Maryland Board of Pharmacy
Public Meeting Minutes– June 21, 2000

Attendance

Commissioners Present: President, Stanton Ades, Secretary W. Irving Lottier, Treasurer, Melvin Rubin, Commissioners Laura Schneider, Donald Yee, Wayne Dyke, John Balch, Raymond C. Love, Ramona McCarthy-Hawkins, Jeanne Gilligan-Furman, Reverend William Johnson, Barbara Faltz-Jackson.

Board Counsel: Paul Ballard, Linda Bethman.

Board Staff: LaVerne Naesea, Executive Director, Michelle Andoll, PCO, James Slade; Legislative/Regulatory Officer

Visitors: Geraldine Valentino, Paul Kasemayer, Milton Moskowitz, Howard Schiff, Robyn Elliott, Nathan Gruz, Katherine Lavrina, Catherine Putz, Barbara Newman, Mary Jane Peiterson, Jeanne L. Brinkley, Janice Emerling, Cheryl Tow-Nelson.

Introductions

President Ades asked guests to introduce themselves.

Recusals

President Ades asked if any Board member had a conflict with any of the agenda items. There were none noted.

Approval of Minutes

The following corrections were made to the minutes of May 17, 2000:
P. 4 First paragraph "…will inform appropriate candidates" "only upon written request" added.
P. 5 Change "MPhA under Pharmacy Practice Committee to "ASHP" .
P. 6 Omit transcriber's notes.
P. 7 Under "Questions and Informational" correct spelling of signature, add in last sentence
the Board agreed that the electronic signature would be acceptable "as long as it meets the Format of Prescription regulations."

Raymond Love made a Motion that the corrections to the Minutes be accepted. Laura Schneider seconded the Motion. The Board approved the Motion.

Executive Director's Report/Executive Committee Report

The report was given by LaVerne Naesea.

Staffing Updates

Dietra Gale is the new Health Occupations Investigator working with Michelle Andoll on compliance issues. This is a new position at the Board.

Tianna Haines has been working in a temporary position. She is now in a contractual position as an Office Assistant II.

Vladimir Konstantinov, Database Specialist, has had his status changed from temporary employee to contractual, a position shared with the Board of Social Work.

DHMH Retreat
LaVerne Naesea attended the DHMH Spring Leadership Retreat. The DHMH retreat goals were defined broadly. The Board of Pharmacy must define its specific goals. The following were selected for the five-year strategic planning, where proposed goals will be developed for Board consideration: Board members Jean Gilligan-Furman, Melvin Rubin, Laura Schneider, Ramona McCarthy-Hawkins and Stanton Ades; Staff members Tamara Banks, Jim Slade, Michelle Andoll, Sharon Demory-Cornish, and LaVerne Naesea. The Committee will meet Friday, June 23, 2000 to discuss the structure and make recommendations to the Board.

Managing for Results Plan
The Board has prepared a Managing for Results Plan 2002. Copies are available in the Board office. These are measurable goals that the Board had to come up with for the fiscal year 2002.

NABP Annual Meeting
Michelle Andoll and LaVerne Naesea attended the meeting. In the back of the agenda packet are attachments from that meeting. Jean Furman was on the Task Force looking at technician competency.
NABP acknowledges that there needs to be some kind of standardized education for technicians. They would encourage registration of technicians and possibly licensing of technicians in the future. which would fall under the Board of Pharmacy's supervision. LaVerne Naesea also stated that there was much information at the conference on the appropriate use of technology by Boards and pharmacies.

Board of Pharmacy Annual Report
The report was distributed at the MPhA convention in Ocean City and at the Annual Convention meeting which was attended by LaVerne Naesea. Michelle Andoll, and James Slade. Ms Naesea attended a number of classes on drug uses and herbal remedies.

USP 2000 Quinquennial Meeting
Michelle Andoll attended a scientific symposium on the future of pharmacy practice and the pharmaceutical industry. A report on that conference is in the 6/21/2000 Board packet.

Purchase of MPhA Law Books
LaVerne Naesea asked the Board to reconsider its vote of 2 months earlier authorizing the purchase of law books from the MPhA. She recommends that the Board rescind its previous vote so the purchase of the books can be put out on formal bid as required by State Law. A motion to rescind the previous action was made by Jeanne Furman and seconded by Ray Love, and passed by the Board. Ramona McCarthy-Hawkins made a motion to place a bid request for printing of the pharmacy law books, seconded by Laura Schneider. The Board approved the Motion.

Guest Presenters
PEAC
Milton Moskowitz, speaking for the Pharmacy Education and Assistance Committee, passed out brochures for a seminar to be held on October 19, 2000. The Board and PEAC have worked for some time on this type of seminar. . PEAC asked the Board for $4000 to support the seminar, and to provide mailing labels for all the pharmacists in the State of Maryland. He thanked the Board for allowing him to speak at this meeting, and for the support of the Board. Irving Lottier stated that the Board already has a contract with PEAC to monitor pharmacists referred to them, which could be amended to include the $4000 rather than putting it out for bid. Jeanne Furman moved that the contract be amended to include the $4000 for the seminar. Ramona McCarthy-Hawkins seconded the Motion. The Board approved the Motion.

Sunset Review
Robyn Elliott, a legislative analyst for the Department of Legislative Services for the Maryland General Assembly presented an overview of the Sunset Review Process. The Program Evaluation Act calls for each Board and each Commission to be evaluated about every 10 years. This is called a Sunset Review. At the end of the evaluation, Legislative Services could recommend discontinuance of a unit, but the process is more a way to justify continuing the Board's existence, and allows Legislative Services and the General Assembly to look at the overall operations of the Board to determine if the Board has been able to keep up with changes in the industry, either through regulation or if there needs to be statutory changes. This summer, the Board will have a preliminary Sunset Review carried out by Ms. Elliott. The process has already started, with her having met with some members of the Board and Staff. If, as a result of the preliminary review it is decided that a more in-depth review is needed, a full review will be performed next summer. Ms. Elliott stated that this review is different from a legislative audit in that it is not primarily an accounting audit. Programs and processes are the primary focus of the review. It is also an opportunity for the Board to voice its concerns about whatever it has not yet achieved working through DHMH, statute or regulations. General operations are also reviewed, such as determining how smoothly licensing is working, number of and type of complaints, and the Board's activities withi other issues in the industry such as the shortage of pharmacists

Joint Nursing Pharmacy Committee on Portable Drug Kits

David King from Georgetown Infusion, and Terry Twilley from Home Health Corporation served on this committee and presented information on the topic. A memo in the packet explains the charge of the committee . Last year the Board enacted regulations allowing the use of a portable drug kit for licensed home health agencies and hospices. The regulation authorizing this kit was the result of a request by nursing in home care to carry a small quantity of legend drugs that were not patient-specific, for use in urgent emergency situations. The regulations were passed last September, and called for a committee with members from the Board of Pharmacy and the Board of Nursing to meet to develop a list of drug products that may be included in the kit. The list of drug products included in the kit must be approved by both the Board of Pharmacy and the Board of Nursing.

Letters were sent to 23 infusion pharmacies to solicit input concerning this list. David King was the only person contacted who expressed interest in serving on the committee to participate in development of a drug list. Michelle Andoll did not receive commentary from any other pharmacists regarding drugs they thought should be included in the list.

Terry Twilley listed the names of members of the committee. The only resources the nurse has in home care are what is brought with him or her. An example cited by Ms Twilley involves a pharmacy which supplies the medications for the nurse possibly forgetting a medication in the order, or a product being damaged. The minimum length of time for the nurse to receive a replacement is 3 hours. Many times it's the next day before they are able get the medication for the patient. This would severely compromises patient care. Possessing a kit might allow the nurse to avert a call to 911 for possible hospitalization.

Mr. King spoke about the choice of drugs on the list. The list of specific drugs, and the quantities permitted are listed in the Board packet. Dr. Love raised a question about the inclusion of ammonia as a standard drug in the kit because of cardiac effects. Mr. King stated that the appropriateness of ammonia for inclusion in the kit was not studied. Ammonia is included in his emergency drug kits, but he stated that it has not been used in 6 years in his operation.

Examples were cited where use of drugs which are requested to be in the emergency kit did or would have been medically and financially advantageous to the patient.

On a question of whether a protocol for administering the medications would be included with the kit, nursing said that that each member of the committee brought their own protocol to the meeting and this information was used to determine the maximum allowable doses. Nursing believed that they were asked to come up with the list of drugs included in the kit, but that the protocol was dictated by the regulations. The drugs included in a particular emergency kit are also dictated by the population of patients in a particular area.

The kits are labeled on the outside with the expiration date, which is the date of the earliest expiration date of any drug in the kits . They are also equipped with sensors for heat and cold. The nurses will be required to carry them inside a building when they are not being transported.

A question was asked as to whether steroids are included in every emergency kit, and which steroids would be included. Some home care company kits include steroids, others do not. The same steroids were not included by all companies. The Board wants to research further the issue of which steroids could be allowed to be used. In addition, the question of the whether ammonia inhalants should be included in the emergency kits was requested to be reviewed. A Motion was made by Dr. Love that the medications and products requested to be allowed in the kits be approved except that the committee would research the current status of ammonia inhalants and also make specific recommendations for corticosteroid injections to be included in the kits before those items would be considered for Board approval. The Motion was seconded by Commissioner McCarthy-Hawkins and approved by the Board.

Two other issues are related to the Committee's work. One is that the regulations specifically provided for kits through licensed home health agencies and hospices. Many home infusion pharmacies employ their own nurses and have a need for such a kit, but the pharmacy is not licensed as a home health agency or hospice. They hold what is called an RSA. Michelle Andoll asked Jim Slade to look into changing the regulations to accommodate this situation.

Second, there is a newsletter that goes to the home health community. It may be useful to explain to the home health community why certain items, such as some forms of Sodium Chloride, require prescriptions to be dispensed, and why they would have to be included on the list of drugs allowable in this controlled kit. One main reason that one form of Sodium Chloride requires a prescription and another does not is that the OTC product has certain patient information required on the label. An article was presented in the packet, submitted by the committee, explains this. The committee would like to have the Board review this article and absent any objections publish it in the Maryland National Health and Home Care Association. In paragraph 3 of the article, the wording specifying that manufacturer labels must contain the federal legend statement will have to be changed to reflect the current FDA required statement.

Advance Nurse Practice – Nurse Midwives

Presenters: Mary Jane Peitersen, Jeanne Brinkley, Janice Emerling, Cheryl Tow-Nelson.

The Board of Nursing asked to make a presentation to the Board of Pharmacy to promote a better understanding of the practice of midwifery and the proposed changes in the formulary.

Mary Jane Peitersen stated she was not there to defend the prescribing privilege of practicing midwives, their education or ways that they were disciplined. Rather, she said that she will talk about the practice of Board-certified nurse midwifery and is consulting with the Board about the formulary, as the regulations require.

Jeanne Brinkley , a member of the original committee which worked on the formulary, provided historical background. In 1989 pharmacists recommended that there be a formulary for nurse midwives rather than blanket prescriptive power. Ms Brinkley said that at that time, nurses primarily worked with labor and delivery, but now nurse midwives address primary care and hence have a greater need for a wider prescriptive range than previously needed.

A question was raised about the framework required by the regulations. The framework that the Board received doesn't include primary care and the Board asked if there was an updated framework. Mary Jane Peitersen said the framework was updated in 1995. However that framework does not include primary care. Ms. Peitersen said nurse midwives have 3 scopes of practice:. the independent scope, dealing with ante partum, delivery, post partum; family planning; and women's health care. Every nurse midwife has an elaborate joint management framework. The one from Hopkins is over 500 pages long. The nurse and physician talk about what they will jointly manage and what circumstances will require a referral to the physician. Ray Love pointed out that the framework does not specify things outside of reproductive and family planning functions. He felt that the approval being requested authorizes the use of medication which would

be outside of their current mandate and that the Board of Pharmacy would want assurances from the Board of Physician Quality Assurance before giving our approval to the requested changes in the formulary.

On questioning about when the Board of Pharmacy last was consulted about the formulary, Ms Peiterson said that they had come before the board about 3 years ago with the issue of working with drug-addicted mothers, and being allowed to prescribe methadone. Dr. Love stated that part of the concern that he has is that there is a provision in the statute for an annual review. Ms. Peitersen said that is true, but there was nothing significant ready to give the Board earlier.

A problem mentioned by Jeanne Furman is that if the formulary allows classes of drugs to be prescribed, some medications will be prescribed by nurses which should only be prescribed by specialists like infectious disease specialists, or wound care specialists. With the bacterial resistance to common antibiotics, overuse of antibiotics is also a concern. Another concern is that anti-diabetic medication is not included on the formulary.

John Balch suggested that a pharmacist be placed on the Midwifery Committee. Mary Jane Peitersen agreed, but the regulations do not specify a pharmacist on the Joint Committee. Stanton Ades suggested that the Midwifery Committee follow their own regulations and include the Pharmacy Board in appointing members to that Joint Committee. The Board expressed concern about the latitude in prescribing medications, and the fact that a review is not performed annually, as specified in the regulations. The Board was also concerned about the placement of certain drugs on the list which can be prescribed with independent authority and the list of dugs that requires co-management with physicians. Further, the Board is concerned that a few categories might need to be added or subtracted from the list.

Ms Peiterson indicated that the pharmacist should notice inappropriately prescribed medications. Commissioner Furman asked how the pharmacist would know when a prescription is the result of a consultation with a physician, or an independent decision by the nurse midwife. The pharmacist would have to call the nurse midwife each time to verify any drug written outside the reproductive area. Ms. Peitersen pointed out that to date there have been no lawsuits against nurse midwives due to prescribing medications.

Dr. Love suggested that BPQA, Nursing, and Pharmacy sit down together to work out what is acceptable for the scope of practice. He also said that the regulations clearly state that a review must be conducted annually, and that has not occurred.

Board Counsel Report

Paul Ballard reported that Linda Bethman attended a meeting on prosecution of Internet site crimes. Ms. Bethman reported that as much as 35% of the Pharmacy outlets on the web may be illegal. The Consumer Protection Division may ask the Board of Pharmacy for assistance. Ray Love made a Motion that the Board send a letter to the Attorney General offering the Board's consultation and cooperation in investigating Internet pharmacies. The motion was seconded by Barbara Faltz-Jackson. The Board approved the Motion.

Regulation and Legislation Update

James Slade reported that he had drafted a letter to be sent to the Department for consideration for Departmental Legislation, asking for a Task Force to study the pharmacy shortage in Maryland. The department will examine whether there is a shortage, why there is a shortage, and ways to go about resolving it. No text has been drafted yet since the actual package is not due until August 1, 2000. A motion was made by Ms Jackson to request the Department to include this in their legislative package; seconded by Ms Furman. The Board approved the Motion.

Regulations Status Report

James Slade informed the Board that he is finishing the proposed regulations on Unlicensed Personnel and on Form of Receipt of a Prescription, and will be sending them shortly to Michelle Phinney. The outsourcing regulations are still being worked on including some comments from Paul concerning the federal law which may require a change in the text. Comments were also received from the USP and will be reviewed by the Practice Committee.

The delivery of prescription medications should be published in the July 28 Maryland Register.
The Practice Committee reviewed in depth the regulations related to automation, with the MSHP Committee.

Closure of Pharmacies proposed regulations are nearing the end of the formulative stage.

Pharmacy Practice Committee

Dr. Love spoke about the Automation Task Force and the meeting with the MSHP Committee which brought agreement on all points discussed. The draft presented to the Board was not complete, so it will be presented to the Board at the next meeting. Hospitals which have gotten a draft copy of this should understand that this is not complete nor is it an endorsement of their current system.

Medication Error Prevention Task Force

Donald Yee stated that by the July or August meeting the Committee should have recommendations on actions the Board may want to consider. The task force is looking at the recommendations which are easiest to put into place, which have the greatest impact, which will have the greatest impact on the health and safety of the public, and which are the most measurable by the Board of Pharmacy. The Committee is looking at implementing changes in stages – taking certain steps this year, and implementing additional steps next year. Michelle Andoll volunteered to draft a letter to go to other Boards: Nursing, Physicians, and Dental concerning this issue so there will be an interdisciplinary approach to the recommendations.

Narrow Therapeutic Index Drugs

Melvin Rubin reported that Delegate Elliott responded to his request to a meeting between himself, Delegate Bozman, and Delegate Sophocleus about NTI drugs to find

ways to work together on this issue. He replied that he would get back to the Board later with a date.

Licensing Committee

Commissioner Dyke reported that 16 candidates were licensed by reciprocity at this month's meeting. They were: Emebet Alemayehu, Samina Ali, Michael Baker, Wing Chan, Teresa DiRenzo, Susan Drady, Beth Duplaga, Lisa Foglio, Orasa Garland, Rhonda Jones, Sally Malkin, Richard Maude, Romy Mavumkal, Olufunlila Oladunjoye, Eleanor O'Rangers, Angela Pham, and Steven Riley. Commissioner Dyke moved to approve the list, seconded by Commissioner Balch, approved by the Board.

The Laboratory examination was held June 15 and 16, with 5 sessions for the 188 candidates. All assays have been finished and the results are being compiled. Those candidates who have taken and completed all three segments of the examination should be approved for licensure by the end of June. The Committee will meet in July to discuss a new format for the laboratory examination which may be in place by January, possibly as a pilot.

Public Relations Committee

Michelle Andoll summarized the media campaign. John Balch, LaVerne Naesea and Jeanne Furman have been very active on this committee. The Board had a booth at the Baltimore City Flower Mart at which brochures, notepads, and pens were distributed. The School of Pharmacy, the Maryland Pharmacist Association, and a staff pharmacist from Rite Aid helped to staff the booth. The booth won the grand prize, a crystal vase.

The Board had a booth at the MPhA convention in Ocean City, Maryland also, at which note pads, post cards and other items were given out.

The Board will have a booth at the NPA Convention.. Ramona McCarthy -Hawkins reported that the National Pharmacy Association, a group of predominately minority pharmacists is having their 53rd anniversary meeting at the OMNI Hotel in Baltimore July 21, 2000. The NPA holds their convention in conjunction with the student pharmacy convention NPA has chapters in about ½ of the pharmacy schools. Dr. Knapp, Dean of the University of Maryland School of Pharmacy is co-hosting a reception on Friday evening, July 21, at the College of Pharmacy for the group.

Ms. Falts-Jackson will be speaking to the teachers in Prince George's County in October about the kinds of activities in math and science that students could engage in that would be pre-pharmacy activities.

The radio program on consulting pharmacists for advice was very effective. The Board is soliciting spots at some of the chain stores to get out the Board's message over their systems. The Board is also going to send letters to all the pharmacists asking that they include the postcards provided by the Board as part of their service; and will be sending surveys to determine how effective the campaign was.

John Balch suggested that the Board have a booth at the Maryland Nursing Association meeting.

Reverend Johnson offered to coach Board members on public speaking.

There will be another public relations program for National Pharmacy Month (October).

The Board is considering having a public relations seminar to help the Board members respond to media questions. Thought will be given to appointing certain members to be media spokespersons.

Executive Director Naesea said that the Board of Pharmacy Website has grown from 10,000 hits in January to 15,000 hits in May.

Questions to the Board

A pharmacy is requesting a second permit at his location. The Board allows 2 permits at a location provided the location maintain separate inventories and bookkeeping. The pharmacy's intent is to have a separate compounding pharmacy at one location. The Board declined the request because a pharmacy with a full service pharmacy permit is required to fill all reasonable prescriptions.

Two pharmacists complained to the Board that MDIPA audits caused them to have to repay monies received for refilling prescriptions when they had called physicians for additional refills. The pharmacists documented this only in the computer, not on the back of the original prescription. The Board agreed to send a letter to the pharmacies stating that this practice is legal, meets the Standards of Practice of the profession, and is acceptable to the Board as long as the computerized system meets all the requirements of a manual system.

Letter to BPQA

Ms Andoll said that a letter was received from BPQA concerning pharmacists who are using incorrect physicians' name, or incorrect DEA numbers identifying prescribers, in their computer record. BPQA has attempted to discipline physicians for writing certain prescriptions based on pharmacy computer records which proved to be in error. The Board acknowledges the problem, which is partly caused by illegible physician signatures and agreed to bring the issue to pharmacists by use of a transmittal or Newsletter article. This article would also ask pharmacies to report problems that they have in deciphering prescriber information and instructions on prescriptions. This information would be given to BPQA.

On motion from Dr. Love, seconded by Ms Furman, the Board voted to respond to BPQA by way of a letter telling them that we would inform pharmacists of the problem, consider this in Peer Review, and seek involvement of the inspectors from Drug Control to work with us on the issue.

The meeting was adjourned at 12:10 p.m.

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