



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor
Richmond, Virginia 23230

(804) 367-4456 (Tel)
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Tentative Agenda of Meeting

March 12, 2008

9:00AM

<u>TOPIC</u>	<u>PAGE(S)</u>
Call to Order: Bobby Ison, Chairman	
• Welcome and Introductions	
• Reading of emergency evacuation script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	1-12
• December 12, 2008	
• February 13, 2008 Formal Hearings	
Call for public comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.	
Formal Hearing: Thomas O'Rourke, Pharmacy Technician	sent separately
Consideration of consent orders (if any)	
Reports:	
• Report of the Director, DHP, Sandra Whitley Ryals	
• Report on Board of Health Professions-Jennifer H. Edwards	
• Executive Director's Report-Scotti Russell	
• Personnel and compliance unit changes	
• report on disciplinary program-Cathy Reiniers-Day	
• report on licensing, newsletter, other activities-Caroline Juran	
• report on the prescription monitoring program-Ralph Orr	
Legislation:	
• Update on General Assembly 2008-Scotti Russell, Elaine Yeatts	13-18
Regulations: Scotti Russell, Elaine Yeatts	
• Update on ongoing regulation processes	
• Exempt action to correct 18VAC110-20-530 from Title 63.1 (repealed) to Title 63.2	19-20
• Exempt action, HB1222, volunteer pharmacists, 18 VAC 110-20-75	21-24
• Emergency regulations to establish expiration dates for facilities, determine dates, begin discussion	

- Emergency regulations to implement a drug donation program, HB85, begin discussion 25-76
- Unprofessional conduct definition, begin discussion 77-91

Adjourn

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

The Patient Safety (CQI) committee will meet immediately following the Board meeting.

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

December 12, 2007
Second Floor
Board Room 1

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

CALL TO ORDER: The meeting was called to order at 9:10AM.

PRESIDING: Bobby Ison, Chairman

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

MEMBERS ABSENT: Gerard Dabney

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Ralph Orr, Program Manager, Prescription Monitoring Program
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant
Sandra W. Ryals, Director, DHP, was present for part of the meeting

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

APPROVAL OF AGENDA: With one addition to the agenda, a question related to compliance with USP 797, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for September 12, 2007, October 10, 2007, and October 27, 2007. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS: There were no public comments received.

LEGISLATION UPDATE: Ms. Yeatts and Ms. Russell provided an update on legislative proposals by the Board. The Department has received permission to draft for introduction the three pieces of legislation requested by the Board to include scheduling of lisdexamphetamine and oripavine, allowing the Board to mandate up to two hours of

continuing education on a specific topic annually with prior notification, and removing specific expiration dates of licenses from the statute to allow the Board to stagger some of its renewal processes. To date, only the scheduling bill has been drafted.

REGULATIONS:

- Update on Pedigree Rules

Ms. Russell stated that the final rules establishing a pedigree system are under administrative review in the Governor's office.

- Adoption of fast-track change to remove inactive fee from PSD regulations

Ms. Yeatts explained that when the Board previously removed the inactive status for practitioners of the healing arts selling controlled substances (PSDs), 18 VAC 110-30 et seq, the Board inadvertently failed to remove the fee for this status.

Motion:

A motion was made and passed unanimously to approve the fast-track regulation as presented to remove the inactive fee for PSDs. (motion by Beckner, second by Brown)

- Petition for rulemaking, Ken Dandurand, 18 VAC 110-20-515

Mr. Dandurand had submitted a petition for rulemaking requesting the Board to amend 18 VAC 110-20-515 that requires any pharmacist participating in remote processing for hospitals and nursing homes to be licensed in Virginia. The Board discussed the matter and agreed that a requirement for a Virginia pharmacist to be involved in the dispensing process is necessary for public protection. It is essential for accountability in the event of a prescription error. If an error is made by a pharmacist not licensed in Virginia, the Board has little authority to take action. This is different from pharmacists working in mail order pharmacies because patients who have prescriptions filled there do not have an expectation that the pharmacists filling the prescriptions are licensed in Virginia. This is not the case with a patient in a hospital in Virginia who has a reasonable expectation that the pharmacy services are being delivered by persons licensed in Virginia.

There are differences in statutes and regulations governing the practice of pharmacy, therefore, pharmacists who provide prescription processing for hospitals and long-term care facilities from remote locations need to be familiar with Virginia requirements for a prescription. Obtaining a license in Virginia is not burdensome, but it does require passage of a jurisprudence examination, assuring familiarity with Virginia laws and regulations.

The petitioner also cited section 276 on remote processing of a prescription for retail pharmacies, but subsection B of that section does require that "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." The Board believes patients in hospitals and nursing homes should have the same protection.

Motion:

A motion was made and passed unanimously to deny the petition for rulemaking for the reasons stated during the discussion. (motion by Ross, second by Kozera)

**GUIDANCE DOCUMENT ON
DROP BOXES:**

The Board reviewed a draft guidance document allowing pharmacies to use a secured drop box for the purpose of allowing patients to leave new prescriptions and refill requests at the pharmacy during hours the prescription department is closed. There was some discussion about the wording of the location of the drop box. The draft read, "The drop box must be located in a visible area within the pharmacy..." and some Board members felt that this was confusing because it might be construed to mean that the drop box must actually be in the prescription department. The term "pharmacy" sometimes connotes the "prescription department" in larger pharmacies such as grocery stores, "big box" retailers, or hospitals. The consensus was to change "within the pharmacy" to "within the permitted facility" to clearly allow the box to be outside the prescription department but still have to be inside the licensed location. There was also some discussion as to whether "visible area" should be changed to either "observable area" or "conspicuous location". The consensus was to leave it as "visible area".

Motion:

A motion was made and passed unanimously to approve Guidance Document 110-32 as amended by the Board to allow pharmacies to use a drop box for collection of written prescriptions and refill requests. (motion by Brown, seconded by Kozera)

**GUIDANCE DOCUMENT ON
CE SANCTIONS:**

Ms. Russell advised that at the last meeting, the Board had approved new sanctions for persons performing pharmacy technician functions without being registered or properly in a training program. In making revisions to current guidance documents, staff was able to combine two guidance documents into one related to approved sanctions. Staff made a minor change to the current language in CE sanctions to reflect actual practice and needs approval of the Board. The change would allow staff to offer the approved sanctions in second-time CE cases in a pre-hearing consent order without specific approval by a committee of the Board in each case.

Motion:

A motion was made and passed unanimously to approve the revised Guidance Document 110-09 which combines the old 110-09 and 110-19, and incorporates sanction changes made at the previous Board meeting. (motion by Brown, second by Kozera.

NOIRA FOR RULES ON
DEFINING
UNPROFESSIONAL
CONDUCT

Ms. Yeatts and Ms. Russell explained that July 2007 changes in statute to the Board's grounds for disciplinary action took effect. One of those changes gave the Board the authority to take action against an applicant or licensee for unprofessional conduct as defined in the Board's regulations. The Board discussed the possible need for further defining unprofessional conduct in regulation, and reviewed such regulations of some other boards within the Department as well as other states. The consensus of the Board was that it did need to promulgate rules to define unprofessional conduct, specifically with respect to ethics and patient confidentiality.

Motion:

A motion was made and passed unanimously to publish a NOIRA for the consideration of promulgating regulations to define unprofessional conduct. (motion by Abernathy, second by Beckner)

REPORT OF DHP DIRECTOR

Sandra Whitley Ryals, Director, DHP, gave the Board an update on several issues.

• Budget

Ms. Ryals reported that, as a recommendation of the Virginia Health Reform Commission, there is a modest proposal in the budget to have a health care workforce data center housed at DHP which would collaborate with other stakeholders in forecasting demand for health care practitioner demand and workforce planning. Some Boards are already collecting workforce data as part of the renewal process, so DHP would be a natural fit for the location of the data center.

The Department has additional budget requests for initiatives related to meeting key performance measures, primarily related to the disciplinary performance measure.

There are some budget requests related to new auditing requirements for risk management, trying to prevent any misappropriation or other mishandling of the Department's finances.

In general, there are additional restrictions on any discretionary spending, particularly on discretionary travel. DHP already had fairly restrictive travel policies in place, but now all discretionary travel goes through one additional layer of scrutiny, which is the Secretary's office.

- Other Legislation

In addition to the Board of Pharmacy's legislative initiatives that have already been discussed, the Department is seeking legislative relief to streamline and make more efficient the ability to obtain documents needed for an investigation.

BOARD OF HEALTH PROFESSIONS REPORT

Ms. Edwards provided a report of BHP activities of interest to the Board of Pharmacy. She stated that, at the last BHP meeting, an AARP representative spoke to the Board and stated they are looking at some of their legislative initiatives to include requiring reporting of medication errors to this agency, requirements for health care professionals to show continued competency in order to renew a license, requiring hospitals to have some type of continuous quality improvement program, and allow suspension of a license with a pattern of medical errors.

EXECUTIVE DIRECTOR'S REPORT

- NABP

Ms. Russell provided a report on both the NABP Fall legislative conference and the NABP/AACP District II conference. She stated that NAPLEX was back on line October 1, 2007, and that everything seems to be working well. She stated that the next annual conference is in Baltimore, MD, on May 17-22, 2008.

- Disciplinary program report

Ms. Reiniers-Day presented the Board's disciplinary caseload report and stated that there were 174 cases at the enforcement level, 82 cases at the probable cause level, 4 cases at the informal conference level, 6 cases at the formal hearing level and 38 cases at the APD level. Further, there were 259 cases at the Compliance Tracking level, which includes cases wherein continuing education documentation and/or monetary penalties are due.

- Licensing Report

Ms. Juran reported that the Board had issued over 800 licenses since the last meeting, and currently has over 25,000 licensees.

- Pilot Program Report

Ms. Juran provided a summary of the pilot and robot programs the Board is currently monitoring. Ms. Abernathy stated that this information was very interesting and helpful and requested that this information be available on the website. Ms. Russell stated that the orders approving the pilot programs are public information and could be scanned and made available on the website.

Action Item:

Staff will have all current pilot orders scanned and put on the website, as well as adding future orders as they are entered

- Report on the Prescription Monitoring Program

Mr. Orr stated that there are now 18.9 million records in the data base. He also provided the Board with information concerning the recent PMP conference and the positive feedback received. Mr. Beckner stated that he had attended the conference and was very



impressed with the quality of the conference and commended Mr. Orr for his efforts. Mr. Orr also reported on the new online training module partnership with VCU School of Medicine on pain management, and stated that it was Board-approved for three hours of continuing education.

**SUMMARY SUSPENSION
AND APPROVAL OF A
CONSENT ORDER**

Motion for Closed session:

Mr. Kozera 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 a possible summary suspension and to reach a decision regarding a consent order. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Elizabeth Revere, Howard Casway, Clay Garrett and Amanda Mitchell attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

Motion to Reconvene:

Mr. Kozera 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 meeting.

**Motion in the matter of
JOAN Y. GARNER
Pharmacy Technician
Registration Number:
0230-002932:**

Mr. Beckner moved, and the Board voted unanimously in favor of the motion that, according to the evidence presented, the pharmacy technician practice by Joan Y. Garner poses a substantial danger to the public, and therefore, the registration of Joan Y. Garner to practice as a pharmacy technician be summarily suspended with a consent order offered to Ms. Garner for the revocation of her registration in lieu of a hearing.

**Motion in the matter of
Clay Douglas Jones
Pharmacist
License Number:
0202-204609**

Mr. Stredler moved, and the Board voted unanimously, to accept the consent order signed by Clay D. Jones for the indefinite suspension of his pharmacist license.

REGULATIONS CONT:

- Adoption of proposed regulations, 18 VAC 110-20-10 et seq., from periodic review

The Board reviewed draft recommended amendments to its general regulations, 18 VAC 110-20-10 et seq. The amendments had been recommended, subsequent to a periodic review, by the Regulation Committee and staff. The Board reviewed each amendment and made some changes to the committee recommendations. The draft



recommendations as amended are attached to the minutes as Attachment A.

Motion:

A motion was made and passed unanimously to adopt, as proposed regulations, the draft as presented with the agenda and amended by the Board. (motion by Beckner, second by Brown)

USP 797

Mr. Ison stated that there is a hospital in the Tidewater area which will be moving within the next 18 months and did not want to incur the costs of capital improvements at the current facility to comply with the clean room standards of USP 797. Ms. Russell stated that the Board's guidance document 110-36 advises that although current law requires compliance with USP 797 for sterile compounding, the Board will not inspect for compliance with physical standards until June 30, 2008. She stated that pharmacies have had to comply with the standards since the law was enacted several years ago, but that because USP was in a revision process of these standards and because costs of compliance with physical requirements was so high for some hospitals, the Board had deferred inspecting for compliance with physical standards until June 2008 to provide time for completion of USP revisions. Those revisions were published last week, and become effective July 1, 2008. Ms. Russell stated that the Board had already pushed back the date for compliance several times waiting on the USP changes. She suggested that if this hospital is inspected and cited after July 1, the Board could consider that situation on its own merits. After some discussion, the consensus of the Board was that it should not further push back the compliance date for physical standards.

ADJOURN:

With all business concluded, the meeting adjourned at 4:00 p.m.

Elizabeth Scott Russell
Executive Director

Bobby Ison
Board Chairman

Date

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

Wednesday, February 13, 2008
Fifth Floor
Conference Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:30 a.m.

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT: John O. Beckner
Gerard Dabney
Jennifer H. Edwards
Leo H. Ross
Brandon K. Yi

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

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

FELICIA A. JONES
Registration # 0230-007065

A formal hearing was held in the matter of Felicia A. Jones following the summary suspension of her pharmacy technician registration on December 6, 2007, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Jones was not present at the hearing. The Panel proceeded in Ms. Jones' absence as the Notice of Formal Hearing dated December 6, 2007, was mailed to Ms. Jones' legal address of record, both regular and certified mail. Mr. Ison ruled that adequate notice was provided to Ms. Jones and the hearing proceeded in her absence.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

CLOSED MEETING:

Mr. Beckner moved, and the Panel voted 6-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose to reach a decision in the matter of Felicia A. Jones. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, and Howard Casway attend the closed meeting.

RECONVENE:

Mr. Beckner moved, and the Panel voted 6-0, 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. Yi moved, and the Panel voted 6-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann, and that Felicia A. Jones' right to renew her pharmacy technician's registration be revoked (Attachment #1).

ANGEL D. ROBESON
Registration # 0230-010971

A formal hearing was held in the matter of Angel D. Robeson following the summary suspension of her pharmacy technician registration on December 5, 2007, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Robeson was not present at the hearing. The Panel proceeded in Ms. Robeson's absence as the Notice of Formal Hearing dated December 5, 2007, was mailed to Ms. Robeson's legal address of record, both regular and certified mail. Mr. Ison ruled that adequate notice was provided to Ms. Robeson and the hearing proceeded in her absence.

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

CLOSED MEETING:

Mr. Beckner moved, and the Panel voted 6-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose to reach a decision in the matter of Angel D. Robeson. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, and Howard Casway attend the closed meeting.

RECONVENE:

Mr. Beckner moved, and the Panel voted 6-0, 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. Yi moved, and the Panel voted 6-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett and amended by the Panel and read by Mr. Casway (Attachment 2).

Mr. Yi moved, and the Panel voted 6-0, that Angel D. Robeson's right to renew her pharmacy technician's registration be revoked.

DANA L. POLSTON
Registration #0230-009673

A formal hearing was held in the matter of Dana L. Polston following the summary suspension of her pharmacy technician registration on August 24, 2007, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

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

Nan Dunaway, DHP Pharmacy Inspector, and Karen Moore, Pharmacist, Bayview Pharmacy, testified on behalf of the Commonwealth.

Ms. Polston testified on her own behalf.

CLOSED MEETING:

Mr. Beckner moved, and the Panel voted 6-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose to reach a decision in the matter of Dana L. Polston. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day and Howard Casway attend the closed meeting.

RECONVENE:

Mr. Beckner moved, and the Panel voted 6-0, 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. Yi moved, and the Panel voted 6-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett and amended by the Panel and read by Mr. Casway (Attachment 3).

Mr. Yi moved, and the Panel voted 6-0, to continue Ms. Polston's pharmacy technician's registration on indefinite suspension. Said suspension shall be stayed upon evidence that Ms. Polston has submitted the required application and fees for the renewal of her registration and upon evidence that she has signed a Recovery monitoring Contract with HPIP.

KIMBERLEE A. BROWN
License # 0202-204577

Mr. Garrett presented a signed Consent Order to the Board for consideration in lieu of proceeding to the formal hearing regarding this matter.

DECISION:

Mr. Yi moved, and the Panel voted 6-0 to modify standard language per board counsel, accept the amended Consent Order and authorize Ms. Russell to sign the Consent Order when received. The Consent Order made certain Findings of Fact and Conclusions of Law and reinstates Ms. Brown's pharmacist license with terms and conditions (Attachment 4).

CARLEEN C. PHILPOT
Registration # 0230-005520

Ms. Reiniers-Day presented a signed Consent Order to the Board for consideration in lieu of proceeding to the formal hearing regarding this matter.

DECISION:

Mr. Beckner moved, and the Panel voted 6-0 to accept the signed consent order for the indefinite suspension of Ms. Philpot's right to renew her registration (Attachment 5).

OTHER:

Ms. Russell and Ms. Reiniers-Day discussed Orders and Consent Orders that are already entered wherein respondents participate with the Health Practitioners' Intervention Program ("HPIP"), however, for a variety of reasons, there are additional terms and conditions. It was requested that the Panel authorize the sending of pre-hearing Consent Orders to these respondents wherein the only term requires their compliance with their HPIP contract.

Mr. Beckner moved, and the Panel voted 6-0 that pre-hearing Consent Orders be offered to certain respondents

with existing Orders or Consent Orders wherein the only term requires their compliance with their HPIP contract. Further, the Panel gives the Executive Director the authority to enter the document on behalf of the Board.

ADJOURN:

With all business concluded, the meeting adjourned at 3:00 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Bobby Ison, Chairman

Date

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Report of the 2008 General Assembly (As of 3/3/08)

Board of Pharmacy

HB 21 Schedule I hallucinogenic drugs; includes salvia divinorum and salvinorin A thereas.

Summary as passed House:

Salvinorin A as a Schedule I hallucinogenic. Includes Salvinorin A in controlled substance Schedule I as a hallucinogenic drug.

Patron: O'Bannon

02/19/08 House: Bill text as passed House and Senate (HB21ER)

02/19/08 House: Impact statement from VCSC (HB21ER)

02/19/08 House: Impact statement from DPB (HB21ER)

02/20/08 House: Signed by Speaker

02/22/08 Senate: Signed by President

HB 85 Prescription Medication Donation Program; established.

Summary as passed House:

Donation of prescription medications. Requires the Board of Pharmacy to promulgate regulations to establish a Prescription Drug Donation Program to accept certain unused previously dispensed prescription drugs, and re-dispense such drugs to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. This bill requires the Board to promulgate regulations to implement its provisions within 280 days of enactment. This bill also provides that, notwithstanding the due course effective date of the bill, provisions of current law shall remain in effect until regulations promulgated by the Board for the establishment of the Program become effective.

Patrons: Landes; Senator: Ruff

02/27/08 House: Senate amendment agreed to by House (93-Y 4-N)

02/27/08 House: VOTE: --- ADOPTION (93-Y 4-N)

02/29/08 House: Enrolled

02/29/08 House: Bill text as passed House and Senate (HB85ER)

02/29/08 House: Impact statement from DPB (HB85ER)

HB 383 Occupational therapy assistants; licensing and regulation.

Summary as introduced:

Licensing and regulation of occupational therapy assistants. Defines occupational therapy

assistant and establishes requirement of a license to practice as an occupational therapy assistant. This bill is identical to SB 134 (Houck).

Patron: O'Bannon

02/19/08 House: Enrolled

02/19/08 House: Bill text as passed House and Senate (HB383ER)

02/19/08 House: Impact statement from DPB (HB383ER)

02/20/08 House: Signed by Speaker

02/22/08 Senate: Signed by President

HB 403 Health care providers; those responding to disaster immune from liability.

Summary as passed House:

Health care provider liability protections. Provides that, in the absence of gross negligence or willful misconduct, health care providers who respond to a disaster are immune from civil liability for any injury or wrongful death arising from the delivery or withholding of health care. This immunity only applies (i) if a state or local emergency has been or is subsequently declared in response to such a disaster, and (ii) if the emergency and subsequent conditions caused a lack of resources, attributable to the disaster, rendering the health care provider unable to provide the same level or manner of care that would have been required in the absence of the emergency. The bill also allows persons who hold licenses or certificates evidencing their professional or mechanical skills who render aid involving that skill during a disaster to receive reimbursement for their actual and necessary expenses. The bill also combines the definitions of the terms "man-made disaster" and "natural disaster" as contained in the Commonwealth of Virginia Emergency Services and Disaster Law of 2000 into the term "disaster" and adds the term "communicable disease of public health threat" to the definition. The bill also expands when immunity attaches for health care providers who abandon patients in order to respond to a disaster to include disasters, emergencies, and major disasters. This bill also makes technical amendments. This bill is identical to SB 657.

Patron: Hamilton

02/20/08 Senate: Passed Senate (40-Y 0-N)

02/21/08 House: Enrolled

02/21/08 House: Bill text as passed House and Senate (HB403ER)

02/22/08 House: Signed by Speaker

02/25/08 Senate: Signed by President

HB 501 Medical malpractice; definition of professional services.

Summary as passed:

Medical malpractice; professional services. Defines the term "professional services in nursing homes" in the context of medical malpractice actions as services provided to a patient by a health care provider, including psycho-social services, personal hygiene, hydration, nutrition, fall

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assessments or interventions, patient monitoring, prevention and treatment of medical conditions, diagnosis or therapy. This bill is in response to the Supreme Court decision in *Alcoy v. Valley Nursing Homes, Inc.*, 272 Va. 37, 630 S.E.2d 301 (2006). This bill incorporates HB 1051 and is identical to SB 602.

Patrons: Hamilton, Scott, E.T. and Watts

02/20/08 House: VOTE: --- ADOPTION (94-Y 1-N 1-A)
02/21/08 House: Enrolled
02/21/08 House: Bill text as passed House and Senate (HB501ER)
02/21/08 House: Signed by Speaker
02/25/08 Senate: Signed by President

HB 605 Nonprofessional entities; practice of medicine.

Summary as passed House:

Nonprofessional corporations; practice of medicine. Clarifies that an entity that employs or contracts with an individual licensed by a health regulatory board may (i) practice or engage in the practice of a profession or occupation for which the individual is licensed, (ii) provide or render professional services related to the profession or occupation for which the person is licensed through the licensed individual, and (iii) enforce the terms of employment or of a contract with the licensed individual.

Patron: O'Bannon

02/27/08 House: Enrolled
02/27/08 House: Bill text as passed House and Senate (HB605ER)
02/27/08 House: Signed by Speaker
02/28/08 House: Impact statement from DPB (HB605ER)
02/28/08 Senate: Signed by President

HB 805 Advance Health Care Directive Registry; created.

Summary as passed House:

Advance Health Care Directive Registry; creation. Requires the Department of Health to make available a secure online central registry for advance health care directives. The registry shall be accessible to health care providers licensed by the Board, through a site maintained by the Department of Health. This bill is identical to SB 290 (Barker).

Patrons: Englin, Albo, Ebbin, Eisenberg, Iaquinto, Moran, O'Bannon, Plum, Rust, Toscano and Ward

02/27/08 House: Enrolled
02/27/08 House: Bill text as passed House and Senate (HB805ER)
02/27/08 House: Signed by Speaker



02/28/08 House: Impact statement from DPB (HB805ER)

02/28/08 Senate: Signed by President

HB 823 Oripavine and lisdexamfetamine; adds to list of Schedule II drugs.

Summary as introduced:

Schedule II drugs; oripavine and lisdexamfetamine. Adds oripavine and lisdexamfetamine to the list of Schedule II drugs.

Patron: Morgan

02/19/08 House: Bill text as passed House and Senate (HB823ER)

02/19/08 House: Impact statement from VCSC (HB823ER)

02/20/08 House: Impact statement from DPB (HB823ER)

02/20/08 House: Signed by Speaker

02/22/08 Senate: Signed by President

HB 1128 Pharmacists; continuing education requirements.

Summary as introduced:

Board of Pharmacy; continuing education. Allows the Board of Pharmacy to require two of the currently required 15 hours of continuing education to be in a specific subject area and exempts this requirement from the Administrative Process Act. Also allows the Board to determine, in regulation, the number of continuing education hours required for inactive status.

Patron: Jones, S.C.

02/13/08 Senate: Constitutional reading dispensed

02/13/08 Senate: Referred to Committee on Education and Health

02/19/08 Senate: Assigned Education sub: Health Licensing

02/28/08 Senate: Reported from Education and Health (14-Y 0-N)

02/29/08 Senate: Passed by for the day

HB 1129 Pharmacy, Board of; expiration of licenses.

Summary as introduced:

Board of Pharmacy; expiration of licenses. Removes the requirement that certain licenses expire on January 1 annually, and instead allows the Board to set an annual expiration date by regulation. Contains emergency regulation clause.

Patron: Jones, S.C.

02/27/08 House: Enrolled

02/27/08 House: Bill text as passed House and Senate (HB1129ER)

02/27/08 House: Signed by Speaker

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02/28/08 House: Impact statement from DPB (HB1129ER)
02/28/08 Senate: Signed by President

HB 1147 Controlled substances; nonresident pharmacies reporting and approval requirements.

Summary as passed House:

Controlled substances; nonresident pharmacies; penalties. Makes it a Class 1 misdemeanor for any person to manufacture, sell, give, distribute or possess with intent to manufacture, sell, give or distribute a Schedule VI controlled substance or imitation controlled substance in violation of the Drug Control Act. The bill requires a nonresident pharmacy to designate a Virginia-licensed pharmacist to be responsible for compliance with all provisions of the Drug Control Act. A nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, must disclose to the Pharmacy Board that it has received certain certifications. The bill also allows controlled substances that are illegally shipped to be seized by law enforcement or by an agent of the Board of Pharmacy.

Patron: Phillips

02/19/08 House: Enrolled
02/19/08 House: Bill text as passed House and Senate (HB1147ER)
02/20/08 House: Signed by Speaker
02/21/08 House: Impact statement from DPB (HB1147ER)
02/22/08 Senate: Signed by President

HB 1222 Charitable medical events; lack of notice to licensing board.

Summary as passed House:

Charitable medical events; lack of notice. Amends criteria which a practitioner of the healing arts must meet in order to render free health care to an underserved population of Virginia, to require that the practitioner to notify the Board of the dates and location of services provided at least 5 business days prior to the voluntary provision of services. This bill also provides that the board shall allow a practitioner of the healing who meets the statutory criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

Patron: Bowling

01/29/08 Senate: Constitutional reading dispensed
01/29/08 Senate: Referred to Committee on Education and Health
02/12/08 Senate: Assigned Education sub: Health Licensing
02/28/08 Senate: Reported from Education and Health (14-Y 0-N)
02/29/08 Senate: Passed by for the day

HB 1445 Schools for students with disabilities; administration of prescription medications.

Summary as passed House:

Administration of drugs; training of educational facility staff. Allows the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by a resident of a private children's residential facility licensed by the Department of Social Services, Department of Education, or Department of Mental Health, Mental Retardation and Substance Abuse Services, or a student in a school for students with disabilities licensed by the Board of Education.

Patron: Abbitt

02/19/08 House: Enrolled

02/19/08 House: Bill text as passed House and Senate (HB1445ER)

02/20/08 House: Signed by Speaker

02/21/08 House: Impact statement from DPB (HB1445ER)

02/22/08 Senate: Signed by President

SB 218 Health Professions, Department of; investigative procedures.

Summary as introduced:

Department of Health Professions; investigative procedures. Clarifies that the Director and investigative personnel may request and obtain patient records, business records, papers, and physical or other evidence in the course of any investigation or issue subpoenas requiring the production of such evidence.

Patron: Edwards

02/19/08 Senate: Bill text as passed Senate and House (SB218ER)

02/19/08 Senate: Impact statement from DPB (SB218ER)

02/19/08 House: Signed by Speaker

02/20/08 Senate: Signed by President

02/27/08 Governor: Approved by Governor-Chapter 37 (effective 7/1/08)

Exempt Action – Consistency with Current Law

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.
2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.
3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.
4. Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.
5. Ensure that the storage area for patients drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.
6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.
7. Provide for the disposition of discontinued drugs under the following conditions:
 - a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by §54.1-3411.1 and 18VAC110-20-400, or destroyed by appropriate means in compliance with any applicable local, state, and federal laws and regulations.
 - b. Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.
 - c. A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.
 - d. Long term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title ~~63.1~~ 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

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HOUSE BILL NO. 1222
FLOOR AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by Delegate Bowling
on January 25, 2008)

(Patron Prior to Substitute—Delegate Bowling)

A BILL to amend and reenact §§ 54.1-2901, 54.1-3001, 54.1-3202, 54.1-3301, and 54.1-3801 of the Code of Virginia, relating to charitable medical events.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2901, 54.1-3001, 54.1-3202, 54.1-3301, and 54.1-3801 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-2901. Exceptions and exemptions generally.

A. The provisions of this chapter shall not prevent or prohibit:

1. Any person entitled to practice his profession under any prior law on June 24, 1944, from continuing such practice within the scope of the definition of his particular school of practice;
2. Any person licensed to practice naturopathy prior to June 30, 1980, from continuing such practice in accordance with regulations promulgated by the Board;
3. Any licensed nurse practitioner from rendering care under the supervision of a duly licensed physician when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of Nursing;
4. Any registered professional nurse, licensed nurse practitioner, graduate laboratory technician or other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the giving of intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine;
5. Any dentist, pharmacist or optometrist from rendering care or services within the scope of his usual professional activities;
6. Any practitioner licensed or certified by the Board from delegating to personnel supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by practitioners of the healing arts, if such activities or functions are authorized by and performed for such practitioners of the healing arts and responsibility for such activities or functions is assumed by such practitioners of the healing arts;
7. The rendering of medical advice or information through telecommunications from a physician licensed to practice medicine in Virginia or an adjoining state to emergency medical personnel acting in an emergency situation;
8. The domestic administration of family remedies;
9. The giving or use of massages, steam baths, dry heat rooms, infrared heat or ultraviolet lamps in public or private health clubs and spas;
10. The manufacture or sale of proprietary medicines in this Commonwealth by licensed pharmacists or druggists;
11. The advertising or sale of commercial appliances or remedies;
12. The fitting by nonitinerant persons or manufacturers of artificial eyes, limbs or other apparatus or appliances or the fitting of plaster cast counterparts of deformed portions of the body by a nonitinerant bracemaker or prosthetist for the purpose of having a three-dimensional record of the deformity, when such bracemaker or prosthetist has received a prescription from a licensed physician directing the fitting of such casts and such activities are conducted in conformity with the laws of Virginia;
13. Any person from the rendering of first aid or medical assistance in an emergency in the absence of a person licensed to practice medicine or osteopathy under the provisions of this chapter;
14. The practice of the religious tenets of any church in the ministrations to the sick and suffering by mental or spiritual means without the use of any drug or material remedy, whether gratuitously or for compensation;
15. Any legally qualified out-of-state or foreign practitioner from meeting in consultation with legally licensed practitioners in this Commonwealth;
16. Any practitioner of the healing arts licensed or certified and in good standing with the applicable regulatory agency in another state or Canada when that practitioner of the healing arts is in Virginia temporarily and such practitioner has been issued a temporary license or certification by the Board from practicing medicine or the duties of the profession for which he is licensed or certified (i) in a summer camp or in conjunction with patients who are participating in recreational activities, (ii) while participating in continuing educational programs prescribed by the Board, or (iii) by rendering at any

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183 volunteers to provide free health care to an underserved area of this Commonwealth under the auspices
 184 of a publicly supported all volunteer, nonprofit organization with no paid employees that sponsors the
 185 provision of health care to populations of underserved people throughout the world, (iv) files a copy of
 186 the license or certification issued in such other jurisdiction with the Board, (v) notifies the Board at least
 187 ~~fifteen~~ *five business* days prior to the voluntary provision of services of the dates and location of such
 188 service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in
 189 compliance with the Board's regulations, during the limited period that such free health care is made
 190 available through the volunteer, nonprofit organization on the dates and at the location filed with the
 191 Board. The Board may deny the right to practice in Virginia to any nurse whose license or certificate
 192 has been previously suspended or revoked, who has been convicted of a felony or who is otherwise
 193 found to be in violation of applicable laws or regulations. *However, the board shall allow a nurse who*
 194 *meets the above criteria to provide volunteer services without prior notice for a period of up to three*
 195 *days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license*
 196 *in another state.*

197 § 54.1-3202. Exemptions.

198 This chapter shall not apply to:

199 1. Physicians licensed to practice medicine by the Board of Medicine or to prohibit the sale of
 200 nonprescription eyeglasses and sunglasses. Contact lenses shall not be sold as merchandise from a retail
 201 business other than one operated by a physician, an optometrist or an optician; or

202 2. Any optometrist rendering free health care to an underserved population in Virginia who (i) does
 203 not regularly practice optometry in Virginia, (ii) holds a current valid license or certificate to practice
 204 optometry in another state, territory, district or possession of the United States, (iii) volunteers to
 205 provide free health care in an underserved area of this Commonwealth under the auspices of a publicly
 206 supported all volunteer, nonprofit organization with no paid employees that sponsors the provision of
 207 health care to populations of underserved people throughout the world, (iv) files a copy of his license or
 208 certification in such other jurisdiction with the Board, (v) notifies the Board at least ~~fifteen~~ *five business*
 209 days prior to the voluntary provision of services of the dates and location of such service, and (vi)
 210 acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the
 211 Board's regulations, during the limited period that such free health care is made available through the
 212 volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may
 213 deny the right to practice in Virginia to any optometrist whose license or certificate has been previously
 214 suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation
 215 of applicable laws or regulations. *However, the board shall allow an optometrist who meets the above*
 216 *criteria to provide volunteer services without prior notice for a period of up to three days, provided the*
 217 *nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.*

218 § 54.1-3301. Exceptions.

219 This chapter shall not be construed to:

220 1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any
 221 physician acting on behalf of the Virginia Department of Health or local health departments, in the
 222 compounding of his prescriptions or the purchase and possession of drugs as he may require;

223 2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as
 224 defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health
 225 departments, from administering or supplying to his patients the medicines that he deems proper under
 226 the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to
 227 §§ 32.1-42.1 and 54.1-3408;

228 3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34
 229 (§ 54.1-3400 et seq.) of this title;

230 4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34
 231 (§ 54.1-3400 et seq.) of this title;

232 5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the
 233 regulations of the Board;

234 6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from
 235 purchasing, possessing or administering controlled substances to his own patients or providing controlled
 236 substances to his own patients in a bona fide medical emergency or providing manufacturers'
 237 professional samples to his own patients;

238 7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic
 239 pharmaceutical agents, from purchasing, possessing or administering those controlled substances as
 240 specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to
 241 prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own
 242 patients those controlled substances as specified in § 54.1-3222 and the TPA formulary or providing
 243 manufacturers' samples of these drugs to his own patients;

244 8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his

22

245 own patients manufacturers' professional samples of controlled substances and devices that he is
 246 authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice
 247 setting and a written agreement with a physician or podiatrist;

248 9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing
 249 to his own patients manufacturers' professional samples of controlled substances and devices that he is
 250 authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice
 251 setting and a written agreement with a physician;

252 10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an
 253 indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a
 254 prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle
 255 of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense
 256 such medication at no cost to the patient without holding a license to dispense from the Board of
 257 Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with
 258 the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall
 259 meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In
 260 lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid
 261 prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in
 262 the program shall not use the donated drug for any purpose other than dispensing to the patient for
 263 whom it was originally donated, except as authorized by the donating manufacturer for another patient
 264 meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor
 265 the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent
 266 patient program pursuant to this subdivision. A participating pharmacy may charge a reasonable
 267 dispensing or administrative fee to offset the cost of dispensing, not to exceed the comparable allowable
 268 fee reimbursed by the Virginia Medicaid program. However, if the patient is unable to pay such fee, the
 269 dispensing or administrative fee shall be waived;

270 11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing
 271 controlled substances to his own patients in a free clinic without charge when such controlled substances
 272 are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The
 273 practitioner shall first obtain a controlled substances registration from the Board and shall comply with
 274 the labeling and packaging requirements of this chapter and the Board's regulations; or

275 12. Prevent any pharmacist from providing free health care to an underserved population in Virginia
 276 who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate
 277 to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers
 278 to provide free health care to an underserved area of this Commonwealth under the auspices of a
 279 publicly supported all volunteer, nonprofit organization with no paid employees that sponsors the
 280 provision of health care to populations of underserved people throughout the world, (iv) files a copy of
 281 the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least
 282 ~~15~~ five business days prior to the voluntary provision of services of the dates and location of such
 283 service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in
 284 compliance with the Board's regulations, during the limited period that such free health care is made
 285 available through the volunteer, nonprofit organization on the dates and at the location filed with the
 286 Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been
 287 previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be
 288 in violation of applicable laws or regulations. *However, the board shall allow a pharmacist who meets*
 289 *the above criteria to provide volunteer services without prior notice for a period of up to three days,*
 290 *provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in*
 291 *another state.*

292 This section shall not be construed as exempting any person from the licensure, registration,
 293 permitting and record keeping requirements of this chapter or Chapter 34 of this title.

294 § 54.1-3801. Exceptions.

295 This chapter shall not apply to:

296 1. The owner of an animal and the owner's full-time, regular employee caring for and treating the
 297 animal belonging to such owner, except where the ownership of the animal was transferred for the
 298 purpose of circumventing the requirements of this chapter;

299 2. Veterinarians licensed in other states called in actual consultation or to attend a case in this
 300 Commonwealth who do not open an office or appoint a place to practice within this Commonwealth;

301 3. Veterinarians employed by the United States or by this Commonwealth while actually engaged in
 302 the performance of their official duties; or

303 4. Veterinarians providing free care in underserved areas of Virginia who (i) do not regularly practice
 304 veterinary medicine in Virginia, (ii) hold a current valid license or certificate to practice veterinary
 305 medicine in another state, territory, district or possession of the United States, (iii) volunteer to provide

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18VAC110-20-75. Registration for voluntary practice by out-of-state licensees.

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of §54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all volunteer, nonprofit organization with no paid employees that sponsors the provision of health care to populations of underserved people throughout the world shall:

1. File a complete application for registration on a form provided by the board at least 15 days prior to engaging in such practice;
2. Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;
3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;
4. Pay a registration fee of \$10; and
5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of §54.1-3301 of the Code of Virginia.

1 VIRGINIA ACTS OF ASSEMBLY — CHAPTER

2 *An Act to amend and reenact § 54.1-3411.1 of the Code of Virginia, relating to donation of prescription*
3 *medications.*

4 [H 85]

5 Approved

6 **Be it enacted by the General Assembly of Virginia:**

7 **1. That § 54.1-3411.1 of the Code of Virginia is amended and reenacted as follows:**

8 § 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

9 A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange
10 for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed
11 from the pharmacy premises from which they were dispensed except:

12 1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in
13 accordance with practice standards;

14 2. In such cases where official compendium storage requirements are assured and the drugs are in
15 manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets
16 official compendium class A or B container requirements, or better, and such return or exchange is
17 consistent with federal law; or

18 3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.

19 B. Pursuant to a voluntary agreement between a nursing home or a hospital and a pharmacy, drugs
20 may be transferred in accordance with subdivision A 2 between the nursing home or the hospital and the
21 pharmacy for re-dispensing to patients of clinics organized in whole or in part for the delivery of health
22 care services without charge, or to the indigent, free of charge, if the following procedures are satisfied:

23 1. The physical transfer shall be accomplished by a person authorized to do so by the pharmacy;

24 2. The person or his authorized representative from whom the prescription medication was obtained
25 shall provide written consent for the donation and such consent shall be maintained on file at the
26 licensed nursing home or hospital;

27 3. The person's name, prescription number, and any other patient identifying information, shall be
28 obliterated from the packaging prior to removal from the licensed nursing home or hospital;

29 4. The drug name, strength, and expiration date or beyond-use date shall remain on the medication
30 package label;

31 5. An inventory list of the drugs shall accompany the drugs being transferred that shall include, but
32 not be limited to, the medication names, strengths, expiration dates, and quantities; and

33 6. Outdated drugs shall not be transferred and shall be destroyed in accordance with regulations
34 adopted by the Board.

35 The pharmacist in charge at the pharmacy shall be responsible for determining the suitability of the
36 product for re-dispensing. A re-dispensed prescription shall not be assigned an expiration date beyond
37 the expiration date or beyond-use date on the label from the first dispensing and no product shall be
38 re-dispensed more than one time. No product shall be accepted for re-dispensing by the pharmacist
39 where integrity cannot be assured.

40 *The Board of Pharmacy shall promulgate regulations to establish a Prescription Drug Donation*
41 *Program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in*
42 *subdivision A2, for the purpose of re-dispensing such drugs to patients of clinics organized in whole or*
43 *in part for the delivery of health care services to the indigent. Such program shall not authorize the*
44 *donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be*
45 *re-dispensed unless the integrity of the drug can be assured.*

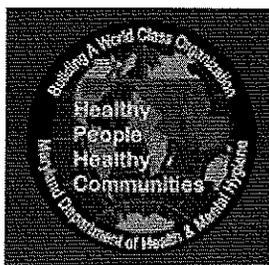
46 C. Nothing in this section shall authorize the donation of unused prescription drugs dispensed for use
47 by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended.

48 D. *A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the*
49 *transfer of any prescription or any consumer information regarding the transferred prescription*
50 *medication pursuant to this section.*

51 **2. That the Board shall promulgate regulations to implement the provisions of this act to be**
52 **effective within 280 days of its enactment.**

53 **3. That, notwithstanding the due course effective date of this act, the provisions in subsection B**
54 **shall remain in effect until regulations promulgated by the Board of Pharmacy for the**
55 **establishment of a Prescription Drug Donation Program become effective.**

25



**MARYLAND
BOARD OF PHARMACY PRESCRIPTION
DRUG REPOSITORY PROGRAM**

**ANNUAL REPORT TO THE GOVERNOR
AND
THE GENERAL ASSEMBLY**

January 1, 2007

26

**MARYLAND BOARD OF PHARMACY PRESCRIPTION DRUG REPOSITORY
PROGRAM**

ANNUAL REPORT

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Anna D. Jeffers, Legislation and Regulations Manager

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EXECUTIVE SUMMARY

This is the first annual report on the operation of the Prescription Drug Repository Program (the "Program") as required by Health-General Article, 15-609(b)(3), Annotated Code of Maryland. A Task Force of stakeholders, listed in Appendix I, worked diligently during the fall of 2005 and the winter of 2006 to provide recommendations to the Maryland General Assembly and the Board of Pharmacy. The General Assembly used those recommendations to introduce and pass Senate Bill (SB) 1059 to establish the Program during the 2006 Legislative Session. The Board of Pharmacy used the Task Force's recommendations and SB 1059 to develop and promulgate regulations to implement the Program. The Board of Pharmacy utilized the statute and proposed regulations to develop the necessary donor and recipient forms, and applications for drop-off sites and/or repositories to be approved for this Program. As soon as promulgation of the regulations is completed, the Program will be fully operational and ready to accept applications for approval of drop-off sites and repositories. It is anticipated that the proposed regulations will be effective by the end of December 2006 or in early January 2007.

INTRODUCTION

Senate Bill 441 – Task Force on the Establishment of a Prescription Drug Repository Program - was passed to study and make recommendations regarding the establishment of a Prescription Drug Repository Program in Maryland. The Maryland Board of Pharmacy (the "Board") chaired and staffed the Task Force for the Department of Health and Mental Hygiene (the "Department"). The Task Force submitted a First Interim Report January 1, 2006 to comply with SB 441.

The Task Force submitted a Second Interim Report on February 28, 2006 that included recommendations that could be considered for use in related proposals for legislation during the 2006 Legislative Session. The Second Interim Report was used as a basis for HB 1689 and SB 1059 - Prescription Drug Repository Program. Both bills passed, and SB 1059 was signed into law on May 6, 2006 as Chapter 287.

The Task Force submitted a Final Report, including recommendations for proposed regulations, on July 1, 2006. The proposed regulations were approved by the Maryland Board of Pharmacy on June 21, 2006 and were published in the Maryland Register on September 29, 2006. The proposed regulations are incorporated into this Report and are attached as Appendix II. Only one comment was received during the official regulatory comment period and that comment requested that the regulations include that the Program is voluntary on the part of drop-off sites and repositories. Since it is clearly set forth in the law that the Program is voluntary, the Board voted that it would be redundant to repeat this in the regulations and recommended final adoption as originally proposed. The effective date of the regulations is forthcoming.

OPERATION OF THE PROGRAM

The Program will consist of three key components: 1) administrative oversight by the Board of Pharmacy (regulatory agency); 2) repositories that are allowed to accept, dispense and/or dispose of drugs that do not meet the criteria for the Program; and 3) drop-off sites that are only allowed to receive and forward donated drugs to a Board approved repository. A description of each Program component follows.

Administrative Oversight Procedures

The Licensing Unit of the Board will receive the applications for approval of repositories and drop-off sites. The Program is completely voluntary and applications may be submitted anytime after the effective date of the regulations. The Prescription Drug Repository Program Application for Approval is attached as Appendix III. Once the application and necessary documentation is complete, the applications will be presented to the Licensing Committee and then the full Board for approval. Since only pharmacies may be approved as repositories, the Board will monitor repositories as a part of its existing annual pharmacy inspection process. Drop-off sites may be either a pharmacy or other health care facility. If the site is a pharmacy, the Board will incorporate monitoring of the site as part of its existing inspection process. The Board is developing procedures for monitoring other health care facilities and anticipates inspecting these sites to insure Program compliance or in some cases developing memorandums of agreement with agencies that are already responsible for monitoring health care facilities to act as the Board's agent.

When the regulations become effective, the Board will be ready to begin the operation of the Program. Forms and information will be available on the Board's website at www.mdbop.org once the regulations are effective.

Designated Repositories and Repository Acceptance, Storing and Dispensing Procedures

The basis for Board approval of a repository will begin with the submission of a Prescription Drug Repository Program Application for Approval. The repository must be a pharmacy that is in good standing with the Board. Pursuant to Health-General Article, § 15-605, Annotated Code of Maryland, Medbank of Maryland, Inc. may also apply to be a repository. The repository will accept and dispense donated prescription drugs or medical supplies received from approved drop-off sites. The repository must designate a pharmacist to accept and inspect the donated prescription drugs and medical supplies. If the donated prescription drugs are ineligible drugs and/or medical supplies, then the repository will dispose of them. The designated pharmacist will also obliterate patient specific information from the labels of donated prescription drugs or medical supplies. Repositories may not resell donated prescription drugs or medical supplies or establish or maintain a waiting list. A repository may charge a fee of not more than \$10 per dispensed prescription. A recipient of the donated prescription drugs or medical supplies may complete a Recipient Form at their prescriber's office or upon receiving their prescription at the repository. See Appendix IV for a sample Recipient Form. The standards and procedures for safely storing donated prescription drugs or medical supplies shall be in accordance with existing State and federal laws and regulations, except that donated prescription drugs or medical supplies must be stored in a secure location separate from other inventories. The standards and procedures for dispensing, shipping and disposing of donated prescription drugs or medical supplies will also be the same standards and procedures currently set forth in State and federal laws and regulations.

Designated Drop-Off Sites and Donation Procedures

The basis for Board approval of a drop-off site will begin with the submission of a Prescription Drug Repository Program Application for Approval. Designated drop-off sites may be a pharmacy or other health care facility that is in good standing with its respective licensing board. Once a donor, or the donor's representative, makes the decision to donate prescription drugs or medical supplies, they may only donate at approved designated volunteer drop-off sites. At the drop-off site, the donor will complete a Repository Program Donor Form and then donate the prescription drugs or medical supplies. See Appendix V for a sample Repository Program Donor Form.

A pharmacist or other health care practitioner at the drop-off site will place the donated items in a sealed bag with the signed Donor Form, label the bag with a control number and place the sealed bag in a secure box designated for prescription drugs or medical supplies donated to the Program. The drop-off site will then forward the sealed bags of donated prescription drugs or medical supplies to an approved repository at least every two weeks. The drop-off site may not dispense donated prescription drugs or devices, resell them, or charge a fee for accepting donations.

CONCLUSION

The Prescription Drug Repository Program Task Force, the General Assembly and the Board worked together to research, develop and establish this Program over a relatively short period of time. The success of this Program will depend on the number of pharmacies and health care facilities that apply to be drop-off sites and repositories. This Program is entirely voluntary on the part of pharmacies and health care facilities. The only potential repository that has been identified is Medbank of Maryland, Inc. (Medbank).

There have been no potential drop-off sites identified at this time. One obstacle for any potential drop-off site is a funding source, or mechanism, for delivering donated prescription drugs and/or medical supplies to the designated repositories. There are some existing "pony" systems available, but not for all potential drop-off site locations. Various non-profit organizations, however, have expressed interest in privately funding certain aspects of the Program. Pharmacies could also offer their participation in the Program as a repository or drop-off site as an additional service to their customers and their communities.

The implementation of a Prescription Drug Repository Program is a national trend, and Maryland can be proud that it is among the states that have tackled this important issue. Maryland's Prescription Drug Repository Program, however, is not a panacea for connecting unused prescription medications with needy patients. Many unused prescription medications are not eligible for donation into this Program. If a bottle of medication has been opened, no matter how expensive or medically valuable to those in need, it is ineligible for the Program. In addition, controlled drugs and medications requiring refrigeration may not be accepted.

Many patients and family members of patients have expressed an interest in donating their unused prescription medications and medical supplies. Many indigent and needy patients are looking for affordable or free prescription medications or medical supplies. The success of the Program will depend on the interest of the pharmacies and health care communities in participating and supporting this Program. Maryland patients, and family members of patients, are ready and willing to participate.

APPENDIX I

TASK FORCE PARTICIPANTS

American Cancer Society

Arnold L. Amass, Pharm. D.

Pharmacy Representative

Lynette R. Bradley-Baker, R.Ph., Ph.D.

Nursing Home Representative

Elizabeth R. Bowerman

Community Health Center

Howard C. Cohen

House of Delegates

Delegate Donald B. Elliott

Delegate David D. Rudolph

Maryland Board of Pharmacy

Donald W. Taylor, Chairman of the Task Force and Board of Pharmacy Member

Pharmaceutical Industry

Philip D. Noguchi, M.D.

Office of Health Care Quality

William Vaughan

University of Maryland, School of Pharmacy

Francis Palumbo, Esquire, Ph.D.

Maryland Medical Assistance Program

Frank Tetkoski

Board of Pharmacy Staff

LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

APPENDIX II

Subtitle 34 BOARD OF PHARMACY

10.34.33 Prescription Drug Repository Program

*Authority: Health-General Article, §§15-601—15-609,
Annotated Code of Maryland*

Notice of Proposed Action

[06-281-P]

The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.12 under a new chapter, **COMAR 10.34.33 Prescription Drug Repository Program**. This action was considered by the Board of Pharmacy at a public meeting held June 21, 2006, notice of which was given by publication in the Daily Record, Legal Section: Misc. Public Notices, June 12—16, 2006, pursuant to State Government Article, §10-506(c), Annotated Code of Maryland;

Statement of Purpose

The purpose of this action is to adopt regulations for the Board of Pharmacy to govern a Prescription Drug Repository Program in Maryland. The purpose of the program is to accept donated prescription drugs and medical supplies for the purpose of dispensing to needy individuals.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. There is a minimal economic impact on the Board staff due to receiving and reviewing drop-off site and repository applications, and issuing confirmations of designation as a drop-off site or repository to permit holders who have applied to be drop-off sites or repositories. This additional workload for the staff can be absorbed at this time. As the program develops, the Board may reassess at a later date the necessity for imposing a fee for applications for designation of drop-off sites or repositories.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+)	Magnitude
	Cost (-)	
D. On regulated industries or trade groups:	(+)	Undeterminable
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Undeterminable

III. Assumptions. (Identified by Impact Letter and Number from Section II.) D. and F. There is a positive unquantifiable economic impact on the public and the regulated industry due to the broader availability of medications for needy individuals.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Department of Health and Mental Hygiene, 201 W. Preston St. Room 512, Baltimore, Maryland 21201, or call 410-767-6499, or email to regs@dhhm.state.md.us, or fax to 410-333-7687. Comments will be accepted through October 30, 2006. A public hearing has not been scheduled.

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Board" means the State Board of Pharmacy.

(2) "Drop-off site" means a pharmacy or other health care facility designated by the Board for the purpose of receiving donated prescription drugs or medical supplies.

(3) Health Care Facility.

(a) "Health care facility" means:

(i) A hospital, as defined in Health-General Article, §19-301(g), Annotated Code of Maryland;

(ii) A limited service hospital, as defined in Health-General Article, §19-301(e), Annotated Code of Maryland;

(iii) A related institution, as defined in Health-General Article, §19-301(o), Annotated Code of Maryland;

(iv) An ambulatory surgical facility;

(v) A rehabilitation facility;

(vi) A home health agency, as defined in Health-General Article, §19-401(b), Annotated Code of Maryland;

(vii) A hospice, as defined in Health-General Article, §19-901, Annotated Code of Maryland;

(viii) A kidney disease treatment facility, or the kidney disease treatment stations and services provided by or on behalf of a hospital, if the facility or the services do not include kidney transplant services or programs;

(ix) The office of one or more individuals licensed to practice dentistry under Health Occupations Article, Title 4, Annotated Code of Maryland, for the purposes of practicing dentistry;

(x) A comprehensive care facility located in Maryland; or

(xi) Other health institutions, services, or programs that may be specified as requiring a Certificate of Need under State law.

(b) "Health care facility" does not mean a hospital or related institution operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts.

(4) "Health care practitioner" means an individual who is licensed, certified, or otherwise authorized under the Health Occupations Article, Annotated Code of Maryland, to provide health care services in the ordinary course of business or practice of a profession and has prescribing authority in this State.

(5) "Pharmacist" means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

(6) "Pharmacy" means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.

(7) "Program" means the Prescription Drug Repository Program.

(8) "Repository" means a pharmacy that applies to and is designated by the Board for the purpose of:

(a) Accepting donated prescription drugs or medical supplies from a drop-off site;

(b) Inspecting donated prescription drugs or medical supplies; and

(c) Dispensing donated prescription drugs or medical supplies for use by needy individuals.

.02 Eligible Drugs.

A. Prescription drugs or medical supplies may be donated at a drop-off site.

B. Prescription drugs or medical supplies may be accepted for dispensing if the prescription drugs and medical supplies are:

(1) In their original unopened and sealed packaging; or

(2) Packaged in single unit doses when the outside packaging is opened if the single unit dose packaging is undisturbed.

.03 Ineligible Drugs.

A. Prescription drugs or medical supplies may not be accepted for dispensing if the prescription drugs or medical supplies:

(1) Bear an expiration date that is less than 90 days from the date the drug is donated to ensure the potency and quality of the prescription drugs or medical supplies;

(2) Have been adulterated, according to the standards of Health-General Article, §21-216, Annotated Code of Maryland, because adulterated prescription drugs or medical supplies have been determined to be a threat to public health;

(3) Are designated controlled dangerous substances by the U.S. Drug Enforcement Administration which has determined that controlled dangerous substances may not be donated under a repository program;

(4) Require refrigeration because the potency and quality may not be guaranteed; or

(5) Have been previously compounded because compounded prescription drugs are patient specific.

B. The repository shall dispose of donated prescription drugs or medical supplies if they are not accepted into the Program for the purpose of dispensing.

.04 Donor Form.

A. A donor of a prescription drug or medical supply shall sign a form containing the following statements:

- (1) That the donor is the owner or the owner's representative of the prescription drug or medical supply; and*
- (2) That the donor intends to voluntarily donate the prescription drug or medical supply to the Program.*

B. The drop-off site shall:

(1) Require that the donor form contain:

- (a) The signature of the donor or the donor's representative;*
- (b) Contact information of the donor or the donor's representative; and*
- (c) The date of donation;*

- (2) Require that the donor form be completed before any donation;*
- (3) Provide a copy of the donor form to the donor or the donor's representative; and*
- (4) Maintain a copy of the donor form for 5 years.*

.05 Drop-Off Sites.

A. In order to become a drop-off site, a pharmacy or other health care facility:

- (1) Shall submit an application to the Board to be designated as a voluntary drop-off site;*
- (2) Shall be in good standing with the Board or the Office of Health Care Quality;*
- (3) May not have a final disciplinary order issued against it by a health occupations board;*
- (4) May not be owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations boards;*
- (5) Shall maintain records of donated prescription drugs or medical supplies; and*
- (6) Shall assign a pharmacist or other health care practitioner the responsibility to accept donated prescription drugs or medical supplies at the drop-off site.*

B. Assigned Pharmacist or Other Health Care Practitioner's Responsibility. A pharmacist or health care practitioner accepting donated prescription drugs or medical supplies at a drop-off site as set forth in §A(6) of this regulation:

- (1) May not delegate acceptance of donated prescription drugs or medical supplies;*
- (2) May refuse to accept hazardous prescription drugs or medical supplies for donation if the decision is based on professional judgment, experience, knowledge, or available reference materials;*

(3) Shall be in good standing with the pharmacist's or health care practitioner's respective health occupations board; and

(4) Shall have fulfilled the requirements of a final disciplinary order that may have been issued against the pharmacist or health care practitioner by a health occupations board.

C. Record Requirements. A drop-off site shall:

(1) Obtain a signed donor form releasing the prescription drug or medical supplies to the Program;

(2) Provide a copy of the signed donor form to the donor; and

(3) Maintain records of signed donor forms for 5 years.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A drop-off site shall:

(a) Place the donated prescription drug or medical supply and the donor form in a sealed bag;

(b) Store the bag containing the donated prescription drugs or medical supplies in an area accessible only to those pharmacists or health care practitioners who have been assigned the responsibility to accept the donated prescription drugs or medical supplies; and

(c) Forward the sealed bags of donated prescription drugs or medical supplies to the repository at least every 2 weeks.

(2) A drop-off site may not:

(a) Dispense donated prescription drugs or medical supplies;

(b) Resell prescription drugs or medical supplies donated to the Program;

(c) Charge a fee for accepting a donation; or

(d) Accept donated prescription drugs or medical supplies until the drop-off site applicant has been approved by the Board.

.06 Repositories.

A. In order to become a repository, a pharmacy:

(1) Shall submit an application to the Board to be designated as a repository;

(2) Shall be in good standing with the Board;

(3) May not have a final disciplinary order issued against it by the Board; and

(4) May not be owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations boards.

B. Designated Pharmacist. A repository shall designate a pharmacist who shall:

(1) Accept donated prescription drugs or medical supplies forwarded by:

(a) A drop-off site; or

(b) A manufacturer regulated by the U.S. Food and Drug Administration.

(2) Inspect donated prescription drugs or medical supplies;

(3) Accept donated prescription drugs or medical supplies that meet the requirements of Regulations .02 and .03 of this chapter; and

(4) Obliterate from the labels of donated prescription drugs or medical supplies patient specific information for which the donated prescription drugs or medical supplies were originally dispensed when it is placed in inventory.

C. Record Requirements. A repository shall:

(1) Maintain a separate inventory of donated prescription drugs or medical supplies;

(2) Maintain separate prescription files for patients receiving donated prescription drugs or medical supplies; and

(3) Submit an annual report on its activities to the Board that includes at least information on the:

(a) Number of recipients by county;

(b) Approximate market value of the prescription drugs or medical supplies dispensed;

(c) 50 prescription drugs or medical supplies most frequently dispensed; and

(d) Total number of donations to the Program.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A repository shall store donated prescription drugs or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.

(2) A repository may not:

(a) Resell prescription drugs or medical supplies donated to the Program; or

(b) Establish or maintain a waiting list for prescription drugs or medical supplies dispensed by the Program.

(3) A repository may charge a fee of not more than \$10 for each prescription drug or medical supply dispensed under the Program.

E. Limitations. A repository is under no obligation to obtain a prescription drug or medical supply that is not in inventory at the time of the request.

.07 Procedure for Dispensing Donated Prescription Drugs or Medical Supplies.

A repository shall dispense donated prescription drugs or medical supplies in compliance with applicable federal and State laws and regulations for dispensing prescription drugs or medical supplies.

.08 Procedure for Shipping Donated Prescription Drugs or Medical Supplies.

A repository shall comply with COMAR 10.34.25 when shipping donated prescription drugs or medical supplies to recipients of this Program.

.09 Procedures for Disposing of Donated Prescription Drugs or Medical Supplies.

A. A repository shall dispose of donated prescription drugs or medical supplies that do not meet the requirements of Regulation .02 of this chapter.

B. A repository shall dispose of donated prescription drugs or medical supplies in compliance with applicable State and federal laws and regulations for disposing of prescription drugs or medical supplies.

C. A repository shall maintain records of disposal of donated prescription drugs or medical supplies.

.10 Determination of Patient Eligibility.

A. A recipient of this program shall be a resident of the State.

B. A health care practitioner with prescribing authority shall:

(1) Determine, at the health care practitioner's discretion, the financial need of a patient to participate in the Program; and

(2) Indicate on the patient's prescription eligibility for this Program.

.11 Recipient Form.

Recipients of a donated prescription drug or medical supply under this Program shall sign a Board approved form before receiving the prescription drug or medical supply to confirm that the recipient understands that:

A. The recipient is receiving prescription drugs or medical supplies that have been donated to the Program; and

B. Entities involved in the program have immunity from liability in accordance with Health-General Article, §15-607, Annotated Code of Maryland.

.12 Record Keeping Requirements.

A. Drop-off sites and repositories shall maintain records required by this Program separately from other prescription records.

B. Drop-off sites and repositories shall maintain the following records for a minimum of 5 years:

(1) Inventory;

(2) Donor forms; and

(3) Prescription records.

S. ANTHONY McCANN
Secretary of Health and Mental Hygiene

APPENDIX III

PRESCRIPTION DRUG REPOSITORY PROGRAM APPLICATION (HG 15-601 - 609)

The Maryland Prescription Drug Repository Program (the "Program") was established to allow Maryland Board of Pharmacy (the "Board")- approved repositories and/or drop-off sites to accept donated prescription drugs and medical supplies for the purpose of dispensing the donated drugs to needy individuals.

An Application Must Be Filed:

- To become a repository that accepts and dispenses donated prescription drugs or medical supplies;
- To become a Board-approved drop-off site that accepts donated prescription drugs or medical supplies for transfer to a repository; and/or
- To notify the Board of a change in location or ownership of a pharmacy/health care facility previously approved to be a repository or a drop-off site under the Program.

Eligible Applicants:

• **Repository:**

The Board will approve an applicant that:

- Is a Maryland licensed pharmacy in good standing with the Board;
- Does not have a final disciplinary order issued against it by the Board; and
- Is not owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations board.

▪ **Drop-off Site:**

The Board will approve an applicant that:

- Is a Maryland licensed pharmacy, or health care facility as defined in COMAR 10.34.33.01B(3), that is in good standing with the Board and or the Maryland Office of Health Care Quality (OHCQ);
- Does not have a final disciplinary order issued against it by a health occupations board;
- Is not owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations board; and
- Assigns a pharmacist or other health care practitioner the responsibility to accept donated prescription drugs or medical supplies at the drop-off site.

PRESCRIPTION DRUG REPOSITORY APPLICATION INSTRUCTIONS

Please review all Program requirements under Health General §15-601 – 609, Annotated Code of Maryland and related regulations before completing the Prescription Drug Repository Application. All questions must be thoroughly answered. A response or explanation must be provided for all questions. An approval may be delayed if appropriate responses to all questions are not provided.

I. Applicant Information

- A. Application Type – Please indicate the services the applicant is seeking to provide in the state. Select one option only.
- B. Please provide all requested information about the pharmacy or health care facility where the service will be provided.
- C. The legal applicant is the individual that is authorized to respond to questions and make any decision regarding the operation of the pharmacy or health care facility. This individual may or may not be the same person that completes the application.

II. Ownership Description - Attach a list of the owners and corporate officers, for all levels of ownership. Include the following on the attachment: Name, Title, Percent ownership, Business address, Telephone Number, and Fax Number.

- A. Indicate the date that the pharmacy/facility initially opened.
- B. Indicate the date of the most recent inspection by the Board, Division of Drug Control, Office of Health Care Quality, and/or other health care facility licensing body in Maryland.
- C. Attach a detailed explanation about any violations (federal, state or local convictions) as requested.
- D. Indicate the type of ownership (select only one). If a corporation, list principal owners, indicate the corporate name, charter state and date of charter, and indicate whether it is a Public or Non-Public corporation.

III. BUSINESS OPERATIONS

- A. Indicate all applicable descriptions of the pharmacy.
- B. Indicate all applicable descriptions of the health care facility services.
- C. If the pharmacy/health care facility conducts business on the internet, describe the services and web site business name(s).
- D. Indicate the hours of operation for each day of the week.
- E. Personnel - List employees' names who will be accepting and dispensing donated prescription drugs or medical supplies, in addition to their scheduled hours and license/permit numbers and expiration dates. The Board must be notified in 30 days of any changes in pharmacists/health care practitioners employment.

IV. CERTIFICATION – Each item must be read and initialed by the legal applicant.

V. LEGAL SIGNATURE – The statement must be read and signed by the legal applicant.

Revised 11/17/06

MARYLAND BOARD OF PHARMACY
4201 PATTERSON AVENUE, BALTIMORE, MARYLAND 21215
410-764-4756 800-542-4964 FAX 410-358-6207
Web site: www.mdbop.org

APPLICATION FOR PRESCRIPTION DRUG REPOSITORY (HG 15-601 - 609)

BOARD USE ONLY

Date Received: _____ Date Approved: _____
Number: _____ Initials: _____

Please refer to instruction for completing the Application. Approval may be delayed if appropriate responses to all questions are not provided.

I. APPLICANT INFORMATION: DATE: _____

A. APPLICATION TYPE:

_____ Repository
_____ Drop-off Site
_____ Repository and Drop-Off Site

B. APPLICANT FACILITY INFORMATION:

1. _____
PHARMACY/HEALTH CARE FACILITY NAME - DOING BUSINESS AS (DBA) OR TRADE NAME

2. _____
CURRENT PERMIT/LICENSE NUMBER

3. _____
STREET ADDRESS

CITY STATE ZIP CODE

4. _____
BUSINESS TELEPHONE NUMBER BUSINESS FAX NUMBER

5. _____
WEB SITE ADDRESS EMAIL ADDRESS FEDERAL TAX ID NO.

C. PHARMACY/HEALTH CARE FACILITY CONTACT INFORMATION:

1. Legal Representative:

Name Title Telephone Fax

2. Person Completing Application:

Name Title Telephone Fax

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APPLICATION FOR PRESCRIPTION DRUG REPOSITORY (HG 15-601 - 609)

Page 2

II. Ownership Description:

A. Date Established: _____

B. Date of Last State Inspection: _____

C. Has the corporation or any officers thereof, or any partners, or the individual owner ever been convicted of violations of any federal, State, or local laws or regulations dealing with drug products or alcohol?

___ No ___ Yes, (If yes, attach a detailed explanation)

D. Ownership Information is attached: Yes ___ No ___

___ Individual Ownership

___ Partnership

___ Corporation

Corporate Name: _____

Principal Owner(s): _____

Charter State/Date: ___ / ___ Non-Public ___ Public ___

III. BUSINESS OPERATIONS

A. TYPE OF PHARMACY SERVICES:

___ Community (less than 10)

___ Hospital

___ Chain (10 + stores)

___ Long Term Care

___ Intravenous Therapy

___ Mail Order/Internet/USA

___ Veterinary

___ Clinic

___ Managed Care

___ Nuclear

___ Correctional Institution

___ Home Health

___ Independent

___ Pharmacy Service Center

___ Research

___ Mail Order/Internet Int'l

___ Nursing Home

___ HMO

___ Consultant

___ Medbank of Maryland, Inc.

___ Other (specify below)

B. TYPE OF HEALTH CARE FACILITY SERVICES:

___ Hospital

___ Nursing Home

___ HMO

___ Clinic

___ Long Term Care

___ Day Care

___ Free Clinic

___ Managed Care

___ Home Health

___ Other (specify below)

C. Services Provided Through the Internet? ___ No ___ Yes

1. Specify Services: _____

2. Website Business Name(s): _____

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APPENDIX IV
PRESCRIPTION DRUG REPOSITORY PROGRAM
RECIPIENT FORM

Date: _____

Name of recipient: _____

Address: _____

Phone Number: _____

Email address (optional): _____

List of prescription drugs or medical supplies received: _____

The recipient understands that:

The recipient is receiving prescription drugs or medical supplies that have been donated to the program,
and

Entities involved in the program have immunity from liability in accordance with Health-General
Article, §15-607, Annotated Code of Maryland.

Signature of Recipient



APPENDIX V

PRESCRIPTION DRUG REPOSITORY PROGRAM

DONOR FORM

Date of Donation: _____

Name of donor: _____

Address: _____

Phone Number: _____

Email address (optional): _____

List of donated prescription drugs or medical supplies: _____

I hereby certify that I am the owner, or the owner's representative, of the prescription drug(s) or medical supply(s) donated today. My donation of the prescription drug(s) or medical supply(s) to the program is voluntary.

Signature of donor

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DEFINITIONS

Rule 4729-35-01 [Update effective 01/01/2006]

As used in Chapter 4729-35 of the Administrative Code:

- (A) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code and in rule 4729-9-01 of the Administrative Code.
- (B) "Drug repository program" has the same meaning as in sections 3715.87 to 3715.873 of the Revised Code.
- (C) "Hospital" has the same meaning as in section 3715.87 of the Revised Code.
- (D) "Institutional facility" has the same meaning as in rule 4729-17-01 of the Administrative Code.
- (E) "Licensed health care professional" has the same meaning as in section 3715.872 of the Revised Code.
- (F) "Nonprofit clinic" has the same meaning as in section 3715.87 of the Revised Code.
- (G) "Original sealed and tamper-evident unit dose packaging" includes single unit dose packaging of oral medications from a manufacturer or a repackager licensed with the federal food and drug administration, or from a pharmacy licensed as a terminal distributor of dangerous drugs, and includes injectables, topicals, and aerosols in the manufacturer's or repackager's unopened original tamper-evident packaging.

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**ELIGIBILITY REQUIREMENTS FOR A PHARMACY,
HOSPITAL, OR NONPROFIT CLINIC**

Rule 4729-35-02 [Effective 01/01/2004]

A pharmacy, hospital, or nonprofit clinic may elect to participate in the drug repository program, pursuant to sections 3715.87 to 3715.873 of the Revised Code, if all of the following requirements are met:

- (A) Must be licensed as a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code.
- (B) Must comply with all federal and state laws, rules, and regulations.

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DONATING DRUGS

Rule 4729-35-03 [Effective 01/01/2004]

- (A) The following may donate a dangerous drug, pursuant to the eligibility requirements of rule 4729-35-04 of the Administrative Code, to a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program:
- (1) A licensed terminal distributor of dangerous drugs.
 - (2) A licensed wholesale distributor of dangerous drugs.
 - (3) A person who was legally dispensed a dangerous drug pursuant to a patient-specific drug order.
- (B) A person electing to donate an eligible dangerous drug shall not have taken custody of the drug prior to the donation. The person may direct the donation through a terminal distributor of dangerous drugs.
- (C) A person who resides in an institutional facility and was legally dispensed a dangerous drug pursuant to a patient-specific order may elect to sign and date a donor form prior to donating a drug, which shall state "from this day forward I wish to donate all my remaining unused drugs that are eligible, pursuant to rule 4729-35-04 of the Administrative Code, to the drug repository program".
- (D) A person designated by durable power of attorney, a guardian, or other individual responsible for the care and well-being of a patient may make the decision to donate an eligible dangerous drug.

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ELIGIBLE DRUGS

Rule 4729-35-04 [Update effective 01/01/2006]

All dangerous drugs, except controlled substances and drug samples, may be donated to a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program if the drugs meet all of the following requirements:

- (A) The drugs are in their original sealed and tamper-evident unit dose packaging. The packaging must be unopened except that the drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. If the drugs were packaged by a pharmacy the name of the pharmacy and any other pharmacy identifiers must be removed from the packaging prior to dispensing to a recipient patient. This may be accomplished by removing the drug from the pharmacy packaging or by removing the name from the outside packaging of a multiple dose unit dose packaging system.
- (B) The drugs have been in the possession of a licensed healthcare professional and not in the possession of the ultimate user.
- (C) The drugs have been stored according to federal food and drug administration storage requirements.
- (D) The drugs must have an expiration date of six months or greater.
- (E) The packaging must list the lot number and expiration date of the drug.
- (F) The drugs must not have any physical signs of tampering or adulteration.
- (G) The drug packaging must not have any physical signs of tampering.
- (H) All confidential patient information must have been removed from the drug packaging.

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