

Maryland Board of Pharmacy

Public Board Meeting – December 19, 2001

President Ades called the Public Session of the December 19, 2001, Board meeting to order at 9:12 a.m.

Attendance:

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

Board Counsel: Paul Ballard, Assistant Attorney General, and Linda Bethman, Staff Attorney

Board Staff: LaVerne Naesea, Executive Director; Michelle Andoll, Pharmacist Compliance Officer; James Slade, Legislative/Regulations Officer; Joan Lawrence, Public Education Officer; Shirley Costley, Personnel/Fiscal Officer; Tamarra Banks, Information Services Manager; Angela Long, Executive Secretary; Deitra Gale, Compliance Specialist; and Doris James, Licensing Supervisor

Absent: None

Guests: Gilbert Cohen (PEAC); Howard Schiff (MPhA); Kathryn Lavriha, (Barr Labs); Laura Short (Taro Pharmaceuticals); Nathan Gruz (MPhA); Mike Ayotte (CVS/Pharmacy); and Jack Freedman (Division of Drug Control)

Introduction

President Ades asked each guest to introduce him or herself.

Recusals

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

Corrections and Approval of Minutes (10/2001)

Page 2, under Patient Safety Conference, first sentence add “*Ms. Furman*” who also attended the conference

Page 2, under Upcoming NABP Conferences, change “New York City” to “*Cooperstown*,” New York

Page 4, under Automation Regulations, fifth sentence, should read “*Dr. Love stated the idea is being considered by the Task Force, however, the use of matrix style drawers was no longer state of the art.*”

Page 4, under Automation Regulations, third paragraph, six sentence, add “*Dr. Love*”, and “*MD Society of*” ..Health Systems....

Page 7, under Web Site Statistics, third sentence, reverse “are they” to “*they are*”

Page 8, under Informational, first sentence should read “*MPhA*”. Also, delete “*APhA*”

Board Action

Pres. Ades reminded participants that the November 2001 Public Board session was canceled. Ms. Schneider moved for acceptance of the October 17, 2001, public meeting minutes as amended. The motion was seconded by Dr. Love and passed by the Board.

President/Executive Committee Report

Drug Therapy Management Workgroup

Pres. Ades reported that the Workgroup met on December 12, 2001. Pharmacy representatives from the Workgroup will next meet with Med Chi’s Legislative Committee to review the text of the draft proposed legislation, discuss concerns and determine next steps. The meeting is tentatively scheduled for January 7, 2002.

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Mr. Schwartz, Med Chi's attorney, indicated to Pres. Ades that Drug Therapy Management should not be routinely used by multitudes of retail pharmacies; nor does Med Chi expect that multitudes of retail pharmacists will engage in collaborative agreements with physicians. Med Chi's desired conditions are that DTM will be: 1) limited to very few retail pharmacies in the State; 2) considered a verification/certification process that the Boards of Pharmacy and Physicians will authorize; and 3) based on protocols and agreements that would need to be followed by pharmacists and physicians. Pres. Ades indicated that the workgroup has made significant progress in working with Med Chi's attorney, but it that Med Chi may still be resistive.

Pres. Ades indicated that a draft of proposed bill language is in circulation, but revision will be made. Ms. Naesea stated that the next draft to circulate will exclude the definition for 'institutional facilities.' She also noted that she had received written comments on the draft from BPQA, which she had not completed reviewing. Dr. Love said that the definition for 'institutional facilities' would be negotiated between Med Chi and the Workgroup pharmacy representatives at the planned meeting. Dr. Love suggested that the Practice Committee also review the definition of 'institutional facilities' (in terms of addressing specifically what pharmacists can do outside of hospitals and communities) when it revises its long term care regulations. He added that hospital regulations have been adopted that allow pharmacists to operate under certain protocols. He said that when the Practice Committee addresses the board's LTC regulations, which have a broader coverage of institutional facilities, a similar set of regulations could be offered. Dr. Love said that Catherine Crowley, of the MD Hospital Association, is extremely interested in protecting the status quo of pharmacist's management of hospital patients, noting that it appears that the MD Hospital Association interprets the Attorney General's opinion to mean that current practices can be continued. This would indicate their preference for excluding hospitals from the proposed statutory and regulatory language.

Pharmacy Shortage Task Force

Pres. Ades reported that the Shortage of Pharmacy Workgroup met on December 3, 2001. A wide range of organizations were represented, including participants from the Higher Education Commission, CVS Pharmacy, MPhA, Neighbor Care, DLLR, BPQA, Western MD Health Education, School of Pharmacy, MSHP, the Maryland Board of Nursing and DHMH. During the meeting, the group reviewed its charges to: 1) assess the expanding role of pharmacists; 2) evaluate emerging technologies; study the effects of federal and state laws on the practice of pharmacy; 3) formulate an action plan that will provide a framework to implement the Task Force findings; and 4) submit a final report by August 2002. The balance of the first meeting entailed members determining which tasks needed to be completed in order to meet its charges and developing a set of initial assignments for participants to perform. The next meeting will be held on January 28, 2002.

Bio-Terrorism Task Force

Pres. Ades reported that the Bio-terrorism Task Force held several meetings in November and December. Membership includes Board members Stanton Ades, Laura Schneider, Melvin Rubin and Raymond Love in addition to volunteer pharmacist members Phil Cogan and Bart Reagan. The group has designed a plan to package and dispense large amounts of drugs to specific areas in the State. Task Force deliberations have included reviews of the role that pharmacy should play in the implementation of local and state or plans, and of statutory/regulatory changes that may need to be waived in cases of state emergencies. The Task Force's final recommended plans will be presented to the Board and then submitted to the Secretary of DHMH for review and consideration with the Governor's state plan. Ms. Joan Lawrence is staffing the Task Force, which meets weekly. Pres. Ades thanked Mr. Cogan and Mr. Reagan for their interest, input and dedication.

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Nursing Dispensing Committee

Ms. Naesea stated that DHMH's Deputy Secretary Richard Proctor's assistant, Kim Mayer, requested the Board to recommend one non-Board member pharmacist and one Board member to the reconvened Nurse Dispensing Task Force. After discussion with the Board's Executive Committee, Donald Yee and Phil Weiner's names were submitted to Roz Goldner, the state's Nomination and Appointments Officer. Mr. Yee stated that the Committee reviewed its purpose and anticipated outcomes at the first meeting. They will address issues related to the nurse shortage and lack of funding in the Health Department to provide adequate physician support.

Ms. Andoll, who attended the second meeting, reported that the Committee issued a survey to local health departments to determine the types of drugs currently dispense and by whom. The survey results will indicate the need to further develop the formulary. According to state policy, nurses can dispense only drugs that are on the formulary. Ms. Andoll suggested that Board representatives pay close attention when the Committee works on drugs to include on the formulary. Also, Ms. Andoll indicated that the committee discussed the use of a pharmacy dispensing software program that met record keeping requirements. Mr. Weiner advocated for the purchase of the software packages, however, most other Committee participants felt the purchase was cost prohibitive.

Ms. Andoll reported that the Committee is concerned that nurses have resources to maintain and track required audits and other paper trails. In addition, the Committee discussed a train-the-trainer program in which trained certified nurses could train other nurses to dispense allowable medications. Ms. Eva Hunger's name was suggested to develop this training program. Ms. Hunger is affiliated with Springfield Hospital and taught nurses for the Department. Ms. Andoll mentioned that the Board would be later asked to recommend a pharmacist to consult with the trainer in developing the curriculum. She said that Don Fedder name was mentioned as a consulting pharmacist and that he has been contacted. Mr. Fedder is a professor at the School of Pharmacy and an independent pharmacist in Baltimore City. He holds a Doctorate in Public Health. Ms. Andoll stated that the Board should support Mr. Fedder's appointment or suggest other recommendations. Dr. Love suggested the Executive Committee submit a recommendation(s). Ms. Andoll will contact Don Fedder, send an email to Board members for other suggestions and get additional information for the Executive Committee regarding the expected extent of consultant's commitment. Dr. Love requested that Ms. Andoll ask if the consultant will be reimbursed.

Representation Protocol

Pres. Ades reported that Council of Boards and Commission met December 3, 2001, at which time they discussed board members' liability and immunity. He stated that sometimes Board members act in good faith, but not necessarily with the full faith and knowledge of the Board. Public Education Officer, Ms. Lawrence is developing a protocol specifically for Board of Pharmacy members, that will restrict Board members from engaging in situations that could cause lawsuits (specifically in the areas of anti-trust, civil rights, defamation and conflicts of interest) and that they will also ensure full board support and endorsement of specific ideas. He stated that adherence to the protocols by Board members will protect both the Board themselves individually. Pres. Ades emphasized that when representing the Board, only Board approved policies and information should be presented and that members will need to abide by the protocols once voted upon.

PEAC

Mr. Gil Cohen reported that PEAC has 29 cases and received 5 new cases in the past month, of which 8 are board referred. PEAC has developed a new position for a full-time paid Director of Development. They will soon present their year-end report, including demographic on participants. Pres. Ades asked whether a

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job description had been developed for the position. Mr. Cohen replied yes and that the position would be directly responsible to the Committee and the Board of Pharmacy and attend all meetings. The new person will work directly under supervision of Anthony Tommasello. Mr. Rubin stated that 29 cases is a large number for one month. He asked if PEAC has sufficient staff to assist with the cases. Mr. Cohen said that 4 more volunteers had joined PEAC. Mr. Rubin mentioned that the Board plans to meet quarterly with PEAC. Mr. Cohen stated that the new Director would be the person the Board will be meeting with. Ms. Furman suggested that PEAC's demographic report show data on relapsed rates of Board referred cases. Mr. Balch asked about the number of referrals from Southern MD, Eastern Shore or Western MD and whether there are PEAC volunteers in those areas. Mr. Cohen replied that out of the 5 new cases received, one was from Eastern Shore with one volunteer in that area, and two were from Western MD with two volunteers.

Ms. Naesea indicated that she met with Milton Moskowitz on Monday, and he mentioned that PEAC wants to become a partner with the Board to begin identifying and offering treatment to impaired pharmacists in the MD community. He had several ideas on how PEAC could recruit more impaired pharmacists to seek treatment before they threatened the safety of MD citizens. She told him that she would inform the Board and that he should put in writing how they see PEAC expanding, as well as the role that they would play specific to working with the Board of Pharmacy in identifying problems.

Secretary/Budget Report

Mr. Lottier reported that the Budget Committee met on the 1st quarter budget activity FY 2002. The following are highlights from the Report:

- Budget Appropriation FY 2002, \$950,000.
- Actual expenditures, to date, \$185,392.
- Additional, \$175,000 in unanticipated expenditures are projected for the remaining of the fiscal year.
- Permanent staffing expenditures, estimated, \$498,000 an average of \$41,000 a month. A total expenditure of \$117,000 has been made in this category during the first quarter. All permanent positions are currently filled.
- The Board will fund the Office Secretary III from surplus funds. Due to the hiring freeze, the licensing secretary position will not be filled until the hiring freeze is lifted. Ms. Naesea mentioned that the Board submitted an exception request to DHMH, and received indication that the Board request is being seriously considered based on the overload the Board staff is experiencing.
- Temporary employees for first 3 months of the fiscal year and estimated expenses for the remaining of FY 2002, may create up to a \$21,000 deficit.
- Postage items purchased for the quarterly newsletters cost \$250, including one-time fee of \$125 for permit imprint and a \$125 annual fee.
- Bulk mail labeling is done by the State Use Industries, Women's Correctional Institute for \$735.00 per issue.
- First quarter combined traveling expenses for Board and staff members totaled \$3,240, which includes in/out state travel and training allowance. \$7,400 pending travel expenditure. 46% of allocated travel funds were spent during the first quarter of the year. Travel funds remaining equal \$12,500 for FY 2002.
- The Board has contacted the Office of Planning to conduct analysis of space requirements and develop space design for future needs, which cost \$8,000.
- The Board has awarded a printing contract for the annual report to Patricia Litho Inc. in the amount of \$3,595.
- The Board has granted MPhA an additional \$8,000 to co-sponsor an HIV/AIDS Seminar that provided pharmacists with a better understanding of drug dispensing and interaction for HIV/AIDS patients.

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The Board asked the Budget Committee if the Board is on schedule with the 2002 budget. Ms. Naesea mentioned that we anticipated the Budget being \$1,050,000. She reported that a position was not included when the Board submitted the initial project budget two years ago to DHMH, which was the licensing secretary. The licensing secretary and licensing clerk were changed because we borrowed the positions' PIN (Permanent Identification Numbers) to make the Database Specialist position permanent. Ms. Naesea also stated that the Executive Committee was consulted regarding the additional funds that were allocated to MPhA for HIV/AIDS Seminar because the conference enrollment exceeded its projected attendees by 100 persons.

Mr. Lottier also reported that he received a copy of a letter of support from Secretary Benjamin regarding the adopting of emergency regulations to raise fees. (Copy of letter attached to permanent minutes.)

EXECUTIVE DIRECTOR'S REPORT

MD Healthcare Commission Fee Proposal

Ms. Naesea reported that Maryland Healthcare Commission is proposing to decrease their biannual fee charges from \$34.00 to \$32.00, effective July 1, 2002. This proposal is a result of expanding the number of professions that will need to pay fees and does not mean that the proposed increase to MHCC's budget allowance has changed. The Board determined that it should still oppose pharmacists being charged a fee for the services since pharmacists are not reimbursed through insurance.

Legislative Presentations

Ms. Naesea reported that the Board had been engaged in several legislative presentations over the past two months. Two key presentations were the Sunset Review before the House and Senate Committees. Ms. Naesea attended both presentations, and indicated that the Board of Pharmacy received an overall good report. However, the analyst expressed concern about pharmacist license fees being increased. Ms. Naesea stated that she testified that the Board had revised its earlier proposal to increase the fees to \$200, and had voted to reduce the increase to \$150 for pharmacist practitioners. The Sunset Review analysts projected that the Board would have a surplus of over a million dollars over a five-year period at a fee of \$150.00. Ms. Naesea explained to the Committees that there were certain items that were not included in the Board's projected budget, such as the eGov mandate and contractual personnel who are projected to become permanent. When added to the projected five-year budget, the funds will be expended with no surplus by the sixth year of the new fees. Ms. Naesea said that after she justified the budget, the Committee seemed receptive, but legislature will still have to approve the increases.

Ms. Naesea also reported that the Sunset Review recommendations included language related to non-discoverability. Specifically, it recommended that any quality assurance programs required by the Board of Pharmacy be protected against discoverability in civil court. Ms. Naesea mentioned that although Mr. Slade and others who reviewed the report feel the language is awkwardly phrased, Mr. Ballard (Board Counsel) indicated his feeling that it should meet the need of protecting quality assurance programs. Ms. Furman mentioned that the Patient Safety Coalition is working on their final interim report, which will be available in January 2002, and she will report on it at the next board meeting.

Ms. Naesea mentioned that the Council of Boards scheduled a formal briefing before the Senate Education, Health and Environmental Affairs Committee in Annapolis on January 16, 2002, beginning at 11:00am until 1:00pm (same day as the next Board meeting). A reception will follow the briefing. The Council of the Boards is encouraging each board Chairman and Administrator to attend the presentation and be prepared to answer questions. Ms. Naesea stated that the briefing is intended to inform and educate the Senate committees that make decisions regarding legislation that affect the Boards and Commissions. She said that some of the Boards have volunteered to provide individual presentations but most will be included in an omnibus presentation. The Board will put together a packet similar to what was prepared last year.

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Ms. Naesea asked members to forward any information or subject areas they thought should be included to Ms. Lawrence. Since the event is planned on the Board meeting date, Ms. Naesea suggested that Mr. Rubin, Mr. Slade and Ms. Lawrence attend to represent the Board. Ms. Faltz-Jackson will also be attending as the Board's representative on the Council of Boards and Commission. Other legislative involvements by the Board were discussed later during the Board meeting.

Legislative Audit

Ms. Naesea informed the Board that it is currently under audit. She mentioned that the Board should be audited every two years, but that this audit is less than two years. She said it may relate to other Boards that are currently under scrutiny for their operations and the fact that a previous audit of all of the Boards and Commission determined some problems with the way that some Boards managed license record keeping, expenditures and time keeping functions. According to Ms. Naesea, thus far the reviewed comments have been quite positive. Ms. Costley mentioned that the auditors said that the Board appears to have its records in order.

Building Lease/Space Renovation

Ms. Naesea reported that she was one of the signers from Boards and Commission to extend the building lease for two additional years. The Board of Social Work was the only Board whose Director refused to sign the lease extension. She mentioned that no significant efforts had been made by DHMH to locate a new location after plans to move to Spring Grove 'folded.' The Board of Social Work is interested in acquiring more office space. There are tentative plans for the 5th and 2nd floor tenants to move to the Reisterstown Plaza facility, which could provide an opportunity for more space. Ms. Naesea stated that most of the Boards requested additional meeting room space. Dr. Love asked whether BPQA would be moving. Ms. Naesea replied that Office on Planning is not making plans around BPQA. They have consistently indicated they would be moving, but have not made any significant plans.

Ms. Naesea stated that because of the hiring freeze, the Board has sufficient space at this time, however once the Licensing Secretary comes on Board, we will need additional space. She asked the Executive Committee to approve the Board's development of a floor plan to reconfigure space that would accommodate projected staff and allow for additional growth as needed. Board members, interns and temporary staff would also be provided with sufficient space to perform tasks. The plans have been completed and are available at the Board office for the board members to review. She mentioned renovations are projected to begin in January 2002, and that there may be additional charges related to the purchase and assembly of additional partitions.

Board/Staff Workload Issues

Ms. Naesea mentioned that the State has a hiring freeze in place and that professional staff currently work overtime three to four days a week. She announced the introduction of a plan to convert the Office to a compressed workweek so that professional staff do not 'burn-out' trying to keep up with the workload. The compressed work week entails giving staff the option of working nine or ten hours a day instead of 8 hours daily. Professional staff could minimally have 4 hours off each week up to a full day off each week in exchange for working longer days. Ms. Naesea stated that there would be some days and periods when staff would not be allowed to take off. For example, staff will not be allowed to take off on scheduled board meeting days, nor possibly during periods when establishment renewals are scheduled (December/January).

Ms. Naesea also proposed that the Board members consider not assigning any additional special task force or committees until the Board close out current special groups. Ms. Furman re-iterated her concern regarding the way the Board's task forces are not structured. Ms. Andoll suggested that the Board members have training on facilitating task forces. Ms. Furman volunteered to help develop guidelines for

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task forces conducted by the Board. Mr. Ballard recommends for task forces not to have voting members other than Board members. He stated that the task force member's purpose is to advise the Board.

Ms. Naesea mentioned that this is a format that the Board indicated in the strategic plan. She said she would develop an initial document based on the discussion for review by Ms. Furman and future presentation to the Board.

Board Member Nominations

Ms. Naesea reported that three board members terms would be ending within the next six months. John Balch and Donald Yee's terms will expire in April and they may be re-nominated. Ms. Faltz-Jackson's second four-year term ends in June and she may not be re-nominated. Ms. Naesea mentioned that the Board will include an article in the Newsletter in January, regarding the nomination renewals and will contact required associations.

State Advisory Council on Medical Privacy and Confidentiality

Mr. Rubin reported that he has been attending the State Advisory Council on Medical Privacy and Confidentiality over the past 5-6 months. The Committee was created by the 2000 Legislature with the objective to provide the General Assembly with information and recommendations on emerging issues related to confidentiality of medical records. It also was assigned to monitor developments in federal laws regarding confidentiality related to health care information, technology, telemedicine, and provider/patient communications. Mr. Rubin expressed concerns related to the Committee's plans to provide information on the rights of consumers to the public, before providers have been properly informed of all the final provisions of HIPAA. He would not want to see patients demanding specific records from pharmacists before they have received clear rules of disclosure, as they may be affected by HIPAA. The Committee is hindered by a lack of attendance of members, often not having a quorum to approve minutes or motions, very minimal staffing and by a complete lack of funding. Mr. Rubin will continue to participate in the meetings.

Prescriptive Authority Meeting

Ms. Naesea mentioned that she received a call from Secretary Benjamin's office requesting a meeting regarding the prescriptive authority. She informed Pres. Ades of tentative meeting dates and notified Board members that they should inform her if they were interested in attending the meeting. Mr. Ballard mentioned that he was invited to the meeting as well, but did not have much information on its purpose.

2002 Board Meeting Dates

Ms. Hamlin referred Board members to the 2002 Board meeting schedule, which was inserted in the Board packets. She mentioned that she may make revisions/changes based on meeting times for the Practice Committee. She also mentioned that board members should return the new board packet binders at the end of each meeting. She stated that she would also collect any documents for shredding that were left in binders.

Board Counsel Report

Free Sale Certificates

Mr. Ballard reported that the Ms. Naesea had requested advice regarding free sale certificates that are routinely submitted by certain manufactures and/or distributor for her signature. Ms. Naesea was concerned that the content of these certificates may be too broadly stated and requires the Board to make attestations that are not authorized by the Board's statutes and regulations. He reviewed a free sale certificate and based upon his review, provided a letter that supported Ms. Naesea's concerns. He indicated

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that he does not believe that the Board has an obligation to provide these free sale certificates. If the Board does choose to continue to provide these certificates, it may wish to consider adopting regulations to allow it to charge a fee for providing this service. He recommended that the Board not sign any certificate regarding a matter that is outside the Board's authority to regulate. Instead, a certificate should be signed only if its contents are limited to claims that are within the Board's jurisdiction to regulate, and which claims can be verified by the Board's records. He also recommends that in order to insure the accuracy of the free sale certificates, Board members or staff must review the manufacturer and/or distributor's request, the applicable statutes and regulations, and the licensing files of the manufacturer and/or distributor. He said there is no statute or regulations that requires the Board to issue these certificates. Therefore, the Board may refuse to provide free sale certificates, or may charge a fee for their insurance provided that the Board first adopts a regulation authorizing such a fee.

Board Action

Dr. Love moved that the Board no longer sign free sale certificates. The motion was seconded by Ms. Faltz-Jackson and passed by the Board.

Legislative/Regulations Report

Legislation Report

Mr. Slade thanked Ms. Naesea for handling Drug Therapy Management while he was on vacation. He noted that the Legislative Session begins January 9, 2002.

Regulations Report

Mr. Slade referred participants at the meeting to the inserted regulations status report. He mentioned that the only change in the report is that comments had been received regarding the Patient Safety Regulations. The Committee briefly discussed the regulation comments.

Committee Reports

Pharmacy Practice Committee

DDC Inspection Process

Dr. Love reported that the Sunset Review recommended that the Board assist the Division of Drug Control (DCC) in developing a pharmacy inspection database to be used jointly by the Board and DDC. There was discussion about the current paper system in place and its weaknesses. The Practice Committee discussed this issue extensively at their December 3, 2001 meeting and concluded that the Board should offer the assistance of its staff database programmer to work with DDC to develop an inspection program to be implemented in lieu of paper, within one year. The Committee also asked that DDC appoint a liaison to work with Board staff by the beginning of March but would not make recommendation until Ms. Naesea assess manpower and availability. Ms. Naesea responded that she is aware of the need to address this issue, and she would make provisions for this to occur because it is critical to the operations of the Board. Mr. Jack Freeman mentioned that DDC has an information technology person. He suggested that the IT person and database programmer meet to develop a strategy.

Board Action

Dr. Love moved that the Board appoint a staff representative to meet with a representative in the Drug Control Division to discuss administration by March 1, 2002, with a goal to establish an inspection database within a year. The motion was seconded by Mr. Balch and passed by the Board.

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Misbranding

Dr. Love reported that the Practice Committee has determined that when medications are prepared for distribution to a patient and that patient never receives those medications and the medications are kept within the pharmacy, they may be re-dispensed. However, they may not be put into a stock bottle, but would have to be returned to the shelf in a prescription vial or container. Once they are removed from the stock bottle, the expiration date is one year from the day it was removed from the stock bottle or less if expiration date on the original bottle was less. The Committee also addressed the consequences of a drug being recalled, since the lot number of the original stock bottle might not be available. If there is a drug recall, it should be treated as a recall drug. Dr. Love mentioned that Ms. Andoll has prepared language regarding this matter for the newsletter. Ms. Andoll asked Mr. Freedman if he had heard from Anita Richardson. Mr. Freedman replied that the FDA has taken the position that drugs that do not have a lot number are misbranded. He sent a letter to Anita Richardson, from whom he expects a reply shortly. DDC proposed to FDA that when a drug is put back on the shelf, any that have been prepared before it was dispensed would be considered recalls. Mr. Freedman suggested that the Board contact with FDA directly about this issue. Dr. Love mentioned that the Board will approach this issue in the manner described and will go forward with their procedure until FDA contradicts the process. Ms. Andoll stated that she understands when the letter was received those to whom it was sent indicated that this was not a FDA issue. She stated that someone at FDA nonetheless said they would prepare a response.

Generic Substitution

Dr. Love reported that there was a communication to the Board regarding the use of blanket form letters from prescribers instructing pharmacists not to make generic substitutions for any of his or her patients. The question was whether these letters are adequate to prevent generic substitution by the pharmacist. The Committee felt that guidance for this issue existed in the Medical Assistance requirements, which require the prescriber's instructions on generic substitution to be on each prescription order. The Committee concluded that a general form letter is not sufficient to prevent generic substitution of a specific prescription. Ms. Andoll commented that the Committee also considered the current way records are kept in pharmacies and the untold number of patients that would be affected by a single letter in reaching this decision. Ms. Schneider suggested that this issue be addressed in the Board's Newsletter. Ms. Andoll replied she would follow up with an article.

Syncor/Sanitization

Dr. Love reported that the Committee received a question regarding contaminated containers being reused to transport radio-pharmaceuticals. The issue is that the containers become contaminated when used syringes are placed back into the container. Without the use of disposable plastic liners, the lead containers may become contaminated. However, some practitioners reuse the containers, even though they are contaminated. The Committee reiterated that this type of activity would be prohibited by the recently modified code of conduct regulations that require pharmacists to ensure proper hygienic and sanitation procedures in the dispensing process. The regulations will be enforced against practitioners that use contaminated containers to transport medications. In the specific case of radio-pharmaceuticals, the liners of containers need to be changed and sanitized appropriately to reduce the potential of any biological contamination.

Impoundment Regulations

Dr. Love thanked Ms. Bethman for drafting the impoundment regulations. Dr. Love presented the draft regulations for Board approval. Ms. Bethman pointed out a typo in section A(C) Article Section 21-1113C1. The Board amended Section B(2)(C), which should read "demonstrate the existing of expressly written."

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Mr. Rubin moved to accept the Impoundment Regulations with the corrections. The motion was seconded by Mr. Balch and passed by the Board.

Unlicensed Personnel/Technicians

Mr. Rubin stated that he would institute a time limit for the Task Force to complete expected tasks. He indicated that there will be a January meeting and one more meeting in February. Following the February meeting Mr. Rubin will review the work of the group and meet with Mr. Slade to draft the new changed areas into the current regulations and forward them to the Practice Committee to review.

Medication Errors Task Force

Mr. Yee reported that the Board had an Appreciation Celebration for task force members on December 12, 2001. Ms. Furman mentioned that they told the members that the Board may re-convene the group to revamp the regulations, if the Board receives comments on the Discoverability regulations. If not, Ms. Furman said the task force work is complete. Ms. Naesea stated that there the recommendations included a sub-group of the Task Force regularly producing public information articles on patient safety, for the newsletter and website. Ms. Furman replied that participants assigned to specific tasks stop coming to the meeting because once the Board came up with the final recommendations, people began to lose interest.

Board Action

Dr. Love moved that the Board dissolve the Medication Error Task Force and remove it from the agenda. He further proposed that the Board request assistance from former members of the task force, as needed. The motion was seconded by Ms. Faltz-Jackson and passed by the Board.

Ms. Furman mentioned that she presented a summary of the work by the Medication Error Task Force to the Patient Safety Coalition and most of their work is a mirror of the Task Force. Mr. Slade stated that the Medication Error Task Force did a presentation to the Joint Committee, Health Care Delivery and Financing Committee at the end of October. He thanked Pres. Ades, Allan Friedman and Howard Schiff for attending. Ms. Naesea mentioned that Mr. Slade and Ms. Andoll performed an excellent job in putting together the report.

Medical Devices

Dr. Love mentioned that the Practice Committee considered the regulation of medical devices, which are labeled with a caution against sale without an order from a healthcare provider. The Committee suggested that the matter be referred to the Attorney General's office to clarify the term "devices" and whether these devices fall under the Board's jurisdiction. Mr. Ballard requested that the Board put the request in writing.

Reciprocity – List of Candidates

Mr. Dyke reported that the Reciprocity meeting was held on December 18, 2001. He presented the names of candidates for licensure for reciprocity in Maryland. There were 13 candidates scheduled to take the examination, with all passing the examination and oral competency test.

Candidates - Passed

Micheal Castagna	Stanley Friedman	Mary Heldreth
Shingyee Huang	Ngozi Ikeji	Monika Johnson
John Nazzaro	Todd Nesbit	Tony Phillips
Kimberly Sherin	Ann Simoneau	Dawit Tsegaye
Barbara Van Horn		

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Ms. Faltz-Jackson moved to license the 13 candidates. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

Renewal vs. Reinstatement

Mr. Dyke reported that the Licensing Committee met on December 18, 2001. The Committee discussed the renewal and reinstatement process. Mr. Dyke indicated that Ms. Banks commented on some of the systems that are available regarding electronic licensure. Ms. Banks indicated that they have been looking at NABP's system, but it has not been tested yet. She will continue to research other systems for electronic licensure.

Dr. Love asked how much time it takes to process a reciprocity candidate through NABP. He stated he had communication from people expressing frustration that they have not been able to get people hired from out of state through reciprocity. Mr. Dyke responded that our process is probably better than most states. It takes about 6-8 weeks for reciprocity depending on how fast other States and NABP respond but that administer a test every month.

Mr. Dyke mentioned that the Florida State Board decided to only honor reciprocity candidates who have taken the NAPLEX within 12 years. NABP has solicited states' responses to this new policy. He also asked the Board to decide whether it would allow the reciprocation of Florida license pharmacists into Maryland based on the new policy. Mr. Ballard informed the Board that MD law allows the Board to waive any examination requirement for an applicant who is licensed to practice pharmacy in any other state, if that state grants a similar waiver to licensees of this state. There was significant discussion regarding how the term 'similar' should be interpreted. Mr. Ballard advised that it should be interpreted literally to mean that if MD reciprocity candidates to Florida can not reciprocate unless they have pass the NAPLEX within 12 years of the reciprocity request, then Florida pharmacists desiring to reciprocate to Maryland can not be waived of Maryland's state requirements. Board members determined that this was too narrow an interpretation since a precedence had been established by Board waivers provided to pharmacists reciprocating from Delaware. Maryland will consider any pharmacist licensed in Delaware for reciprocity, even though Delaware requires that a pharmacist has been actively practicing in the past 3 years in order to be considered for reciprocity. Thus, members agreed that the Board interpretation of the term 'similar' allows some flexibility. Board members were particularly supportive of this position in light of the pharmacist shortage in Maryland.

Board Action

Mr. Dyke moved that in light of shortage of pharmacist, the Board inform NABP and Florida that the Board will allow reciprocity of candidates from Florida candidates without any encumbrances. The motion as seconded by Dr. Love and passed by the Board.

Mr. Rubin mentioned that NABP is opposed to the State accepting it because of the 12-year limitation. Dr. Love stated that he did not think the Board's position would be challenged.

Revised Licensing Applications

Mr. Dyke reported that the Licensing Committee has extensively revised the renewal and reinstatement processes. He described the activities related to processing Board applications. The first step involves mailing the application two months before renewal and then following up with a letter prior to the expiration of the license to remind that the application has not been received. If an applicant sends their completed application back to the Board at least 14 days prior to expiration, a letter will be mailed to the applicant informing them that they may practice until their license application has been processed. If the application is received later than 14 days before the license will expire, then the licensee can not practice if

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his or her application is not process before the license expires. The Committee decided that on the day of expiration, another application would be mailed. If the application is received 30 days or more late or up to 45 days late, then the Board will take progressive steps toward reviewing and appropriately responding with possible disciplinary actions

Non-Renewed Established

Mr. Dyke stated that Ms. Banks would forward a list of non-renewed establishments on a monthly basis to DDC. The Committee was instructed not to publish in the newsletter or website any non-renewed establishments. He also mentioned that Mr. Rubin developed a punch list available for pharmacy permit holders that are planning to close. The list breaks down the regulations and provides user-friendly information. The field representatives will collect the list when they perform the final inspections.

Technology and Automation Report

Technology Committee

Ms. Banks reported that the Technology Committee will meet in the first week of January 2002. She also mentioned that the website is being remodeled and that the Committee will review the content before it is launched.

Web Site Statistics

Ms. Banks reported that the Board requested information about the research being performed on its website by the Chelmsford School System. She indicated that she is still awaiting a response, but indicated that the technical staff at Chelmsford believe that one of the student computer labs are 'hitting' the site.

Ms. Banks reported that some companies have been apparently unintentionally sending viruses to the Board's email address. She reported sending letters to those companies informing them of their email users' activities. So far, companies are responding with quick action.

Ms. Banks mentioned that there has been a 50% increase in website visits from South American and Caribbean countries.

Ms. Banks stated that the Board's website will be audited by DHMH to ensure we are in compliance with website guidelines. She said she is not sure of the exact date of the audit but was told it would be sometime in January. When asked by Board members about the kinds of information the auditors will be reviewing, Ms. Banks replied that they will be ensuring that the Board is in compliance with ADA, dated materials are current, information on the website is accurate, and that the website links work. They will also review minor systems.

MPhA Database

Ms. Banks reported that MPhA requested the Board to develop a database linking the pharmacies with their legislative districts. MPhA's intent is to allow the legislature to contact their area pharmacies to get drug inventory. She hopes that MPhA will share the information once completed. Ms. Naesea mentioned that she received a call from Ms. Arlene Stevenson, who has requested the Board's entire database of pharmacist volunteers for the bio-terrorism group. She asked Ms. Stevenson if the state plans to distribute the report to local departments. Ms. Stevenson replied she would integrate it into the larger state plan.

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Public Relations Report

Pharmacy Related Concerns & Medication Safety Brochures

Ms. Faltz-Jackson stated that the Practice Committee reviewed and approved the Consumer Information and Medication Safety brochures. Ms. Faltz-Jackson moved that the Board approve the brochures presented. The motion was seconded by Dr. Love and passed by the Board.

Citizen Advocacy Annual Meeting

Ms. Faltz-Jackson reported that Ms. Naesea attended the Citizen Advocacy Annual Meeting and it was full days' of intense work. Ms. Naesea recommended that the Board different staff and Board member attend of these meetings in future years because the topics were relevant to several areas of importance to the Board. Ms. Naesea mentioned that she apprise the Board of the next scheduled meetings. Ms. Naesea also mentioned that the people at the meeting were impressed with Ms. Faltz-Jackson presentations on information related to Board activities. Ms. Faltz-Jackson mentioned that this was the first time the Board of Pharmacy has a specific track at an annual meeting. She said that in speaking with the Executive Director, he indicated that they would be interested in doing a presentation or training for the Council of Boards.

Appreciation Celebration

Ms. Faltz-Jackson thanked everyone for supporting the Public Relations Committee's Appreciation Celebration. She especially thanked Ms. Lawrence for coordinating the event.

HIV/SEMINAR – Final Report

Ms. Lawrence thanked the Board for participating in the HIV/AIDS Seminar. She reported that 230 attendees were present at the seminar. Mr. Lottier stated that a small group of people did not receive their CE credits. Ms. Lawrence asked that Mr. Lottier have them contact her for that information. Ms. Naesea thanked Mr. Howard Schiff for all of the activities that MPhA provided to support the seminar.

Board of Pharmacy 100th Anniversary

Ms. Faltz-Jackson mentioned that the Board of Pharmacy will be celebrating its 100th Anniversary this year and that an event is planned for sometime in the spring. Ms. Lawrence will provide more information at a later time.

Council of Boards

Ms. Faltz-Jackson reported that the Council of Boards discussed Board member liability issues at its last meeting. She mentioned that Ms. Casey Lewis is the new chair of the Council of Boards. Ms. Faltz-Jackson recommended that the Board assign a pharmacist Board member and consumer member to the Council of Board. Ms. Faltz-Jackson mentioned that the technical, business, and trade are involved with the MD Department of Education website. She asked that the Board secure more information about this and keep abreast on the Department of Education's involvement. She said there is money available for science and math from the Eisenhower grant project. She mentioned that the Board might want to do some type of workshop with a grant from the project.

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Informational

Ms. Naesea reported that NABP is requesting volunteers from the Board to go assist in writing the NABP examination questions particularly those related to the ones in MD. She recommended that Mr. Rubin and Ms. Andoll attend. She mentioned it is an all expense paid meeting. Mr. Rubin indicated that he would not be available to participate. Ms. Andoll indicated that she will follow-up.

Ms. Naesea reported that NABP is recruiting candidates for the Advisory Committee on Examinations open positions and asked if any Board members want to submit a candidate. Mr. Yee said that he is interested and also suggested that Ms. Andoll attend.

President Ades adjourned the Public Board Meeting at 12:40pm.