

**Maryland Board of Pharmacy
Public Minutes**

October 18, 2006

Officers Present: Mark Levi, President, Donald Taylor, Secretary

Commissioners Present: Margie Ann Bonnett, David Chason, Joe DeMino, Harry Finke Jr., Jeanne Furman, Mayer Handelman, Alland Leandre, Rodney Taylor, and Michael Souranis

Commissioners Absent: Cynthia Anderson

Board Staff Present: LaVerne Naesea, Executive Director; Patricia Gaither, Administration and Public Support Manager; Shirley Costley, Licensing Manager; Anna Jeffers, Legislation and Regulations Manager; Tamarra Banks, MIS Manager; Colin Eversley, Compliance Investigator; Vanessa Thomas-Gray, Compliance Secretary and Alicia Carter, Secretary

Board Counsel: Linda Bethman

Guests: Jack Freedman, Steve Riggan, CVS Pharmacy; Scott Vehovic, Walgreens; Cynthia Boyle, University of Maryland School of Pharmacy; Carla Showacre, Pharmacist/Adjunct at Anne Arundel Community College; Ron Nicholson, Vet Centric; Soumi Saha, BOP Intern; Carey Potter, NACDS, Diane Darvey, NACDS; Gil Genn, NACDS; Howard Schiff, MPhA; Hammad Shah, Vet Centric; Michele Shuster, Vet Centric; Dan Lyons, UMB Pharmacy Student, Tom Dunn, UMB Pharmacy Student; Claire Leocha, UMB Pharmacy Student; Dan DeMonico, UMB Pharmacy Student; Thao Vuong, UMB Pharmacy Student; John Weitts, UMB Pharmacy Student; Tony Tommasello, PEAC; Jennifer Zile, Student at UMD SOP; Melvin Rubin, Pharmacy; Chris Wilburn, Walgreens; Chandra Mouli, DDC; Teresa McCay, UMMC; and Mike Swarner, Target Pharmacy

I. Introduction/Recusals – Members of the Board with a conflict of interest relating to any item on the agenda were asked to notify the Board at this time. There were no recusals.

II. Approval of Minutes September 20, 2006

-Page 1 – Anna Jeffers correct title is Legislation and Regulations Manager instead of Legislation Officer

-Page 5 – 18 the words *registration and registrations* was added

-Initials of technicians were added on page 19

-Registration.....duplicate registration fees were added on page 10

-Code of conduct and adapted to include pharmacy technicians

- Pharmacy Technicians were added to the Monetary Penalties Chapter
Penalties will be assessed at either \$2,500 or \$1,000
- Added definition of “Operational Support” to Standard of Practice for unlicensed Personnel.
- Deleted several sections that no longer applied in Unlicensed Personnel Chapter.

Motion: Mark Levi moved to accept the minutes with corrections. The motion was seconded by Jeanne Furman

Board Action: The Board voted unanimously to approve the motion.

Mr. Levi conveyed the Board’s expressions of sympathy to Alland Leandre, Board member regarding the loss of his mother.

III. President/Executive Committee Report – Mark Levi

Treasurer

Nomination for Treasurer – Voting ballots were handed out for the office of Treasurer. Jeanne Furman and Joseph DeMino were nominated for Treasurer. The ballots were marked by the Commissioners and then collected. *Jeanne Furman was elected as Treasurer.*

District I & II Meeting

Mr. Levi commented that the NABP/AACP District I & II meeting hosted last week by the Maryland Board of Pharmacy and the Maryland School of Pharmacy went very well. Mr. Levi also stated that he was impressed with the presentation given by Katherine Eban.

Donald Taylor thanked LaVerne Naesea, Executive Director, Board staff, and the School of Pharmacy representatives for their hard work in facilitating the District I & II meeting.

Ms. Naesea also thanked Patricia Gaither, Administrative and Public Support Manager and Summar Goodman, Public Information Officer for their hard work facilitating the Conference.

Committee Assignments

Mr. Levi assigned Board members to the following Committees and Task Forces:

<u>Practice</u>	<u>Licensing</u>	<u>Disciplinary</u>
Dave Chason-Chair	Mike Souranis-Chair	Mayer Handelman-Chair
Rodney Taylor	Joseph DeMino	Don Taylor
Jeanne Furman	Cindy Anderson	Harry Finke Jr.

Cindy Anderson
Harry Finke Jr.

Alland Leandre
Jeanne Furman

Rodney Taylor
Alland Leandre

Legislative

Don Taylor-Chair
Mayer Handelman
Mike Souranis

Public Relations

Margie Bonnett-Chair
Jeanne Furman

Emergency Preparedness

Don Taylor-Chair
Dave Chason
Cindy Anderson

Subcommittees

Drug Therapy Management – Rodney Taylor, Dave Chason
Long Term Care – Mayer Handelman, Mark Levi
Distributor Regs – Jeanne Furman, Chair, Joe DeMino
Nurse Dispensing Formulary – Dave Chason, Rodney Taylor
Council of Boards – Mark Levi, LaVerne Naesea

IV. Executive Director’s Report – LaVerne Naesea

Meeting with DHMH on Pharmacy Inspections/Personnel Issues

Ms. Naesea reported that Mark Levi, Donald Taylor and she met with Deputy Secretaries Van Mitchell and Michelle Gourdine and representatives of the Division of Drug Control Monday, September 25th. The purpose of the meeting was to discuss whether the Board of Pharmacy should conduct its’ own inspections of pharmacies and discontinue having DDC act as it’s agent. The Board has been requested to submit a Timeline/Plan of how this transition would be assumed by the Board of Pharmacy. Pin numbers for the Division of Drug Control would not be lost as a result of the Board assuming responsibility of performing its’ own pharmacy inspections. Drug Control will continue to perform the initial inspections of Wholesale Distributors as well as inspections of Dental and Physician offices and the closure of pharmacies (e.g. emergency closures of pharmacies) until further instruction from the Deputy Secretaries. It is expected that the Board of Pharmacy will assume the role of performing its’ own pharmacy inspections sometime after July 1, 2007 (no later than October 1). There would not be any legislative changes involved, and it is expected that only procedural changes would occur internally.

Meeting with Janet Nugent

Ms. Naesea also informed the Board that she met with Janet Nugent, Director of Personnel for DHMH, about concerns for recruiting Board staff, specifically about the Compliance Officer position. Ms. Nugent seemed very amiable to working with the Board to facilitate increasing the salary for recruitment of the Compliance Officer position. Ms. Naesea stated that there are two options that could be taken to increase the salary for the position. One option would be to submit requests individually for increases for managers and personnel. The other option would be to go through the legislature to

get Special Appointments and Salary Spending authority. Ms. Nugent suggested that the Board explore both approaches. Ms. Nugent cannot directly support the Board in the legislative approach. Ms. Naesea suggested that the Board pursue the legislature approach or identify persons in the legislature to amend the Board's statute to allow for Special Appointments and Salary Spending authority. Ms. Naesea asked the board to vote on this issue.

Motion: Jeanne Furman moved that the Board pursue Special Appointments and Salary Spending authority for all staff positions. The motion was seconded by Donald Taylor.

Board Action: The Board voted unanimously to approve the motion.

Division of Drug Control Report

Ms. Neasea gave the Inspection Report for September 2006 for the Division of Drug Control.

Pharmacy Inspection	59
Opening Inspections	10
Closing Inspections	7
Board/DEA/DDC Special Investigations	0

Mr. Levi stated that the Board, when it assumes the duty of performing pharmacy inspections, plans to hire a pharmacist as the Chief Inspector and to utilize pharmacy technicians to perform most of the pharmacy inspections. Additionally, the Board plans to work closely with the Division of Drug Control to revamp the entire inspection process.

Ms. Naesea introduced Soumi Saha from the University of Maryland School of Pharmacy, 4th year student. Ms. Saha will be on rotation at the Board for 4 weeks.

V. PEAC (Pharmacist Education and Assistance Committee) Client Update

Mr. Tommasello disseminated to Board members information regarding PEAC's administrative structure. Mr. Tommasello reported that PEAC is currently monitoring 28 cases, of which 11 are self-referred and 17 are Board referred. PEAC has completed a training program at the University of Maryland Medical system. Training was provided by PEAC to Mark Summerfield and the hospital staff. Approximately 25 to 30 people received CE credits as a result of taking the training. Theresa McCoy has framed "Duty to Report" posters that will be given to pharmacies.

Mr. Tommasello gave an overview of the PEAC administrative structure. He also stated that the Harbinson Group would provide information regarding fundraising and marketing at the Quarterly Monitor Meeting. A PEAC Advisory Board is in the process of being developed. The agenda for the Quarterly Monitor Meeting was on the 2nd page of the hand-out provided to Board members for information if they are able to attend the meeting. Bernie Nowak, Addictions Counselor, will provide information on how to recognize the addict's defense mechanisms. A brief summary of the training at the University of Maryland will also be presented.

The question was asked about where pharmacy volunteers fit in the PEAC Administrative Structure? Mr. Tommasello explained that the volunteers are the monitors. There are also volunteers that serve on the sub-committee which assists with the development of PEAC's outreach program.

The question of how many pharmacies have posted the "Duty to Report" poster was asked? Mr. Tommasello explained that he did not know how many pharmacies have received the posters, and stated that DDC has offered to take posters with them while conducting their pharmacy inspections. It was suggested that PEAC find out if pharmacies have posted the "Duty to Report" poster.

VI. Long Term Care – Mayer Handelman

Mr. Handelman reported that the Long Term Care Task Force met Tuesday, October 17th, regarding the Assisted Living Regulations as it pertains to pharmacies. Comments were sent to the Office of Health Care Quality Assurance. Mr. Handelman stated there are four items the Task Force would like OHCQ to address.

- 1) Medication Chart Review
- 2) Physicians to sign orders quarterly
- 3) Quality Assurance
- 4) Compliance Packaging

Mr. Handelman explained that OHCQ stated that this was the first review and the Regulations would be revisited. The Task Force suggested that the quarterly review of the Nurse Practitioner be combined with the Pharmacy review. Mr. Handelman stated that he was informed that it was legal to repackage prescriptions. Clarification was provided to Mr. Handelman informing him that federal law states that you cannot repackage prescription drugs after they have been dispensed. Mr. Handelman felt strongly that the patient's safety should be the first priority.

VII. Legislation and Regulation Manager Report -Anna Jeffers

A. Regulations - Status

Ms. Jeffers reported the recent changes to the Pharmacy Technician Regulations after the Board reviewed comments received during the public comment period.

1. p. 19 - added “data entry” before the words “pharmacy technician.”
2. p. 42 (new version) changed word “American” to “Accreditation”
3. p. 44 (new version) a grammatical change to item 11 added in the word “have been” or “will be.”
4. p. 46 (new version) change to the sentence “someone would have to provide satisfactory proof to the Board of the applicant’s graduation from a pharmacy technician training program approved by the Board.” The word “graduation” has been replaced with the words “successful completion.”
5. p. 46 – under item C 3 – “a applicant that doesn’t meet the requirements of A or B of this regulation shall provide written verification from a pharmacist permit holder that the applicant has worked in the pharmacy area of a pharmacy operated by the same permit holder continuously for 6 months since January 1, 2006.” change – “scratch out for 6 months.”
6. p. 47 - Section D (new version)– “added an additional requirement for pharmacy students.” Added – “students must pass an examination approved by the Board as set forth in Regulation .06 in this chapter.”
7. p. 49 – bottom of the page (new version) – “any changes in course contact shall require a new application approval from the Board.” changed to – “shall require notification and approval from the Board.”

Public comments were received from AHAP, University of Maryland, Department of Pharmacy Services, Delegate Rudolph, Leslie Feldman, Alan Freedman, ANCBS, MSDE, Anne Arundel Community College, Mel Rubin, Howard Schiff, several pharmacy students, Dean Knapp and Cynthia Boyle of The Maryland School of Pharmacy.

Mr. Levi asked for comments regarding the proposed regulations. A question was asked about technicians not being allowed to accept returned prescription medications. It was explained that this would not occur often and should not present a problem for the pharmacists. Another question was asked about pre-fill boxes of 30-day supply of medications being filled by people with disabilities. Pharmacists inspect these boxes after they are filled by these people. Concern was raised about these particular people being unable to pass a pharmacy exam. It was also stated that distinguishing what is being dispensed has to be considered and a suggestion to change the statute was made. There was concern that the effects of the requirements may cause some people to lose their jobs. It was suggested that a letter be written to the Practice Committee.

Stephanie Baker, A.A. College, asked for clarification of the guidelines for training as stated on page 47 (new version) of the draft. Training programs should be no longer than 6 months from an accredited college as stated in the law. Concern was raised about pharmacy students being required to submit to a criminal background check. It was stated that pharmacy students who are not in Experiential Learning Program should be held to a higher standard than regular technicians. John Watson, School of Pharmacy Student Body President, asked about 3rd or 4th year students’ rights being limited since they are allowed to make rounds, and why are they being labeled as pharmacy

technicians. Mr. Watson suggested that the designation should be left to the supervising pharmacists. Mr. Levi explained that the regulations have to follow the guidelines of the passed statute. It was further explained that when a student is not in their delegated Experiential Learning Program and are performing pharmacy acts then they are considered a pharmacy technician. Steve Riggan, CVS, asked what is the time limit when a student can take the exam? It was stated that if a student is in a training program, they have 6 months to take the exam before registration.

Diane Darvey, NACDS, asked that their comments letter be included in the record. She also asked for clarification of the change made on page 19 regarding data entry? Mr. Levi stated the word “data entry” was placed before the word technician. NACDS expressed concern about tracking data entry by technicians. Mr. Levi felt that there should not be a problem tracking data if the initials of technicians were indicated. Ms. Darvey’s next comment referred to pharmacy technician training programs and examinations. Ms. Darvey stated a concern about training pharmacology to technicians may be difficult. Donald Taylor stated that pharmacology should be taught to technicians at a very basic level. Ms. Darvey feels that the Board should define what is basic pharmacology in the regulations. She also expressed concern about the approval exams, and the registration period. It was explained that there would be a grace period for exams to be approved and for technicians to be registered. Mr. Taylor stated that as exam criteria are developed, the requirements would become clearer.

Claire Leocha and Janet Shay, students from the University of Maryland School of Pharmacy, made the comment that students regulated under the technician regs would not want to stay in a pharmacy where they are employed if their abilities are limited. It was also commented that it is important that students get the opportunity to work because it provides students with experience. It was also commented that some students would choose to leave the state should more restrictions be required. The fee of \$45 per year registration fee for pharmacy students was felt to be a burden. Mr. Levi explained that Maryland is one of the few states that does not register students working as a technician. He further stated that students are able to pay the fee since they are being paid. Mr. Levi suggested that students might want to present their concerns to the legislature. Another student suggested that the School of Pharmacy and the Board work together on the issues of exams and criminal background checks to lessen the transition process for students. Ms. Boyle, Maryland School of Pharmacy, stated that she inquired of the School Council whether the School could conduct criminal background checks on students. Because the School of Pharmacy is a state school and background checks are not required for their employees, it is *not* mandatory of students to have criminal background checks. However, when students are in a rotation and an employer requires a background check, at that time students are informed of the request.

The definition of “on site” was asked to be clarified. It was defined as meaning “four walls.” It was also clarified that most criminal background checks are submitted to the Maryland State Police. The Licensing Committee should receive a copy of the request that was submitted to the State Police so they can begin to process the registration. It is the applicant’s responsibility to pay for the background check. Trainees are to apply for

registration after they have completed a pharmacy technician course. Applicants have 6 months to apply for registration. The question was asked if various members of the Board were satisfied that their current employers' training programs meet the requirements of the regulations. The members all stated yes. PEAC services are also available to technicians should they need their services.

Motion: Mark Levi moved that the Pharmacy Technician Regulations be accepted as presented by Anna Jeffers. The motion was seconded by Jeanne Furman.

Board Action: The Board voted unanimously to approve the motion.

Legislation and Regulation Manager Report – Anna Jeffers

B. Regulations

Ms. Jeffers reported that the Prescription Drug Repository Regulations were published September 29, 2006. Also published were the Pharmacist Administration of Influenza Vaccination Regulations on October 13, 2006 and the Therapeutic Index notice was published and becomes effective November 1, 2006. The Licensing of Wholesale Prescription Drug or Device Distributors draft is in progress. The Board approved and will begin the promulgation process shortly on Sterile Pharmaceutical Compounding Regulations.

The Physicians and Pharmacists Therapy Management Contracts – Sunset Extension provisions were presented.

Motion: Mark Levi moved to accept the Physician and Pharmacists Therapy Management Contracts regulations as presented by Anna Jeffers. Dave Chason seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

State Board of Pharmacy – The Means of Notification of Renewal Revised were presented.

Motion: Mark Levi moved to accept the Means of Notification of Renewal Revised as presented by Anna Jeffers. Dave Chason seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

State Board of Pharmacy – Pharmacist Rehabilitation Committees – Membership (revised) were presented to the Board.

Motion: Mark Levi moved to accept the State Board of Pharmacy – Pharmacist Rehabilitation Committees – Membership with revisions as presented by Anna Jeffers. Dave Chason seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

VIII. Administration and Public Support – Patricia Gaither

Personnel Update

Ms. Gaither reported that Anna Jeffers' position has been upgraded.

Public Information Officer Report – Patricia Gaither for Summar Goodman

Ms. Gaither gave a summary of the District I & II meeting's budget. 17 states were represented. Ms. Gaither will provide an update of funds raised and expenditures from the Conference during next months meeting.

IX. Management Information Services – Tamarra Banks

Ms. Banks reported that the work with Towson University on the in-house Board database is being continued. She also reported that the number of pharmacy inspections were up as compared to last month.

X. Practice Committee Report

Constituent Reponses

- A. Dorcus Taylor – Corrective Managed Care Pharmacist – Maryland Pharmacy Program.

Question: What restriction measures will the Board of Pharmacy place on the method or manner in which the public will obtain "Plan B"?

- B. The Board will not place any additional restriction on Plan B in Maryland.

Motion: Mark Levi moved to accept the Practice Committee's letter to Dorcus Taylor concerning whether pharmacists in Maryland will be required to place restrictive measures on the method or manner in which the public will obtain Plan B.

Board Action: The Board voted unanimously to approve the letter to Dorcus Taylor.

Reinstatement of Revoked Pharmacist – presentation and discussion

Anna Jeffers presented proposed regulations drafted pursuant to HB 1569 State Board of Pharmacy – Revocation of License – Sale of Drug Different from that Ordered. The proposed regulations include four conditions whereby the Board may consider a request for reinstatement of a license of an individual whose license has been revoked under Criminal Law Article, § 5-702, Annotated Code of Maryland. Those conditions are:

- (1) The individual has petitioned the Board for reinstatement.
- (2) The petition for reinstatement is made to the Board after the expiration of 5 years after the revocation;
- (3) The individual has met the requirements of COMAR 10.34.13 to reinstate a license; and
- (4) The individual has made restitution to aggrieved persons that may have resulted from a violation and conviction of Criminal law Article, § 5-702, Annotated Code of Maryland.

Motion: Mark Levi moved to accept the Reinstatement of Revoked Pharmacist under Criminal Law Article, § 5-702, Annotated Code of Maryland as presented by Anna Jeffers. The motion was seconded by Dave Chason.

Board Action: The Board voted to unanimously approve the motion.

C. The Board reviewed the Inspection Form for consideration. Training will be provided to the Division of Drug Control on the new inspection form.

Motion: Mark Levi moved to accept the Institutional Pharmacy Inspection form but not to implement the USP 797 compounding section at this time. The motion was seconded by Dave Chason.

Board Action: The Board voted to unanimously approve the motion.

Licensing Committee – Michael N. Souranis

Shirley Costley reported that there has been an increase in the number of pharmacists renewing online since mailing the post card reminders. The Tax Liability Applications have been mailed. Additionally, the licensing stats for the month of September were reported.

Disciplinary Committee – Mayer Handelman

Procedure for Emergency Suspensions

Division of Drug Control concern about impoundment and associated the costs with impoundment was raised. There has been recent needs for the Division of Drug Control to perform Emergency Impoundment of Drugs at pharmacies. The Board and the Division of Drug Control have not had resources to move and store drugs after an order has been issued. The Division of Drug Control asked whether the Board could advance funds to pay for removing and storing drugs. Ms. Naesea has requested from DDC itemization of the costs to impound drugs.

The Public Session adjourned at 11:52 am.

