(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF BOARD MEETING

September 3, 2008
Second Floor
Conference Room 4

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

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| CALL TO ORDER: | The meeting was called to order at 9 a.m. |
| PRESIDING: | David C. Kozera, Chairman |
| MEMBERS PRESENT: | Gill B. Abernathy<br>John O. Beckner<br>Willie Brown<br>Jennifer H. Edwards<br>Bobby Ison<br>Leo H. Ross<br>Michael E. Stredler<br>Brandon K. Yi |
| STAFF PRESENT: | Elizabeth Scott Russell, Executive Director<br>Cathy M. Reiniers-Day, Deputy Executive Director<br>Caroline D. Juran, Deputy Executive Director<br>Howard M. Casway, Senior Assistant Attorney General<br>Sandra Whitley Ryals, Director, DHP<br>Elaine J. Yeatts, Senior Regulatory Analyst, DHP<br>Sharon Davenport, Administrative Assistant (business portion)<br>Elizabeth Revere, Disciplinary Program Specialist (disciplinary portion) |
| QUORUM: | With nine members present, a quorum was established. |
| APPROVAL OF AGENDA: | Mr. Kozera announced that a possible summary suspension will be considered following the formal hearing. |
| APPROVAL OF MINUTES: | The Board reviewed draft minutes for the June 4, 2008 Board Meeting; June 4, 2008 Panel Formal Hearings; June 17, 2008 Ad Hoc Committee-Drug Donation; June 19, 2008 ICC-Robotic Pharmacy System; June 25, 2008 SCC; July 1, 2008 TCC; July 17, 2008 SCC; July 23, 2008 Ad Hoc Committee-Drug Donation; July 31, 2008 SCC; and August 14, 2008 TCC. There were several technical corrections to the minutes of the June 4, 2008 Board Meeting. |
| **Motion:** | **The Board voted unanimously to approve the minutes as presented and amended by the Board. (motion by Beckner, second by Edwards)** |

PUBLIC COMMENTS: There were no public comments.

REPORT, DHP DIRECTOR Sandra Whitley Ryals, Director, reported on the Virginia Performs measures. She stated that Visual Research had developed a new method of measuring the department's outcomes with respect to its performance measures, and the Board was provided with fourth quarter statistics on the new measures. The 250-day goal for dispensation of patient care cases has been divided into three separate measures to better reflect the progress being made. The measures are clearance rate, age of pending caseload, and time to disposition. She stated that while there is still work to do, there has been significant progress in achieving the goal of closure of 90% patient care cases within 250 days.

Ms. Ryals stated that with the worsening revenue projections for the state, all agencies were being required to submit plans for 5, 10, and 15 percent cuts in budget. Although DHP is a non-general fund agency, it is also being asked to submit reduction plans. More details about budget cuts are expected to be released in December.

She also reported on upcoming legislation submissions for inclusion in the administration package. Ms. Ryals stated that while it is difficult for her to turn down requests of boards for legislative proposal submissions, she has been directed by the Secretary to only submit proposals deemed essential and that fit the Governor's initiatives. She stated that for this reason, and because of significant concerns expressed by interested parties, the two proposals from the Board of Pharmacy, CQI and mandatory reporting, are not included in her submissions this year. She stated that she is moving forward with a proposal for collection of fees to cover the costs of disciplinary processes, which is not without controversy, but it is an effort to assess some program costs to those persons who have had disciplinary proceedings. Florida uses this user fee approach to recoup costs. She stated that other proposals going forward were the result of other internal committees seeking more efficient and cost-effective ways of doing business, and looking at non-performing and non-government activities. She should be able to report more about the legislative proposals in December.

LEGISLATION UPDATE: Ms. Russell stated that the opposition on the two legislative proposals was primarily from the National Association of Chain Drug Stores. The issue with the CQI proposal related to concerns about required disclosure of work product in civil proceedings. Ms. Russell stated that currently there did not appear to be a way to address these concerns in state law to the satisfaction of NACDS. She stated over the next year, the proposed regulations to

implement the federal Patient Safety Act may become effective and would have been vetted by the various organizations. There are some protections from disclosure for voluntary reporting provided in these regulations. Once these regulations become effective, there may not be a need for a state requirement, or if there still is, there may be a better way to structure the requirement for CQI to use the federal protections. She stated that the objections to the mandatory reporting of impairment or other grounds for suspension of a license were varied, but included concern about persons being reported by persons not qualified to make determinations of impairment or incompetence. Based on NACDS comments, staff looked at changing the proposal to voluntary reporting with some protection from civil liability, but ultimately it was decided this initiative, particularly if changed from mandatory to voluntary, was not essential to agency operations.

Gerard Dabney joined the meeting at approximately 10 a.m.

REGULATION UPDATE:

Ms. Yeatts provided the Board with an update of ongoing regulatory processes. She stated that the proposed package resulting from regulation review is currently in the Governor's office awaiting approval to publish, as are the packages for emergency regulations for expiration date changes and fast-track regulations for changes to nuclear pharmacy regulations.

- Emergency Regulations for a Drug Donation Program

The Board reviewed draft regulations included in the agenda package that were developed by the ad hoc committee for establishing a drug donation program. The Board made an amendment to 18 VAC 110-20-750 B 4 to eliminate a need for a further definition of "restricted distribution system". It corrected the numbering in 18 VAC 110-20-770. Also, a change was made to 18 VAC 110-20-780 B to tie any dispensing fee directly to the allowable fee in § 54.1-3301, subsection 10 rather than tie the fee to the Medicaid dispensing fee directly. Ms. Russell stated that the Virginia Association of Free Clinics may be seeking a change to that section of law this next session, to increase what can be charged for a dispensing fee for manufacturer donated drugs as the current language does not cover costs.

**Motion:**

**The Board voted unanimously to adopt as emergency regulations, the draft regulations in the agenda package as amended by the Board, and publish a NOIRA for the replacement of emergency regulations. (motion by Ison, second by Brown)**

- Exempt PPG Regulations

Ms. Yeatts explained that the Department of Planning and Budget had developed standard regulations for public participation

guidelines and was requiring all agencies to adopt them. She stated that she had worked closely with DPB staff in the development and as a result, the standard regulations are not that different from the current PPG regulations. There is the ability for a Regulatory Advisory Panel under the new regulations, but this is not new for the Board, as it has frequently used such entities in developing regulations.

**Motion:**

**The Board voted unanimously to adopt the exempt PPG regulations, 18 VAC 110-11 and repeal the existing PPG regulations, 18 VAC 110-10. (motion by Stredler, second by Yi)**

- Consider proposing regulations for defining unprofessional conduct

The Board reviewed draft of proposed regulations that would define unprofessional conduct included in the agenda package.

**Motion:**

**Mr. Beckner moved to adopt the draft presented as proposed regulations, with a second by Mr. Ross. The Chairman called for discussion.**

The Board members had a number of questions concerning the wording of the draft document. Ms. Yeatts explained that a number of Boards had such regulations and that some of these were similar, some specific to pharmacy. Ms. Russell stated that staff had tried to include the types of activities for which the Department had received complaints in the past, but for which the Board has no authority to take actions, such as physical assault on a patient by a pharmacist, speaking of confidential information loudly enough where it was overheard by others, and using patient identifying information to initiate a personal relationship. Ms. Abernathy had a concern that one of the definitions could be construed to mean that a pharmacist's refusal to dispense a prescription could fit. Board members expressed concerns that the provisions were too broad and could capture activities not problematic. Mr. Casway explained that many grounds for disciplinary action were purposely broad, because if too narrowly drawn, then it would be impossible to make findings of a violation in many cases in which the Board would want to take action. Ms. Russell stated that the Board could defer any action on this matter until the next meeting, have the regulation committee meet and possibly accept public comment, and have a recommendation for the Board in December.

**Motion:**

**The Board voted unanimously to table the original motion, defer this matter until December, and refer it first to the regulation committee for further review and recommendation. (motion by Yi, second by Beckner)**

GUIDANCE DOCUMENT 110-25

Ms. Russell advised the Board that there had been a recent suspension of a physician's license by the Board of Medicine who had specialized in pain management. The Board had received numerous inquiries that the existing guidance document did not answer questions related to whether pharmacists could fill new prescriptions in these circumstances. The existing document only addresses refills. Ms. Russell stated that because most of the inquiries were related to Schedule II-IV controlled substances, she also checked with DEA as to its policy with respect to physicians no longer in practice. A representative of DEA stated that DEA's policy was consistent with the Board's guidance document, and could be extended to new prescriptions, but asked that there be an additional sentence advising pharmacists to more closely scrutinize these prescriptions before filling or refilling for validity when the prescriber had been suspended or revoked for violations related to prescribing. The Board reviewed draft changes to the guidance document as presented in the agenda package.

**Motion:**

**The Board voted unanimously to approve the amended guidance document as presented. (motion by Beckner, second by Stredler)**

GUIDANCE DOCUMENT 110-36

The Board reviewed a request sent by the Virginia Hospital and Healthcare Association asking for further delay, until March 2009, in requiring compliance with USP Chapter 797 standards for sterile compounding. The request suggested that the Board could grant waivers to hospitals under the provisions of 18 VAC 110-20-120. Ms. Russell stated that the waiver provision is not appropriate in this case because the requirement is in statute, not regulation, and the Board does not have the authority to waive a requirement of statute. Additionally, a hospital pharmacy would most likely not qualify for a waiver under this section because it would not meet the criteria to be a limited-use pharmacy. The Board discussed the fact that it had already delayed enforcement of the physical requirements of Chapter 797 at least three times since 2004, the most recent being the last board meeting with the delay until October 2008. There were no motions in this matter, but the Board asked Ms. Russell to respond to the request, addressing the concerns, and restating the Board's decision of June 2008.

BHP REPORT

Ms. Edwards reported that the Board of Health Professions had not met since the last Board of Pharmacy meeting, so she had no report at this time.

EXECUTIVE DIRECTOR'S REPORT

Ms. Russell stated that after a competitive bidding process, the contract for the pharmacy technician examination had been awarded to Schroeder Measurement Technologies, Inc. (SMT).

The committee that evaluated the proposals included herself, Mr. Yi, Mr. Kozera and Ms. Juran. She stated that the current vendor, ICPT, would continue administering the examination until December 31, 2008, and SMT would pick up administration on January 1, 2009. She advised that the examination committee would be reviewing the job analysis for this examination at some point after the new vendor takes over the process.

DISCIPLINARY REPORT

Ms. Reiniers-Day presented the Board's disciplinary caseload report as of September 2, 2008, and stated for patient care cases only there were 23 cases at the enforcement level, 38 cases at the probable cause level, 8 cases at the APD level, 7 cases at the informal conference level, 4 cases at the formal hearing level and 15 cases at the pending closure level. For all BOP cases, there were 57 cases at the enforcement level, 91 cases at the probable cause level, 7 cases at the informal conference level, 5 cases at the formal hearing level and 11 cases at the APD level.

LICENSING REPORT

Ms. Juran reported that the Board issued 946 additional licenses since the last full Board meeting on June 4, 2008. Of those licenses issued, 312 were for pharmacists, 14 for pharmacies, 507 for pharmacy technicians and 17 for physicians selling controlled substances. Ms. Juran also reported that the Board's Web site now includes a link to NABP's Web site regarding buying medicine online. This link provides information on obtaining drugs from internet pharmacies and lists the names of internet pharmacies which NABP recommends, does not recommend, or has reviewed. Additionally, the Board has included instructions for obtaining a pharmacist license through examination or reciprocity in a more prominent location on its homepage. Lastly, Ms. Juran stated that in August 2008, an informal conference committee approved a robotic pharmacy system for Virginia Hospital Center Arlington Pharmacy. It was approved for three years from the date of implementation; however, the Board has not yet been informed of the specific date for implementation.

FORMAL HEARING

RICHARD B. LAKES
Pharmacist
License Number:
0202-004156

A formal hearing in the matter of Richard B. Lakes was held to discuss his petition for reinstatement of his pharmacist license that was mandatorily suspended on March 30, 2007, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy in Virginia.

William Clay Garrett, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Mr. Lakes appeared and was not represented by counsel.

Vicki Fox, DHP Senior Investigator, testified on behalf of the Commonwealth.

Richard B. Lakes testified on his own behalf.

Mr. Yi stated that he works for Giant Pharmacy, had not supervised Mr. Lakes and could make a fair and impartial decision in this matter. There were no objections from Mr. Lakes or the remaining board members.

Closed Meeting: Mr. Stredler moved, and the Board voted unanimously, to enter into a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Richard B. Lakes. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell, Caroline Juran and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation

Reconvene: Mr. Stredler 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 meeting were heard, discussed or considered during the closed meeting.

**Decision:** **Mr. Stredler moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett, amended by the Board and read by Mr. Casway (Attachment #1).**

**Mr. Beckner moved, and the Board voted seven in favor of the motion, two opposed the motion, and one abstention, for the reinstatement of Mr. Lakes' license. The motion failed as three-quarters of the Board's vote is required for the motion to pass. (Attachment #1).**

Mr. Dabney departed at approximately 3:30 p.m.

SUMMARY SUSPENSION:

Closed meeting**:** Mr. Stredler moved, and the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Elizabeth Revere, Howard Casway, Wayne Halbleib and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

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| MARK MANNERS<br>Pharmacy Technician<br>Registration Number:<br>0230-004353 | Wayne Halbleib, Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present. |
| Reconvene**:** | Mr. Stredler moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting. |
| **Decision:** | **Mr. Beckner moved, and the Board voted unanimously in favor of the motion that, according to the evidence presented, the pharmacy technician practice by Mark Manners poses a substantial danger to the public; and therefore, the registration of Mark Manners to practice as a pharmacy technician be summarily suspended and that a Consent Order be offered to Mr. Manners for the indefinite suspension of his registration in lieu of a hearing.** |
| ADJOURN: | With all business concluded, the meeting adjourned at 3:45 p.m. |

Elizabeth Scott Russell
Executive Director

David C. Kozera, Board Chairman

Date