

Maryland Board of Pharmacy

Public Board Meeting – August 21, 2002

President Ades called the Public Session of the August 21, 2002, Board meeting to order at 9:10 a.m.

Attendance:

Commissioners Present: Stanton Ades, President; John Balch; Melvin Rubin; Ramona McCarthy-Hawkins; Raymond Love; W. Irving Lottier, Jr.; Jeanne Furman; and Donald Yee

Absent: Wayne Dyke; Rev. William Johnson; Laura Schneider (resigned)

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

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

Guests: Jack Freedman (DDC); Peter Smith (PEAC); Kathryn Lavriha, (Barr Labs); Milton Moskowitz (PEAC); Lynette Bradley-Baker (CVS); Phil Cogan (MPHA); Stacey Poole, TAP Pharmacy; Felicia Scott, UMBC; and Brian Hopkins, UMBC

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 (07/17/02)

Page 7, under Licensing Committee, 2nd Board action regarding the discussion on reciprocity, delete from the first sentence “*end the English oral competency examination.*” The first sentence should read “*Dr. Love moved that the Board adopt the MPJE examination as the necessary exam for reciprocity once the Board is able to make administrative arrangements to implement the process.*”

Board Action

Dr. Love moved for acceptance of the July 17, 2002, public meeting minutes with amendments. The motion was seconded by Mr. Balch and passed by the Board.

President/Executive Committee Report

Bio-Terrorism Task Force

Pres. Ades reported that the Bio-Terrorism Task Force last met on July 19, 2002. At that meeting, the training sessions were discussed. Training registration forms were mailed to all pharmacists and technicians who previously registered as volunteers. The form included the training dates & times, the availability of continuing educations credit and outlined the training objectives and speakers. Three (3) different site locations will be used for four sessions.

Mr. Rubin and Mr. Cogan have been working on the deployment plans. Mr. Rubin stated that they are developing codes for each pharmacist depending on where they reside. Ms. Lawrence circulated sample

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badges that will be issued to the trained volunteers and explained the security logo on the badges. Ms. Banks mentioned that the pharmacists' licensing database could identify volunteers.

Executive Director's Report

New Law Books

Ms. Naesea reminded Board members of the lengthy discussion held at the last Board meeting regarding updating the Pharmacy Board law book. She inserted in the Board packet a proposal from Lexis outlining the content and quantity of the law books. Ms. Naesea stated that Mr. Schiff (MPhA) indicated that the commentary component of MPhA's law book project [for which the Board had provided a grant of \$25,000 in 2000] is completed. Mr. Phil Cogan said that the commentary plus the statute and regulations were combined in the MPhA project. Mr. Cogan stated that MPhA is in the process of also producing complimenting CD-Roms. He mentioned that MPhA would like the opportunity to bid on the Board project to update the law books.

Ms. Naesea reported that Lexis is currently contracted with the state because they produce many of the regulation books and supplements for other state units, including the Department of State Documents. She mentioned that if the Board contracts with Lexis, the Board would not have to go out on bid. If the Board decides to go out on bid, which they could, than Lexis will have to compete with MPhA and other bidders. Regarding timelines, Ms. Costley mentioned that although the process for bidders to submit their bids takes 3-5 days, it would also take approximately 4-6 weeks before Procurement & Contracts could approve the solicitation: then they would put it out for bids, review submission, choose the bidder and submit the contract, which would take another month for approval.

Ms. Naesea said that the Board has two options: the Board can subcontract with Lexis or bid it out. Mr. Rubin mentioned that if the Board selects Lexis, the Board would have an updated revision of all regulation and legislative changes through 2002 completed and published in 60 days. Mr. Cogan was asked when MPhA could have all their changes completed. Mr. Cogan said that he spoke to Judge Fader who indicated that all the changes could be completed by the first of the year 2003.

Dr. Love asked whether Lexis had included provisions in their proposal for electronic updates. Mr. Rubin responded that electronic updates had not been discussed with Lexis. Pres. Ades requested that the Board close the meeting to discuss the Lexis' cost proposal for updating and reproducing the law book.

Board Action

Mr. Lottier moved that the Board close the public session to discuss the Lexis proposal. The motion was seconded by Dr. Love and passed by the Board.

After much discussion and reviewing the Lexis proposal to provide law books to the Board, the Board decided to exercise the contract with Lexis. Determination of the exact quantity to purchased was delegated to the Executive Committee after reviewing the costs for specific quantities of the book and companion CD-Rom.

Board Action

Dr. Love moved that the Board re-open the public session to the public. The motion was seconded by Mr. Yee and passed by the Board.

Pres. Ades reported that the Board decided to exercise its right to amend the state contract with Lexis and not issue the contract for bids.

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Board/Staff Satisfaction Survey

Ms. Naesea mentioned that last year the Board began its five –year strategic plans and that the Board had identified several areas where it would work towards achieving an 80% satisfaction rate among Board and staff. The survey results were distributed to the Board and staff to review. Ms. Naesea stated that of the eight areas evaluated, Board and staff only rated three areas in which they were 80% or better satisfied: 1) the level of involvement of Board and staff members; 2) the quantity, quality and timeliness of information received from Board and staff members (Board member rated only); and 3) the point of contact directory for Board members (staff rating only). She directed Board members' attention to the comment section, which contained a 68% satisfaction rating for staff training opportunities; a 71% level of satisfaction with communication between staff and Board members; a 77% satisfaction rating by staff with the availability of Board members; and a 44% satisfaction rating by staff regarding the quantity, quality and timeliness of information received from Board and staff members. Ms. Naesea indicated that she is planning a staff retreat to address work place issues. She asked the Board and staff to review the results and submit comments and recommendations to her and President Ades.

Staffing Update

Ms. Naesea reported that the Board has not received responses from DHMH to the Compliance Officer position announcement. Ms. Costley stated that DHMH personnel staff is reviewing the applications. The posting date expired on August 12, 2002. Personnel have requested a list of the interview panel from the Board, as well as questions for the interview. Ms. Naesea stated that Pres. Ades has assigned Ms. Furman, Dr. Love, Ms. Naesea and himself as panelists for the interview process. Mr. Rubin and Mr. Lottier will be alternative panelists. Dr. Love asked about the timeline for hiring. He expressed concern that persons who may be interested in the position might become disinterested because of delays and that the Board will lose good prospects. Ms. Costley will email the list of panelists to Personnel. The Board members indicated their available dates to meet with a Personnel representative.

Ms. Naesea also reported that the Office Secretary III and Licensing Clerk positions are now permanent. She announced that Ms. Angela Long, Secretary III, had elected not to accept her position, which became permanent in July 2002. The Board is interviewing the top qualified applicants for both positions.

Ms. Naesea stated that the Board is still negotiating with the Social Work Board for Mr. Slade to become full-time at the Board.

Ms. Naesea announced that Ms. Schneider resigned as Board member before her term expired. Mr. Rubin told Ms. Naesea that when a Board member resigns before term expires, the Governor would re-appoint another member. Ms. Naesea will contact Ms. Roz Goldner regarding requirements for filling resigning Board member vacancies.

Ms. Naesea mentioned that Ms. Faltz-Jackson was the Board's representative at the Council of Boards meetings. The Board needs to assign another representative. Mr. Rubin volunteered to attend the August meeting.

New Building Lease

Ms. Naesea reported that the Board would be signing a 10-year building lease agreement for the current offices, effective February 1, 2003. The rate has actually decreased, however, additional services were added. Ms. Naesea asked whether the Board wanted to follow through with the Board's renovation plans since the new lease had been signed. Mr. Rubin suggested that the Executive Committee make that determination.

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Audit Report

Ms. Naesea reported that the Boards and Commissions received preliminary comments on its legislative audit. Four (4) specific comments were related to the Board of Pharmacy. They regarded approved verification systems in licensing, which had been changed since the last audit; and the Board's per diem. She said she would mail the final report and the Board's response to Board members once they are completed.

Legislative/Regulations Report

BoP Regulations Status Report

The BoP regulations status report was included in the Board packet. The only update to the report was that the Patient Safety regulations were under review and seemed to have been delayed by Carol Benner of the Office of Health Care Quality. He received a message the morning of the Board meeting in which Ms. Benner and Richard Proctor had requested a briefing on the proposed regulation issues. Mr. Slade stated that he would brief Mr. Proctor and asked whether anyone was interested in joining him. Ms. Furman replied she would like to attend the briefing.

Automated Medication Systems – Notice of Final Action

Mr. Slade included, the notice of final action for the Automated Medication Systems regulations in the Board packet.

Monetary Penalties – Notice of Proposed Action

Mr. Slade included the notice of proposed action for Monetary Penalties and Reinstatement of Expired Licenses for Pharmacists regulations in the Board packet. The reinstatement regulations were published for comments and are due by August 26, 2002.

Reinstatement of Expired Licenses for Pharmacists

Mr. Slade reported that the Board voted last month to abolish the lab exam for initial applicants for licensure. He included in the Board packet a memorandum related to the need to abolish the lab exam for reinstatement applicants. The Board decided to start the process to abolish the lab exam by March 2003, so that June applicants would not have to take the exam.

Board Action

Dr. Love moved that the Board adopt the changes made to the reinstatement of expired licenses for pharmacist's regulation as submitted. The motion was seconded by Ms. Furman and passed by the Board.

PEAC

Mr. Milton Moskowitz reported on behalf of PEAC. PEAC has 35 cases; of which 7 were Board referred. At the retreat, PEAC decided to increase the length of a contract for self- or Board-referred cases for an extended monitoring period. He stated that PEAC had developed a rapport with the Board; their reporting to the Board is coming along very well and they are attending the Disciplinary Committee meetings on a monthly basis.

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PEAC is enhancing and developing procedures for non-compliance cases and how to refer them to the Board. They are enhancing their monitoring by reviewing the monitoring practice on an annual basis. They discussed student issues related to controlled substance abuse problems, as well as, how the school is responding to abuse by students. PEAC also discussed at the retreat the Board members knowledge of addiction and PEAC's conducting some additional in-services.

PEAC is still seeking a full time Administrator. Mr. Moskowitz thanked Ms. Naesea and the Board for all their support. He also thanked and acknowledged Ms. Gale, Ms. Furman and Mr. Rubin for attending PEAC's retreat and staying until the end of the sessions.

Ms. Furman stated that a lot of good information was shared, which the Board was not quite aware of. One in particular relates to the PEAC "Decision Tree" that maps out what happens to a pharmacist who relapse and when that person is ready to return to treatment. She stated that PEAC was not reporting (Board referred cases) when a pharmacist would have minor slips. The Board and PEAC decided that on Board referred cases, where a PEAC contract is a part of the consent order, the Board needs to be notified of all infractions. PEAC is concerned about whether confidential information would be protected once provided to the Board. Ms. Furman assured PEAC that confidential information would not become public information. Ms. Furman reported that PEAC discussed relapse issues and how to minimize them before or after the PEAC contract expires. PEAC is interested in inserting an article in the newsletter. Ms. Furman offered to write a short article directed to employers on how to take certain steps and resolutions when substance abuse is found in the workplace. She mentioned that she would seek assistance from Mr. Ballard and/or Ms. Bethman regarding legalities of the information.

PEAC also discussed the lack of pharmacist's opportunities in non-dispensing roles as a future initiative. They asked that Ms. Furman develop a list that PEAC could issue to pharmacists who have surrendered or lost their licenses but are not under a Board contract. This list would consist of information the Board uses for standard terms and conditions of consent orders. Ms. Furman will seek Board approval before submitting the list to PEAC.

Committee Reports

Pharmacy Practice Committee

Dr. Love reported that the Committee met on August 7, 2002. The majority of the meeting was spent on pharmacy assistant issues regarding the statutory changes. There were a few comments regarding the need to re-examine the regulations that already exist under unlicensed personnel. The Committee needs to strengthen the degree to which the Board holds permit holders responsible for background checks and qualifications of persons who have access to patient records and medication. At the next meeting in September, the Committee plans to address the pharmacist-in-charge issues.

Drug Therapy Management

Dr. Love reported that Mr. Slade and he attended BPQA's Practice of Medicine Committee meeting. They presented the DTM 'draft-in-progress' regulations. The general response from BPQA was that the Board is on the right track, however, one physician, who has not been particularly in favor of the progress in the past, expressed some reservations. This person was concerned about requirements for timely notification of physicians when pharmacists change patient regimens. She was informed that physician/pharmacist agreement and protocol have to go before a joint committee then the joint committee makes recommendation to the respective boards. BPQA's committee also discussed the nurse dispensing issue regarding whether a local health department can dispense for multi-physicians. BPQA's interpretation was that it would be permissible. Dr. Love stated that based on the way the statute reads, he does not agree with the interpretation. According to BPQA's current interpretation of their declaratory ruling and the way they

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interpret the statute, the local health department will be able to dispense based on nurse practitioner prescription.

Members of the Board received a copy of a document entitled “Developing Regulations” which had been drafted by Mr. Slade. Mr. Slade stated that at BPQA’s Practice of Medicine Committee plans to take it to BPQA to review in September. He suggested that the Board review the regulations to determine how to define amendments to DTM contracts and protocols so that the Boards are on the same page. The Board reviewed the developing regulations and made additional changes to the document.

The next Practice Committee meeting is scheduled on September 4, 2002, at 1:30pm.

LTC Task Force

Mr. Balch reported that the LTC task force did not meet the month of August. At the last meeting in July, the Task Force decided to invite a representative from the Office of Health Care Quality to the meeting on September 13, 2002, at 3:30pm. Pres. Ades stated that he left a message for Carol Benner and will follow up on that call.

Nurse Dispensing Task Force

Dr. Love reported that a formulary was distributed at the last Board meeting and Mr. Yee asked that Dr. Love assist in reviewing the list. In reviewing the list, they discovered obvious problems with the formulary where drugs were listed in the wrong categories, drugs listed in one particular health department and drugs listed outside the declaratory ruling; which was their response based on those basis.

Mr. Yee reported that the next task force meeting was been re-scheduled to August 22, 2002. Ms. Naesea stated that the task force had not received the Board’s concerns and changes to the formulary. Mr. Yee mentioned that the nurse dispensing task force pre-test questions are the same as the post-test and he feels that the exam should be different.

FDA Hearing on Bar-Coding

Ms. Furman reported that she attended the FDA public hearing on July 26, 2002, to solicit comments on the development of regulations requiring bar codes on all drug products and medical devices. In response to the IOM report, Department of HHS directed the FDA to explore regulatory approaches related to dispensing and administration of drugs. FDA has two panels of experts discussing the pros and cons associated with different aspects of bar-coding.

HIPAA

Mr. Rubin mentioned that although the HIPAA regulations are not the direct responsibility of the BoP, pharmacists who violate them may come before the Board to consider disciplinary action . Therefore, the Board should try to insure that all pharmacies and pharmacists are aware of the new regulations. Mr. Rubin reported that he wanted to send some highlights and references of the HIPAA regulations to establishments by early September.

Board Action

Dr. Love moved that the Board prepare a transmittal to the establishments within the next 2-3 weeks. The motion was seconded by Ms. Furman and passed by the Board.

Mr. Cogan suggested that the highlights be posted on the website.

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Licensing Committee

Reciprocity – List of Candidates

Ms. James reported on behalf of Mr. Dyke. The Reciprocity meeting was held on August 20, 2002. She presented the names of candidates for licensure by reciprocity in Maryland. Twenty-two (22) candidates took the examination; two (2) candidates – Omar Badawi and Pamela Bowman, failed; and two (2) applicants; Donna DiGiantomasso and Patricia Ross are pending passage of the oral competency exam.

Candidates - Passed

Catherine Burnett	John Clark	Beth Collier
Binta Desai	Phoung-Cuc Doan	Mahro Ershadi
John Hoke	Edward Horn	Clarence Howard
Shridhar Iyer	John Lewin III	Angela Odunlami
Nikil Patel	Robert Running	Jibril Abdus-Samad
Mohammed Siddiqui	Michael Streng	David Tran
Gila Unguru	Pei-Sah Upshaw	

Board Action

Ms. Furman moved to license the twenty (20) candidates who passed the exam and to approve the two (2) candidates pending their meeting oral competency requirements. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

Disposal of Medication

Mr. Rubin reported that the Board has large bags of wet lab prescriptions housed in the Board's conference room for disposal. He asked the Board what they want to do with them.

Board Action

Dr. Love moved that the Board arrange for secure disposal of the wet lab prescription medications. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

The Board voted to close the public session to discuss the wet lab update and the report on a licensing candidate. The discussions were deferred until after the last agenda item of the public session was addressed.

Examination for Licensure and Professional Experience Program

Mr. Slade presented the examination for licensure and professional experience program regulations for the Board to review. The Board reviewed and modified the regulations. Mr. Slade mentioned that the Board charges \$100 for the laboratory examination, however, since the Board is eliminating the exam, he asked if the Board wanted to decrease the fee. It was directed that the Board investigate administrative processing fees charged by other state boards.

Board Action

Dr. Love moved that the Board accept the modification to the examination for licensure and professional experience program regulations. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

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Licensing of Wholesale Prescription Drug Distributors

Mr. Slade stated that there was no need to review the licensing of wholesale prescription drug distributors regulation in depth because Mr. Ballard suggested that the Board incorporate medical device language in these regulations. Mr. Slade discussed the issue of how to deal with intra-company inter-state sales of transfer. The Board agreed that the revisions which Mr. Slade had made. Due to the regulations needing more in depth reviewing, the Board recommended that Mr. Slade forward the regulations to the Licensing Committee for review.

Disciplinary Committee

Complaint Form

Ms. Gale presented to the Board the final revision to the complaint form for informational purposes.

Updating Inspection Form

Mr. Rubin presented highlighted information from the revised inspection form that will soon be distributed to pharmacies. The Board reviewed the information and made some modifications. Mr. Rubin will make the changes that were discussed and send it out for comments.

Technology and Automation Report

On Line Renewal System

Ms. Banks reported that the Board received the signed agreements from MHCC and MD State Archives. The Board's on-line renewal system development is scheduled to launch with MHCC on September 1, 2002.

Website Statistics

Ms. Banks distributed a summary of new items on the Board website. She mentioned that the bio-terrorism volunteer form and training registration form can be accessed from the website. Also, the Board can now verify physician and nurse licenses, download OHCQ and HBAM from the website, as well as access HIPAA information. The Board is also linked to local meetings and conferences. Ms. Banks informed Board members that they should notify her by e-mail of meetings or conferences for posting on the website.

Public Relations Report

Board's 100th Year Celebration

Ms. Lawrence reported that Ms. Naesea, Jennie Caldwell, Governor's intern, Sue Ward, Director of the Department of Aging, Toni Price, Public Affairs Officer, Department of Aging, Frank Bailey, Executive Director of AARP and Kelley Coates, Public Affairs Representative of AARP met to discussed working together on a joint initiative. The parties discussed issues related to pill splitting (to reduce medication cost), drug interactions, generic drugs and educating people to consult with their pharmacist and doctor. Ms. Lawrence stated that AARP currently has a \$10 million dollar national campaign focusing on informing seniors to ask their health care provider about the possibility of using generic drugs rather than brand names. The participants at the meeting discussed the possibility of doing joint initiatives among the three parties. These initiatives would be announced at the Board's 100th Anniversary Press Conference on

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October 16, 2002. The representatives from AARP disclosed that they run a national mail-order pharmacy and are currently in legal litigation with a drug manufacturer. AARP also mentioned that they supported the Medicare bill that just failed in Congress.

Ms. Naesea stated that the parties discussed concerns that seniors have with insurance costs escalating every year and whether or not consumers realized the relationship between higher insurance costs and coverage for name brand drugs. The Department of Aging suggested that local aging commissioners could host four regional seminars for seniors and other consumers to discuss the differences between brand and generic drugs with pharmacists. This area of concern was noted as being of high concern in the senior community.

Board members expressed concerns regarding the selected initiative and voted not to engage in it. Ms. Lawrence presented a sample invitation to the proposed press conference and an article showing the Board's historical events through the years.

Ms. Naesea announced that Pres. Ades had suggested that the Board not pursue a luncheon for the 100th year celebration, but to invite past and present pioneers to the press conference to receive recognition awards. Board members expressed concerns about not being clear on the purpose of the Board's 100th year celebration. Pres. Ades explained that the Board received disapproval from DHMH of its plan to host a luncheon following the press conference. He said this was why he decided to eliminate the public luncheon. He stated that the celebration will consist of him being the moderator, giving a history of the Board, announcing past, present and future Board members and leaders, announcing leaders of pharmacies in this state and public officials who are in attendance. He will also explain the past, present, and future Board initiatives. Ms. Naesea mentioned that she was informed by DHMH that if the Board wanted the press involved, the Board should announce some type of new initiative, which is how AARP got involved.

Based on the Board members' concerns regarding the Board's 100th year celebration, the Board decided to have the regularly scheduled Board meeting in its usual format, to send out a press release and to insert the Board's historical events in the newsletter.

MSHP Conference

Ms. Lawrence mentioned that MHSP is having a conference on October 11-13, 2002 and she asked if the Board would be interested in reserving a booth or participating. The Board declined to have a booth, however, Ms. Furman and Dr. Love will be in attendance.

Questions for the Board

DEA # - Prescription Labels

Mr. Rubin mentioned that the Board received an e-mail that the state of Oregon is receiving numerous complaints about pharmacists, employed by chain pharmacies, who insist on placing the doctor's DEA numbers on the patient's label on the bottle. The Board does not prohibit nor require that a DEA number be printed on label bottles.

Canadian Pharmacy

A question was raised as to whether a Maryland resident can get prescriptions from a Canadian pharmacy legally under the state law. Mr. Ballard's, counsel to the Board, advice was that it is generally a violation of federal law for a person to purchase a prescription drug from a foreign pharmacy. If certain criteria are met, the FDA chooses not to penalize persons for purchasing foreign drugs. However, the FDA does enforce these laws when a foreign pharmacy promotes its drugs to U.S. consumers. Therefore, his recommendation to the Board was to refer such foreign pharmacies to the FDA.

WebMD

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Ms. Gale reported that she received a phone call on July 24, 2002 from Nicholas Willard, Director of State Government Affairs for WebMD. He had inquired about the requirements for prescription validity outlined in COMAR 10.34.20.02B(4). Ms. Gale suggested that Mr. Willard send a detailed description of their process for review and approval. The Board instructed Ms. Gale to forward this question to the Practice Committee to review and respond.

Disciplinary Committee Report

Dr. Love moved that the Board close the Public Session to discuss the investigation of three wet lab examination candidates. The motion was seconded by Mr. Yee and passed by the Board.

Wet Lab Examination Candidates

Statutory Authority to Close Session: State Gov't Article §10-508(a)(11)

Topic Discussed: The grading of the wet lab examination

Purpose: To discuss the grading of the wet lab examination

Action(s) Taken: Decisions regarding the grading of the wet lab examination

Dr. Love moved that the Board close the Public Session to discuss the Gregory Danylyk case. The motion was seconded by Mr. Balch and passed by the Board.

Gregory Danylyk

Statutory Authority to Close Session: State Gov't Article §10-508(a)(13)

Health Occupatoins Article, §14-501(d)

Topic Discussed: Licensure application for Gregory Danylyk

Purpose: To consider medical evaluation and make decision regarding licensure application

Action(s) Taken: Considered medical evaluation and made decision regarding possible licensure.

Pres. Ades adjourned the Public Session at 3:00pm.