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DEPARTMENT OF STATE

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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, August 20, 2008 at 9:30 a.m.
PLACE:	861 Silver Lake Boulevard, Dover, Delaware Conference Room A , second floor of the Cannon Building
APPROVED:	

MEMBERS PRESENT

Geoffrey N. Christ, Esq., R.Ph, Professional Member, Chair
Sandra Robinson, R.Ph, Professional Member, Vice Chair
Don Holst, R.Ph, Professional Member
Sebastian Hamilton, R.Ph, Professional Member
Angelo Chiari, R.Ph, Professional Member
Howard Simon, R.Ph, Professional Member
David Bonar, Public Member
David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

Carolyn Calio, Public Member
Michael Hertzfeld, Public Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

Chris Spizzirri, Deputy Attorney General
Nancy Fields, Administrative Specialist II
James Kaminski, R.Ph., Pharmacist Administrator

ALSO PRESENT

Eric Assibey-Marfo
Danielle Gunderson
Richard Hascup
Alex Zanow
Louis Leverson
Theresa Forbes
Johnnymae N'Dione
Christy Crkvenac
Michele Arling
Thomas Kolakowski Jr.
Suzanne Raab-Long

Amanda Warren
Tiffany Soreg
Daniel Insham
Danielle Gunderson
Barbara Gadbois
Wayne Marvel
Barbara Bonk

CALL TO ORDER

Mr. Christ called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

The Board reviewed the minutes of the June 25, 2008 meeting. A motion was made by Mr. Holst, seconded by Mr. Hamilton to approve the minutes with edits. The motion was unanimously carried.

PRESIDENT'S REPORT

Mr. Christ reviewed his appointments with the Board. The appointments will basically remain the same with the exception of adding Mr. Simon on the Legislative Committee. Mr. Christ advised and reviewed the functions of the Board and the Division of Professional Regulation according to statute. Mr. Christ stated he would like to concentrate during his term on collaborative care, the prescription blank issue, streamlining Board processes, and finalizing Regulation 5 amendments as needed. He would like to begin communications with the University of Delaware, stressing the importance of having a pharmacy program in Delaware. He will be attending the upcoming District II meeting and as many of the Delaware Pharmacist's Society and Delaware Society of Health Systems Pharmacists meetings as time permits. Mr. Christ is in the process of drafting correspondence to the Governor reviewing the importance and need of hiring more pharmacist inspectors not only for the pharmacy program but also for other healthcare inspections. Mr. Christ and the Board agree that the inspection program is an integral and required part of the healthcare regulatory process, providing a safe environment for Delaware citizens.

UNFINISHED BUSINESS

Legitimate Medical Purpose - Internet Pharmacy Proposal

Mr. Christ reported that he would be scheduling a Committee meeting to address further statutory language under Title 24 for next year's agenda pertaining to internet pharmacies. The Board was agreeable to this issue.

Regulation 5 Review

Mr. Christ reported that he would be scheduling a Committee meeting to address Regulation 5 issues. Regulation 5 will also address Representative Wagner's concerns of having language explaining parameters of practice for pharmacy technicians. Representative Wagner had forwarded an e-mail to the Board regarding her concerns in this area. The Board requested Mr. Dryden contact Representative Wagner and inform her that they would be addressing her concerns. The Board agreed.

Strategic Plan

Mr. Spizzirri provided an updated Strategic Plan for the Board to review and advised that the Board begin concentrating on the first items which are establishing reinstatement requirements for inactive licensees, establishing technician functions, rules and regulation amendments for a statewide drug take-back program, and the statute changes for final checks.

NEW BUSINESS

License Approval Streamlining

Mr. Christ and Mr. Spizzirri reviewed the possibility of streamlining the licensing process of pharmacists and pharmacies. After discussion, Mr. Bonar made a motion, seconded by Mr. Holst, to permit the Executive Secretary and Division personnel to review and approve pharmacy and pharmacist licensure applications after they meet all requirements necessary for licensure. The Board will review only those applications with issues that require their attention. After the pharmacies and pharmacists are licensed they will be listed on the Board agenda and approved by the Board accordingly. The motion unanimously carried.

Pharmacist-in-Charge Interviews

Mr. Hamilton conducted the pharmacist-in-charge interview for Danielle Gunderson.

Review of Pharmacy Applications

No Pharmacy applications were reviewed at this time. The new licensing approval process will be followed for the pharmacy applications listed on the August meeting agenda.

Pharmacist Licensure Review

Mr. Chiari made a motion, seconded by Mr. Simon, to approve licensure for the following individuals' contingent upon the candidates meeting all the requirements for pharmacist licensure and approved by the Division and Executive Secretary:

- 5.3.1 Sarah Houser
- 5.3.2 Aicha Alaoui Mdaghri
- 5.3.3 Heike Doerr
- 5.3.4 Edward Dowling
- 5.3.5 Michelle Giovannucci
- 5.3.6 Lindi Mayo
- 5.3.7 David King
- 5.3.8 Antonio Mazzamuto
- 5.3.9 Rajashree Mulgaokar
- 5.3.10 Sinoe Naji
- 5.3.11 Angel Nguyen
- 5.3.12 Ayodeji Oke-Owo
- 5.3.13 Ozioma Okoli

- 5.3.14 Chirag Patel
- 5.3.15 Jennifer Runfolo
- 5.3.16 Farzin Sadr
- 5.3.17 Vanessa Scully
- 5.3.18 Prabhakararao Yenduri
- 5.3.19 Erin Crowley
- 5.3.20 Deborah Simon
- 5.3.21 Dorothy Holt
- 5.3.22 Arijit Aichbhaumik
- 5.3.23 Denise Racano
- 5.3.24 Andrea Mesaros
- 5.3.25 Naga Ranjita Potula
- 5.3.26 Leah Hart-Banks

The motion was unanimously carried.

After some discussion and review of the application, Mr. Bonar made a motion, seconded by Mr. Simon to approve licensure for Laura Mandos contingent upon candidate meeting all the requirements for pharmacist licensure. The motion was unanimously carried.

After some discussion and review of the application, Mr. Bonar made a motion, seconded by Mr. Holst, to approve licensure for Gerald Mengang contingent upon candidate meeting all the requirements for pharmacist licensure. The motion was unanimously carried.

After some discussion and review of the application, Mr. Bonar made a motion, seconded by Mr. Hamilton, to approve licensure for Nicholas Zener contingent upon Mr. Zener meeting all the requirements for pharmacist licensure and on the condition that Mr. Zener continue with treatment therapy and that the Board receive quarterly reports from his counselor or facility confirming his ongoing treatment for one full year. Ms. Robinson amended the motion, seconded by Mr. Chiari, that Mr. Zener's license will be suspended if the reports are not received. Mr. Holst and Mr. Christ opposed this motion. The motion carried.

Committee Reports

Joint Practice Committee – No Report

Physician's Assistant Report – Sebastian Hamilton, R.Ph.: Mr. Hamilton met on August 5, 2008. There were six new applicants for licensure, five for controlled substance prescriptive authority and three for prescriptive authority. The next meeting is scheduled for September 9, 2008.

Newsletter – David Dryden, R.Ph., J.D, Howard Simon, R.Ph., Angelo Chiari, R.Ph. and Don Holst, R.Ph.: Mr. Dryden reported that the newsletter had been completed and addressed frequently asked Board of Pharmacy and controlled substance questions as the Board had requested.

Legislative – Howard Simon, R.Ph., Sebastian Hamilton, R.Ph., Don Holst, R.Ph., Geoffrey Christ, R.Ph., Esq., and David Dryden, R.Ph., J.D.: Mr. Christ reviewed the two handouts provided to the Board. The first handout addressed passed legislation for Session 2 of the 144th General Assembly. The second handout was a memorandum from James Collins encouraging the development of a legislative agenda and designation of a legislative committee to advance legislation in the 145th General Assembly, 1st Session.

Mr. Christ stated he wanted to be the Board representative for SB321 which forms a committee to establish a statewide prescription pad with specific criteria pursuant to 16 Del. C. §4797 to eliminate or significantly reduce prescription fraud. Under the parameters of this law the committee shall be comprised of two at-large members appointed by the Governor. Mr. Holst made a motion, seconded by Mr. Chiari, to have Mr. Dryden draft a letter to the Governor requesting that Mr. Simon be added as one of the at-large members. The motion unanimously carried. The letter should state that the Board of Pharmacy feels that it is important and necessary to have pharmacists with a well-rounded background on this committee.

Continuing Education –Michael Hertzfeld, Don Holst, R.Ph. and, Geoffrey Christ, R.Ph., Esq.: Mr. Christ reported that the CE Committee had met on August 20, 2008. The Committee reviewed two non-ACPE submissions pertaining to Emergency Preparedness. After careful review the Committee recommended that the board not approve any continuing education credits for the program submitted. The Committee determined the submissions did not explicitly relate to the contemporary practice of pharmacy (Regulation 1.4.5.3). The Committee also found that they could not award any credits since the program was part of the applicants' employment (Regulation 1.4.5.6.3). Mr. Holst made a motion, seconded by Mr. Bonar, to approve the Committee's recommendation that no continuing education credits would be issued for the submissions. The motion unanimously carried. The Board requested Mr. Dryden forward correspondence to the applicants of their decision.

Consumer Affairs – Carolyn Calio, Michael Hertzfeld, and David Bonar: No report.

Professional Liaison – Angelo Chiari, R.Ph. and Sandra Robinson, R.Ph.: Ms. Robinson reported that DSHP is planning their mid-year meeting and she will report back to the Board.

MPJE Study Committee –Angelo Chiari, R.Ph., Sebastian Hamilton, R.Ph., Sandra Robinson, R.Ph. and James Kaminski: Ms. Robinson reported that she and Mr. Kaminski would be attending a MPJE meeting. Ms. Robinson requested the Board's assistance by asking that each pharmacist member to submit five questions. Ms. Robinson reviewed question parameters.

Hearing Regulation 11 and 18

At 10:37 a.m. the Board went on the record. Mr. Spizzirri stated the purpose of amending Regulations 11 and 18. The Board was introduced. One written comment was entered as an exhibit. Mr. Christ called for public comment. There was no other public comment. Mr. Bonar made a motion, seconded by Ms. Robinson to go off the record for deliberations. Mr. Spizzirri stated that he had not reviewed the regulation changes and was not prepared to talk about them. Mr. Bonar made a motion, seconded by Mr. Hamilton, to table until the next meeting since the D.A.G had not reviewed them. Ms. Robinson amended the motion, seconded by Mr. Holst, by adding to re-notice and re-publish in Delaware Regulations after Mr. Spizzirri had reviewed. The motion unanimously carried.

A motion was made by Mr. Bonar, seconded by Ms. Robinson to go off the record and conclude hearing at 10:45 a.m. The motion unanimously carried.

Ms. Robinson made a motion, seconded by Mr. Hamilton, to take a 15 minute recess before hearing. The motion unanimously carried.

Reopen Hearing for Eric Assibey-Marfo 13-07-07

Wayne A. Marvel, Esq. was legal representative for Mr. Assibey. Barbara Gadbois was Deputy Attorney General for the State of Delaware and the Plaintiffs. The Board went on record at 11:31 a.m. Mr. Spizzirri stated that Mr. Assibey-Marfo had requested the hearing to have his testimony, regarding complaint against him, heard by the Board since he was out of the country at the time of his hearing in March 2008. The Board agreed to hear Mr. Assibey-Marfo's case, which vacated the previous order of suspending his license.

The Board was introduced. Mr. Spizzirri entered the exhibits into record. A motion was made by Mr. Chiari, seconded by Ms. Robinson to go off the record. The motion unanimously carried.

A motion was made by Mr. Holst, seconded by Ms. Robinson, to go back on the record. The motion unanimously carried.

Mr. Christ introduced Ms. Gadbois to begin hearing. Mr. Assibey-Marfo, Ms. Barbara Bonk, and Mr. Dave Dryden testified.

After all the testimony and cross-examination was complete, a motion was made by Mr. Hamilton, seconded by Mr. Holst, to go off the record for deliberations. The motion unanimously carried.

After deliberating, Mr. Hamilton made a motion, seconded by Ms. Robinson, to go back on the record. The motion unanimously carried.

A motion was made by Mr. Hamilton, seconded by Mr. Simon, the Board does not find Mr. Assibey-Marfo guilty of incompetence and gross negligence; therefore, Mr. Assibey-Marfo's license will be reactivated and the suspension will be stricken from his record. The motion unanimously carried.

A motion was made by Mr. Hamilton, seconded by Mr. Holst, to go off the record and close the hearing. The motion unanimously carried. The hearing closed at 2:20 p.m.

Inspection Report

Mr. Dryden reported that nine pharmacies and three controlled substance inspections were performed in the month of July. There are no open investigations currently.

Board Correspondence

NABP e-News dated July 9, 2008 regarding DEA Proposed Rule on Electronic Prescriptions for Controlled Substances.

NABP e-News dated July 9, 2008 regarding NABPLEX/MPJE Candidate Eligibility Based on Actual Graduation Dates.

NABP correspondence dated June 2008 regarding NABP State News Roundup and Delaware's Medication reporting.

NABP correspondence dated July 17, 2008 regarding Florida's Removal for 12 Year Requirement for Reciprocity.

NABP correspondence dated July 17, 2008 regarding President Palumbo's 2008 Appointments.

NABP correspondence dated August 15, 2008 regarding an Update on the Georgia litigation and Score Invalidation.

Correspondence was received from Representative Wagner to U.S. Department of Labor, Employment and Training Administration regarding a Technician Training Program. The Board will be adding language regarding Technicians to statute soon. Mr. Holst stated that Walgreen's/ Happy Harry's received the letter and they are in support as well.

Other Business before the Board

Mr. Kaminski reviewed the following inspection issues:

- An e-mail was sent based on a past declaratory decision to an out-of-state pharmacy where remote order entry was being done for a Delaware facility. The pharmacist(s) doing the remote order entry are required to be Delaware licensed. The pharmacy is not required to be licensed unless it is dispensing into Delaware. The pharmacist providing remote order entry does not have to be physically present in the pharmacy when performing this practice. The Assistant DAG stated that then Boards regulations should be updated to reflect this ruling.
- An e-mail to Governor Minner dated June 23, 2008 from Sandy Brackin Funk, CRNP was reviewed. There is a high increase in the amount of controlled substances being abused in our state recently. Education and regulation seem to be at a minimum here in our state. Mr. Kaminski reminded the Board of his similar concern, large increase in the amount of hydrocodone, methadone and other controlled substances, voiced at a previous Board of Pharmacy meeting. He thought the increase was due to lack of education and enforcement of the regulations due to a staff shortage. Mr. Christ stated he is in the process of drafting correspondence to the Governor regarding this matter.
- Policy and procedures regarding installation of an Omnicell (automation) at a Delaware nursing home were reviewed by the Board of Pharmacy Office. Corrections and comments were addressed to Cassandra Cobo, Pharmacist in charge at Omnicare of Salisbury. Mr. Kaminski recommended that Board approval would be necessary to have professional staff at the nursing home fill the Omnicell containers with drugs sent from the pharmacy. Omnicare will petition the Board for review.
- Mr. Kaminski reported that the pharmacist in charge of Tunnell Cancer Center Pharmacy contacted her supervisor, Sam Roberts, Director of Pharmacy Beebe Hospital re her inspection report. Mr. Roberts would like to appear before the Board to discuss the pharmacy's position. Mr. Kaminski will contact Mr. Roberts to see if he still wants to be put on the agenda.
- The Board office will have two students. A Rachana Patel starting September 2, 2008 and finishing October 3, 2008. Nicole Srivastava starting October 6, 2008 and finishing November 7, 2008.

Ms. Robinson recommended that an Inspectors Report continue for future agendas.

Public Comment

No comments.

Next Scheduled Meeting

The next meeting will be held on Wednesday, September 17, 2008 at 9:30 a.m. in Conference Room A, second floor of the Cannon Building, 861 Silver Lake Boulevard, Dover, Delaware.

Adjournment

Mr. Holst made a motion, seconded by Mr. Chiari to adjourn the meeting. The motion was unanimously carried. The meeting adjourned at 2:45 p.m.

Respectfully submitted,

David W. Dryden, R.Ph., J.D.
Executive Secretary