

Maryland Board of Pharmacy

Public Board Meeting – March 21, 2001

The Public Meeting was called to order at 8:45 a.m.

ATTENDANCE:

Commissioners Present: Stanton Ades, President; W. Irving Lottier, Jr., Secretary; Commissioners: Ramona McCarthy-Hawkins; John Balch; Raymond C. Love; Wayne Dyke; Melvin Rubin; Barbara Faltz-Jackson; Laura Schneider; Jeanne Furman and Donald K. Yee

Commissioners Absent: Reverend William E. Johnson, Sr.

Board Counsel: Paul Ballard, Linda Bethman

Board Staff: LaVerne G. Naesea, Executive Director; Michelle Andoll, Pharmacy Compliance Officer; Deitra Gale, Compliance Specialist; James Slade, Legislative/Regulatory Officer; Tamarra Banks, Network & Information Services; Sharon Demory-Cornish, Personnel Officer; Joan Lawrence, Public Education & Information Specialist; Doris Thomas, Licensing Supervisor, and Sandra A. Hines, Executive Secretary.

Guest: Howard Schiff (MPhA); Robert Vlk (Purdue); Mary Kaysen (DuPont Pharmaceuticals); Jack Freedman (Division of Drug Control); Russell Moy (DHMH-CPHA); Gilbert Cohen (PEAC); Laden Tankut (Student); Laura Borda Short (TARO Pharmaceuticals); Kathryn Lavriha (BARR Laboratories)

INTRODUCTION

President Ades asked each guest to introduce him or herself.

Recusals

There were no recusals of Commissioners due to conflicts of interest.

Corrections and Approval of Minutes

Page 2: third paragraph, third sentence should be “after they have a second review”

Page 4: last paragraph, first sentence should be “from the Health Department whether regulations or statutory changes will be required.”

Ms. Faltz-Jackson moved to accept the minutes with correction amendments. Dr. Love seconded the motion, which was passed by the Board.

President/Executive Committee Report

Update on Law Book Contracts

President Ades announced that Lexis Publishing is ready to distribute the Law Books. Lexis will mail approximately 1,800 books to all the establishments in Maryland, and will supply 200 plus books to the Board for distribution. The Board will provide MPhA with a \$2,500 grant award for a related project to benefit Pharmacies and Pharmacist in Maryland.

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Maryland State Advisory Council

President Ades reported that Dr. Benjamin's office has requested that a volunteer from the Board sit on an Advisory Council to talk about confidentiality and the impact that HIPPA will have on Health Care in Maryland. Ms. Kim Mayer, who will chair the Advisory Council, invited the Board of Physician Quality Assurance, Kaiser Permanente and other Organizations to participate. The Council will meet every second Thursday of the month at 6:00 p.m. The next meeting is scheduled for April 12, 2001 at 201 W. Preston Street, Room L-3. Dr. Love volunteered to sit on the Advisory Council

Shortage of Pharmacist

President Ades announced that he and Ms. Naesea are scheduled to meet with Dr. Benjamin on Thursday, March 22, 2001, to discuss the shortage of pharmacist.

President Ades suggested that the Board's starting time change because at the geographical diversity of the Board members and the time it takes for them to arrive by 8:30 a.m. for Board meetings, during inclement weather. Ms. Furman moved that the Board meetings began at 9:00 a.m. Ms. Faltz-Jackson seconded the motion, which was passed by the Board.

Executive Director's Report

NABP's 97th Annual Meeting

Ms. Naesea announced that she, Mr. Rubin, Mr. Yee, Mr. Lottier, Ms. Furman, Ms. Andoll, and Mr. Slade, will attend NABP's Annual Meeting.

Board of Pharmacy Strategic Planning Update

Ms. Naesea presented draft language for the Strategic Plan to the Board for approval. In order to have the plan published by April, Ms. Naesea requested that the Board submit any comments or recommendations to her as soon as possible.

Senate Budget Hearing

Ms. Naesea reported that the Board's budget request to the Legislature was cut by approximately \$75,000. All Boards had their budget cut.

Pharmacy School

Ms. Naesea reported that she, Ms. Andoll and Ms. Thomas attended the Pharmacy Leadership Society Presentation at the University of Maryland Pharmacy School. They each gave a synopsis of the Board to the Phi Sigma Linden Society.

Kaiser Permanente Training

Ms. Naesea reported that she, Mr. Yee, and Mr. Slade attended a Kaiser Permanente Training. The training focused on clinical practice issues, medication, social work, nursing issues, and clinical needs of end stage patients.

Staffing Updates

Ms. Demory-Cornish formally introduced Ms. Joan (pronounced Jo Ann) Lawrence, the new Public Relations and Educational Specialist, to the Board.

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Ms. Demory-Cornish reported that she is in the process of converting Mr. Vladimir Konstantinov's Data Base Specialist position into a permanent State position. The process will take six to eight weeks.

Ms. Demory-Cornish reported that she is submitting paperwork to Personnel to convert the Board's licensing clerk duties from the Licensing Unit, to an Office Receptionist/Staff Secretary position. This process will take six to eight weeks.

Ms. Naesea reported that the Board shares Mr. Slade, Regulation and Legislative Specialist, with the Board of Social Work (50/50). The Board is interested in hiring Mr. Slade full-time. However, the Board of Social Work is not willing to relinquish its 50% of Mr. Slade's position. Ms. Naesea contacted the Department of Personnel who recommended that the Board of Social Work develop a second full-time Regulations and Legislative contractual position that Mr. Slade can delegate and supervise. After a year as a contractual position, it can be converted to a permanent position.

Ms. Hines announced that the directory of Board members' home addresses and telephone numbers are being updated and to notify her of any changes or corrections. An updated directory of Board staff telephone numbers was distributed to Board members.

Ms. Naesea reported that Ms. Lawrence is in the process of changing the format for the Annual Report. The report should be ready in October.

Board Counsel Report

Attorney General's Letter to Pharmacists

Mr. Ballard reported that the Attorney General distributed a thank you letter to the Maryland Pharmacists Association enlisting Maryland pharmacists' help in getting notice of the Mylan lorazepam and clonazepam settlement to consumers. The refunds are being made available in connection with a \$100 million antitrust settlement entered into by the State Attorney General on behalf of consumers nationwide.

Contact Lens

Mr. Ballard reported that the FDA's Center for Devices and Radiological Health stated that: Contact lenses are classified as medical devices under 21 CFR 886.5916, Rigid gas permeable contact lenses and 21 CFR 886.5925, Soft (hydrophilic) contact lenses.

Contact lenses, including zero powered lenses with enhancement tint, are prescription medical devices as defined in Title 21 of the Code of Federal Regulations Part 801.109 (21 CFR 801.109). FDA originally cleared these devices as prescription devices since it is necessary for an eye care practitioner to evaluate the ocular health and refractive needs of the user, as well as, the fit of the lens to the eye. Since a degree of learned intervention is necessary for the device to be used safely, adequate directions for use by a layperson cannot be written.

If a dispenser sells a contact lens without receiving a valid prescription from an eye care practitioner, it is a violation of the restriction for prescription use that was placed on the device when it was cleared for marketing by FDA. Distributors or dispensers that do not adhere to the prescription labeling requirements misbrand the device. This misbranding occurs at the distributor level, not at the manufacturer level.

Mr. Ballard suggested that the Board of Pharmacy and the Board of Optometry work together to develop an order for establishments to cease and desist in distributing color contact lens without a prescription order.

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Legislative Officer Report

Legislative Update

Mr. Slade reported on the following Bills:

SB 289 entitled Health Care – Programs and Facilities – Pain Management. Ms. Furman testified at the Hearing on February 23, 2001.

SB 334 entitled Nursing Home Residents – Prescription Drugs – Choice of Pharmacy. The Bill has been withdrawn.

HB 418 entitled Drugs and Prescription Records – Impounding and Disposing. The Bill had its second reading.

SB 686 entitled Health Insurance Benefit Cards, Prescription Benefit Cards, or Other Proof of Insurance. Also, HB 807 entitled Health Insurance Benefit Cards, Prescription benefit Cards, or Other Technology. President Ades and Mr. Slade will testify at the Hearing on March 27, 2001.

SB 772 entitled Health Care – Therapy Management Agreements and Cooperative Procedures. The Committee voted in favor of the Bill, but Senator Harris requested a revote.

HB 1032 entitled Maryland Health Care Commission – User Fees. Mr. Slade reported that the Board wrote a letter of concern, noting the inequities of HCC billing practices and other issues

HB 1274 entitled Patients' Safety Act of 2001. Mr. Slade reported that the Board wrote a letter of information. No response was received as of yet.

HB 1376 entitled Patients Safety Improvement Act of 2001. Mr. Slade reported that the Board wrote a letter of information. No response was received as of yet. The Health Care Commission is trying to make both HB 1274 and HB 1376 the same.

HB 1307 entitled Pharmacy Errors. Dr. Love moved that the Board send a letter supporting the amendments to 1307 and thanking Delegate Cole for his willingness to work with the Board. Ms. McCarthy-Hawkins seconded the motion, which was passed by the Board.

HB 1417 entitled Pharmacists – Dispensing Hypodermic Needles – Required Information – Immunity. Mr. Slade reported that the Hearing was canceled.

Regulations Update

Mr. Slade reported on the following Regulations:

Compelling Public Purpose. The Board voted to publish and is currently working on the publication packet.

10.34__, 1999 HB 1062 Consumer Drug Storage and Shipment Safety. USP has not completed drafting the national standards. The Board will do a follow-up after the Legislative session.

10.34.21 Standard of Practice for unlicensed personnel in pharmacies. Effective as proposed March 5, 2001.

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10.34.10 Code of Conduct. The Board voted to publish.

10.34.26 Record of Drug Inventory Acquisitions. The Board is responding to comments.

10.34.20 Format for Prescription Transmissions, formerly Electronic Transmission of Prescription Orders. Effective as proposed December 25, 2000.

10.34.24 Outsourcing. The Board submitted for publication.

10.34.25 Delivery of Prescription Meds. The Board published in the Maryland Register on July 28, 2000 (27:15 Maryland Registry 1431). The Board received, and is responding to comments from interested parties.

Mr. Slade reported that the Board voted to publish the Closing of Pharmacy which will become effective as proposed, although an effective date has not been given.

Mr. Slade reported that the Board voted to publish the Portable Drug Kits for Licensed Home Health Agencies and Hospices which will become effective as proposed, although an effective date has not been given.

Guest Presenters

Russell Moy, MD, MPH, Department of Health and Mental Hygiene, Community and Public Health Administration, discussed the proposed policies for registered nurses.

Mr. Gilbert Cohen, Pharmacy Education and Assistance Committee (PEAC), presented the PEAC update.

Committee Reports

Pharmacy Practice Committee

Dr. Love introduced Dr. Moy to the Board. Dr. Love reported that the Committee has been working with Public Health Nurses on issues involving furnishing medications to the Health Departments. The Local Health Department Nurses are developing a "Policy and Procedure for Registered Nurses Dispensing Prescription and over the Counter Drugs and Devices in Public Health Clinical Practice Settings."

Dr. Love announced that the Policy is limited to dispensing drugs to Communicable Diseases, Family Planning and Reproductive Health, and Alcohol and Drug Abuse. The Board recommended some changes and had open discussion with Dr. Moy. Dr. Love moved that the Board endorse the policy with the recommendations for the changes that the Board made during the meeting. Ms. McCarthy-Hawkins seconded the motion, which was passed by the Board.

Committee Minutes

Dr. Love reported that the Committee reviewed issues on the Health Department Nurses procedures. The Committee reviewed regulations for needed changes. The Committee examined the Regulations on Waiver Pharmacy Permits. The Committee talked briefly about Medication Errors Task Force and the Unlicensed Personnel Task Force issues.

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Licensing Committee

Reciprocity

Mr. Dyke presented the names of the 13 reciprocity candidates: Joyce Adjaottor; Mohamadou Ballo; Helen Chon; Christine Obasi-Coon; Shimelis Deneke; Lisa Desmarais; Susan Donachy; Felicia Edoga; Courtenay Elder; Brian McNeeley; Lashaun Washington; Barbara Watunya and Lisa Zich. Of the 13 candidates, 10 satisfied the requirements by passing the test. Three candidates will have to re-take and pass the written test to reciprocate in Maryland. Mr. Dyke moved that the 10 candidates that met the reciprocity requirements be approved for licensure. Ms. McCarthy-Hawkins seconded the motion, which was passed by the Board.

Lab Exam

Mr. Dyke reported that the Pilot Lab Exam was administered to 16 participants on Tuesday, March 13, 2001. Ms. Schneider proctored the exam, which consists of four (4) sections: Compounding; Calculation, Pharmacy Practice and Counseling during a three hour period. The next regular Lab Exam will be held June 13 and 14, 2001.

Continuing Education Requirements Update

Mr. Dyke announced that the letter requesting pharmacists to recommend CE credits that should be applied by the Board to satisfy continuing educational requirements was published in the March Newsletter.

Mr. Dyke announced that the web site will maintain a list of licensees that are up for renewal and any license that is not renewed by the following month, will be listed on the web site as a non-renewed license.

PEAC Update

Mr. Cohen announced that two representative's from PEAC will do a presentation at the next Board meeting. Mr. Cohen reported that PEAC is currently handling 23 cases, 13 are Board referred, two (2) contracts were completed, and they have one (1) new case. Mr. Cohen reported that the Fiscal Year End for PEAC is March 31, 2001. PEAC will give a full report at the next Board meeting.

Public Relations Committee

Ms. Faltz-Jackson reported that the Committee met on March 14, 2001 and discussed creating an information pamphlet for consumers, entitled "Your Right To Know."

Ms. Faltz-Jackson reported that the Oversight Committee will invite members from the Ryan White Center and PEAC to join the Committee.

Media Campaign

Ms. Faltz-Jackson reported on the following:

The Board may contract with another agency for media campaigning. Ms. Lawrence is researching the replacement.

Ms. Banks and Ms. Lawrence gave a presentation at Apostolic Towers for their Senior Group Fair on March 14, 2001, during National Poison Week.

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The Board will have literature on display at the Maryland Aging Workshop on April 1-3, 2001.

The Board will maintain two (2) booths at the Flower Mart. One booth will show an educational video, and the other booth will be a display area.

Ms. Lawrence will attend the “Educate Before You Medicate” Conference on May 17-18, 2001.

Consumer-Related Activities

Ms. Faltz-Jackson reported on the following:

The Board is invited to participate in the Nurses Health Fair on April 26, 2001 at the Kent Tillman School.

The Board anticipates participating at the Johns Hopkins Health Fair.

The Board will place a quarter-page ad in the University of Maryland Pharmacy School 2001 Yearbook.

The Board will participate in MPhA’s Conference by donating give-a-ways.

Ms. Lawrence announced that the Board anticipates publishing a four (4)-page in-house newsletter in future years.

All Public Relation meetings will be held on the second Wednesday of each month at 4:30 p.m.

Council of Boards Report

Ms. Faltz-Jackson reported that she and Ms. Naesea attended the Council of Board meeting on March 12, 2001. Mr. Landerman, Metro Executive Building Manager, is interested in obtaining a Shuttle Bus service for the Metro Office. Ms. Kathy King, Health Care Financing, spoke on substance abuse. Mr. Irving Pinder, Director, Board of Physician Quality Assurance, was introduced as the new director for the Board of Physician Quality Assurance.

Ms. Naesea reported that Boards and Commissions reviewed the cost estimate for the proposed License 2000 system. She stated that she relayed the Board’s intent not to participate in the purchase of the License 2000 System.

Dr. Love moved that the Technology Committee issue a RFP regarding an on-line system for licensing pharmacists, pharmacies and providing permits to distributors and wholesale manufacturers. Ms. McCarthy-Hawkins seconded the motion, which was passed by the Board.

Questions for the Board

Licensing Requirement for Consulting Pharmacist

Mr. Yee asked the Board whether a consulting pharmacist, licensed outside Maryland, is prohibited from serving Maryland residents. Board counsel will report back to the Board at the next meeting.

Vending Machines

Mr. Rubin presented to the Board a letter from Medic-Vend, about employers offering over-the-counter drugs (Tylenol, aspirin, etc) to their employees by vending machine dispensing. Board Counsel did not feel that the system violated State laws.

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Follow-up Meeting

President Ades announced that he Nominates Ms. Furman as the delegate member and Mr. Lottier as the alternate delegate to attend the 97th Annual NABP Convention. Ms. Faltz-Jackson moved to accept the nomination. Mr. Yee seconded the motion, which was passed by the Board.

President Ades adjourned the Public Board meeting at 11:55 a.m.

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