the standing committee members is unable to attend for all or part of a scheduled conference date. The chair shall appoint committees as needed to expedite the adjudication of cases. These committees may also function as informal conference committees if a case involves a permit.

2. Examination Committee. This committee shall consist of four board members and the Executive Director. The Examination Committee shall meet as required to maintain the integrity, defensibility and current status of the Drug Law Examination. Additionally, the Board delegates to this Committee the approval of the Drug Law Examination for the purpose of licensure.

3. Item Review Committee. This committee shall consist of at least seven pharmacists holding current and unrestricted licenses to practice pharmacy in the Commonwealth of Virginia. The Item Review Committee shall meet as required for the purpose of writing new items for the Drug Law Examination item bank.

4. Regulation Committee. This committee shall consist of five Board members. The Board delegates to the Regulation Committee the authority to consider and respond to petitions for rulemaking. This committee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the development of proposals for legislative initiatives of the Board; the drafting of Board responses to public comment as required in conjunction with rulemaking; conducting the required review of all existing regulations as required by the Board's Public Participation Guidelines and any Executive Order of the Governor, and

any other required tasks related to regulations. In accordance with the Administrative Process Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full Board prior to publication.

5. Pilot Committees. These committees shall consist of two board members who review applications for approval of innovative programs and robotic pharmacy systems and any matters related to such programs.

B. Ad Hoc Committees.
The Chair shall also name such other committees as may be deemed necessary.

C. A majority of a committee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall constitute the act of the committee.

ARTICLE V: GENERAL DELEGATION OF AUTHORITY

1. The Board delegates to Board staff the authority to issue and renew licenses, permits, registrations and certificates where minimum qualifications have been met.

2. The Board delegates to the Executive Director the authority to reinstate licenses, permits, registrations and certificates when the reinstatement is due to the lapse of the license, permit, registration or certificate and not due to Board disciplinary action.

3. The Board delegates to Board staff the authority to develop and approve any and all forms used in the daily operations of Board business, to include, but not be limited to, licensure applications, renewal forms and documents used in the disciplinary process.

4. The Board delegates to the Department of Health Professions' inspectors the authority to issue Compliance Notices upon completion of an inspection, and the Board delegates to the Executive Director the authority to issue letters regarding reported deficiencies to the facilities or licensee.

5. The Board delegates to the Executive Director the authority to sign as entered any Order or Consent Order resulting from the disciplinary process or other administrative proceeding.

6. The Board delegates to the Executive Director, who may consult with a special conference committee member, the authority to provide guidance to the agency's Enforcement Division in situations wherein a complaint is of questionable jurisdiction and an investigation may not be necessary.

7. The Board delegates to the Executive Director, in consultation with the Chair, the review and approval of applications for special or limited use pharmacy permits. If the Executive Director and Chair do not reach consensus regarding the issuance of a permit, or if the requested waivers are unusual or different from those routinely approved, the review and approval may be referred to an informal conference committee.

8. The Board delegates to the Executive Director, in consultation with the Chair, the review and approval, in accordance with regulations, for exceptions to the notice requirements for pharmacies going out of business and for exceptions to notice requirements for pharmacies changing hours of business for more than one week. Should the Executive Director and the Chair not reach consensus, or if the request for exception is unusual or questionable, the review and approval may be referred to a special conference committee.

9. The Board delegates to the Executive Director the authority to grant extensions for continuing education on a one-time basis upon written request of the licensee prior to the renewal date in accordance with regulations. Approval of any request for an extension where the licensee must show good cause or approval of any request for an exemption is delegated to the Executive Director in consultation with the Chair. Should the Executive Director and Chair not reach agreement, the matter shall be referred to a special conference committee.

10. The Board delegates to the Chair, the authority to represent the Board in instances where Board "consultation" or "review" may be requested, but where a vote of the Board is not required and a meeting is not feasible.

11. The Board delegates the approval of continuing education programs to the Executive Director in consultation with one member of the Board.

12. The Board delegates the convening of a quorum of the Board by telephone conference call, for the purpose of considering the summary suspension of a license in accordance with §54.1-2408.1, to the Executive Director or Deputy Executive Director-Discipline. The Board delegates the convening of a meeting by telephone conference call, for the purpose of considering settlement proposals in accordance with §54.1-2400 (13), to the Executive Director or Deputy Executive Director-Discipline. The Board delegates the determination of probable cause for disciplinary action to a special conference committee of the Board, wherein the committee may offer a confidential consent agreement, offer a pre-hearing consent order, cause the scheduling of an informal conference, request additional information, or close the case. The Board further delegates the determination of probable cause, for the purpose of offering a confidential consent agreement or a pre-hearing consent order or for scheduling an informal conference in accordance with established Board guidelines, to the Executive Director or Deputy Executive Director-Discipline.

ARTICLE VI: AMENDMENTS

Amendments to these Bylaws may be proposed by a board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the

Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.

Effective Date:	July 1, 1997
Revised:	October 9, 1997
	August 17, 1999
	June 13, 2001
	September 15, 2004
	June 7, 2005

Deborah L. Dodd
Formal Hearing
June 7, 2005

Motion Regarding the Findings of Fact and Conclusions of Law

Findings of Fact:

1. Deborah L. Dodd holds registration number 0230-004698 issued by the Board to practice as a pharmacy technician in the Commonwealth of Virginia that was summarily suspended pursuant to an Order entered by the Board on March 3, 2005.
2. Based upon the representations of Mr. Schliessmann and Commonwealth's Exhibits 3 and 4, the Chair ruled that there had been adequate notice and that the Board would proceed in Ms. Dodd's absence.
3. On or about December 14, 2004, while employed as a pharmacy technician at Wal-Mart Pharmacy #10-1841, Chesapeake, Virginia, Ms. Dodd was videotaped diverting unknown drugs from the area of the pharmacy where hydrocodone (Schedule III) preparations are maintained. During an interview with a Wal-Mart Pharmacy District Manager, Ms. Dodd admitted to diverting hydrocodone tablets, and, subsequent to a search of her lunch bag, fifty-six (56) tablets of hydrocodone were discovered. Ms. Dodd also admits to diverting hydrocodone tablets for a six to seven month period prior to her termination in January 2005. An audit conducted on or about January 7, 2005, for the period of May 1, 2003, to January 17, 2005, showed a loss of approximately 40,887 hydrocodone-containing tablets.

Conclusions of Law:

The Board concludes that Finding of Fact #3 constitutes a violation of § 54.1-3322(1), (2) and (6) of the Code of Virginia.

Daniel M. Varalli
Formal Hearing
June 7, 2005

Motion Regarding the Findings of Fact and Conclusions of Law

Findings of Fact:

1. Daniel M. Varalli previously held License No. 0202-006335 issued by the Board to practice pharmacy in the Commonwealth of Virginia. Said license was mandatorily suspended by the Department of Health Professions pursuant to an Order entered on August 18, 2004.
2. On or about July 23, 2004, Mr. Varalli was convicted of one (1) felony count of "Conspiracy to Distribute and Dispense Schedule III and IV Controlled Substances and to Use a Communication Facility in Committing and in Causing and Facilitating the Distribution and Dispensing of Schedule III and IV Controlled Substances in Violation of the Controlled Substances Act."
3. Varalli failed to provide evidence that he fully comprehended the nature of his prior violations related to his inappropriate dispensing of controlled substances and his breach of his professional responsibilities to safeguard the health and safety of his patients.

Conclusions of Law:

The Board concludes that Finding of Fact #2 constitutes a violation of § 54.1-3316(7) and (9) of the Code of Virginia.

James J. Mizner
Formal Hearing
June 7, 2005

Motion Regarding the Findings of Fact and Conclusions of Law

Findings of Fact:

1. James J. Mizner previously held License No. 0202-006072 issued by the Board to practice pharmacy in the Commonwealth of Virginia. Said license was mandatorily suspended by the Department of Health Professions pursuant to an Order entered on December 21, 1998.
2. On or about October 20, 1998, in the Circuit Court of Arlington County, Virginia, Mr. Mizner pled guilty and was convicted of fifteen (15) felonies: five (5) counts of grand larceny, five (5) counts of forgery, four (4) counts of embezzlement, and one (1) count of supplying a false statement in an application for payment under the Virginia Medical Assistance Plan.
3. On or about October 20, 1998, in the Circuit Court of Arlington County, Mr. Mizner pled guilty and was convicted of one (1) count of supplying a false statement in an application for payment under the Virginia Medical Assistance Plan, a felony. For a five (5) year period ending in 1998, Mr. Mizner admitted to ringing up cash or co-pay sales as "no-sale" and taking the money, then submitting false third-party claims using patient information to cover the loss.
4. Mr. Mizner testified that his convictions were related to a number of issues including trying to maintain his former wife's lifestyle and supporting his gambling. He has not practiced pharmacy since 1998 and has been in therapy and on medication for depression. Mr. Mizner was incarcerated from November 13, 1998 until July 25, 2000, and was then placed on supervised probation for ten years, however, he was released from supervised probation on October 5, 2004. Since September 2000, Mr. Mizner has been employed with ACT College and is currently the Director of the Allied Health Degree Program. On June 21, 2003, Mr. Mizner received a Master of Business Administration from DeVry University. He testified that, presently, he has no intentions of returning to pharmacy practice but might do so if the right situation materializes in a non-retail capacity.

Conclusions of Law:

The Board concludes that Mr. Mizner violated § 54.1-3316(2), as further defined in 54.1-3315(1), and § 54.1-3316(5) and (7) of the Code.

Motion Regarding Mr. Mizner's Petition for Reinstatement of his License

The Board grants Mr. Mizner's petition for reinstatement of his license and places it on indefinite probation with terms and conditions to include that he shall not practice pharmacy until he decides to return to the practice and has submitted comprehensive reports to the Board regarding his therapy, to include treatment dates, assessment, his current status and prognosis; and has a psychiatric evaluation to include any treatment recommendations for continued pharmacological therapy. Also, he must register as a pharmacy intern and complete an internship of 160 hours of practical experience. Mr. Mizner must give his preceptor a copy of this Order prior to beginning

the internship and the preceptor must send a final evaluation to the Board within ten (10) days following his completion or must notify the Board if he fails to complete the internship. Further, Mr. Mizner must take the drug law examination and complete 60 hours of additional continuing pharmacy education that shall be dated between the time this Order is final and five (5) years of his return to practice. Once he has completed these terms and prior to his practicing, Mr. Mizner will meet with a Special Conference Committee to review his compliance, the reports and to determine any changes to the terms of probation.

LIST OF DOCUMENTS CONTAINED IN ATTACHMENT 10
(Copies can be obtained by contacting the Board)