

Maryland Board of Pharmacy Public Meeting Minutes

Date: December 17, 2008

Name	Title	Today's Attendance		Fiscal Year-to-Date Attendance	
		Present	Absent	Present	Absent
Anderson, C.	Commissioner	x		5	1
Bradley-Baker, L.	Commissioner	x		5	1
Chason, D.	Commissioner/Secretary	x		6	0
Finke, H.	Commissioner	x		6	0
Handelman, M.	Commissioner	x		5	1
Israbian-Jamgochian, L.	Commissioner	x		6	0
Leandre, A.	Commissioner	x		6	0
Matens, R.	Commissioner	x		5	1
Souranis, M.	Commissioner/Treasurer	x		5	1
Taylor, D.	Commissioner/President	x		6	0
Taylor, R.	Commissioner	x		6	0
Zimmer, R.	Commissioner	x		5	1
Bethman, L.	Board Counsel	x		6	0
Banks, T.	MIS Manager	x		5	1
Costley, S.	Licensing Manager	x		5	1
Eversley, C.	Compliance Investigator	x		5	1
Gaither, P.	Administration and Public Support Manager	x		5	1
Goodman, S.	Public Information Officer	x		4	2
Jeffers, A.	Legislation/Regulations Manager	x		6	0
Naesea, L.	Executive Director	x		6	0
Simmons, L.	Executive Secretary	x		4	1
Taylor, A.	Compliance Officer	x		6	0

Subject	Responsible Party	Discussion	Motion	Action/Results
I. Introductions	Donald Taylor, Board President	<p>1.D. Taylor brought the Public Meeting to order at 9:00 A.M. Members of the Board with a conflict of interest relating to any item on the agenda were advised to notify the Board at this time or when the issue is addressed in the agenda.</p> <p>2. D. Taylor asked that all guests introduce themselves and sign in on the attendance list.</p>		
II. Approval of the Minutes	Donald Taylor, Board President	<p>1. Page 3, Section V, Item 3, Add the date to "November 14, 2008"</p> <p>2. Page 3, Section VI, Item 2, Add "persons."</p> <p>3. Page 5, Section VII, Item 2, Add title to "Diane Darvey, "director of regulatory affairs, NACDS,"</p> <p>4. Page 5, Section VII, Item 2, Change spelling of "Voxakis", add title, "president, EPIC Pharmacies."</p> <p>5. Page 6, Section VII, Item 4d, Change "was" to lower case letters.</p> <p>6. Page 8, Section IX, Item 2, Change "freeze" to "freezes" and relocate the period at the end of the sentence.</p> <p>7. Page 9, Section XI, Item 1b, Remove "Long Term care" and add "Comprehensive Care."</p> <p>8. Page 9, Section XI, Item 1c, Add "COMAR 10.34.28 Automated Medication Systems."</p>	<p>Board Action: M. Souranis made a motion to approve the November 19, 2008 minutes as amended.</p> <p>H. Finke seconded the motion.</p>	<p>Board Action: The Board voted to approve the minutes as amended.</p>

Subject	Responsible Party	Discussion	Motion	Action/Results
		<p>(continued from previous page)</p> <p>9. Page 9, Section XI, Item 2a, Remove “permitted” and replace with “addressed.”</p> <p>10. Page 9, Section XII, Item 2, Change the date to “December 16, 2008.”</p> <p>11. Page 10, Section XI Item 5c, Remove “not “from the last sentence. And remove (continued from previous page).”</p> <p>12. Page 10, Section XII, Item 6, Add “pharmacy technicians” after “4118.”</p> <p>13. Page 10, Section XII, Item 7, Motion Section add “ Motion by the Licensing Committee to routinely issue a letter to applicants with an undisclosed criminal history requesting an explanation of the information contained in the CJIS report. The letter to contain a deadline for a response. Applications would be considered incomplete and the application will expire after one (1) year.</p> <p>2. D. Taylor reported on the visit by the Shanghai FDA delegation. The Shanghai delegates were interested in learning about legislative procedures, professional licensing and inspection procedures in Maryland and the United States, as well as penalties for licensing infractions. Members and staff of the Maryland Board had the opportunity to ask questions regarding the development of laws and regulations in Shanghai, China.</p> <p>3. D. Taylor announced that Raymond Love, Pharm. D. has been appointed Associate Dean at the University of Maryland, School of Pharmacy.</p>		
III. Executive Director	LaVerne Naesea, Executive Director	<p>1. L. Naesea announced that the Executive Committee has approved a recommendation to propose legislation for the 2009 Session to change the renewal period for pharmacy permits from the current annual period to a two year renewal period. The change will reduce workload for the staff by causing permit renewals to occur on the opposite year from the Distributor renewal process. The proposed changes would also spread out the Board’s revenue more evenly.</p> <p>2. L. Naesea reported on the Governor’s directive requiring closure of State Offices and the furloughs, without pay, for all State employees on December 26, 2008 and January 2, 2009.</p>	<p>1. Motion: D. Chason made a motion to approve the proposed legislation changing the period for issuing permits for pharmacies to every other year on an odd year basis.</p> <p>M. Souranis seconded the motion.</p>	<p>1. Board Action: The Board voted to approve the motion.</p> <p>2. All Board staff required to take two (2) unpaid furlough days.</p>
IV. Inspection Program Report	Ann Taylor, Compliance Officer	<p>1. A. Taylor presented the November Compliance monthly statistics for the Board. See Attachment 1, Section C.</p>		<p>Action Item: D. Chason to revise headings on statistical reports.</p>

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V. PEAC Report	Anthony Tommasello, P.E.A.C.	<p>1. A. Tommasello presented the P.E.A.C. statistical report for November 2008. See Attachment 1, Section D. It was noted that there was one positive urine test for a technician that is being addressed by P.E.A.C. in counseling.</p> <p>2. A. Tommasello reported that he met with Dean A. Lin, of Notre Dame College of Maryland, School of Pharmacy to propose that P.E.A.C. provide services to the School's pharmacy students.</p> <p>3. A. Tommasello requested that a meeting be scheduled with Board representatives to discuss how P.E.A.C will bill the Board for additional clients after they reach the maximum number of clients listed in the current contract.</p>		3. Action Item: L. Naesea to schedule a meeting with P.E.A.C. representatives to discuss payment for additional clients.
VI. Guest Speaker: Drug Therapy Management	Allan Friedman, Manager of Government Relations, Kaiser Permanente	<p>1. A. Friedman introduced Neil Wong representing clinical pharmacy programs at Kaiser Permanente</p> <p>2. A. Friedman suggested that Title 12, Subtitle 6A, Therapy Management Contracts and COMAR 10.34.29 be revised by the Legislature in 2009 to eliminate the signature requirement for each patient. He asked the Board to consider supporting a legislative revision. He would be willing to gather and share outcomes data with the Board to supplement the study performed by the University of Maryland. He indicated that if the Legislature does not revise the current law, then Kaiser Permanente representatives will propose that the existing Kaiser Permanente program be exempted from the regulations since Kaiser believes that they qualify for the same exemption that applies to institutional settings such as hospitals.</p>		
VII. Legislation and Regulations	Anna Jeffers, Legislation and Regulation Manager Report	<p>1. A. Jeffers announced that copies of the proposed regulations questions and response letters will be provided to visitors at the Open Meeting, but must be returned at the end of the Meeting.</p> <p>A. Maryland Regulations</p> <p>1. COMAR 10.34.28 Automated Medication Systems</p> <p>a. Informal Comments:</p> <p>i. Mel Rubin</p> <p>ii. Omnicare</p> <p>iii. ASCP</p> <p>b. Board Responses</p> <p>iii. Mel Rubin - 10.34.28 Response to Comment</p> <p>Response approved: "It does appear as if there would be a double check required for a retail pharmacist using an automated system. To avoid confusion the Board has restructured the regulations to create a new Regulation .05 that would address decentralized systems and will renumber Regulation .05 to be .06 to address only remote automated medication systems.</p>	<p>b. iii. Motion: C. Anderson made a motion to approve the letter as presented.</p> <p>M. Souranis seconded the motion.</p>	b. iii. Board Action: The Board voted to approve the motion.

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		<p>(continued from previous page) Therefore, the Board will be moving Section .04A (3) (a) and (b) into the renumbered Regulation .06 Additional Usage Requirements for Remote Automated Medication Systems, since Section .04A (3) (a) and (b) only applies to remote systems. Sections .04B and C will also be moved to the new .06 Additional Usage Requirements for Remote Automated Medication Systems. Those sections address starter doses and the absent pharmacist having access to the system by electronic and visual means. Section .04D, which limits simultaneous access, will be moved and repeated in both the decentralized and remote regulations, since it applies to both. ”</p> <p>iv. Omnicare - 10.34.28 Response to Comment Returned to Practice Committee for further discussion.</p> <p>v. ASCP - 10.34.28 Response to Comment Response approved: “.04A(3) and .04B You had asked why an exception has been made in the draft regulations for “starter doses.” An exception has been made for “starter doses” because Health Occupations Article, 12-605(d) (1) (ii), Annotated Code of Maryland, allows for that exception.</p> <p>To avoid confusion the Board has restructured the regulations to create a new Regulation .05 that would address decentralized systems and will renumber Regulation .05 to be .06 to address only remote automated medication systems. Therefore, the Board will be moving Section .04A (3) into the renumbered Regulation .06 Additional Usage Requirements for Remote Automated Medication Systems, since Section .04A (3) only applies to remote systems. Sections .04B and C will also be moved to the new .06 Additional Usage Requirements for Remote Automated Medication Systems. Those sections address starter doses and the absent pharmacist having access to the system by electronic and visual means. Section .04D, which limits simultaneous access, will be moved and repeated in both the decentralized and remote regulations, since it applies to both.</p> <p><u>.04C</u> In this section “visual means” does indeed mean a video camera. The Board believes this does add value because it serves as a second check for the pharmacist who is not physically present where the automated medication system is located. Additionally, Health Occupations Article, 12-605(b)(2), Annotated Code of Maryland, requires that if “a pharmacist is not physically present where the remote automated medication system is located in a health care facility, the pharmacist shall have access to the system by electronic and visual means in order to ensure the safe and efficient dispensing,</p>	<p>iv. Motion: R. Zimmer made a motion to approve the letter as presented.</p> <p>M. Souranis seconded the motion.</p> <p>v. Motion: R. Zimmer made a motion to approve the letter as presented.</p> <p>M. Souranis seconded the motion.</p> <p>C. Anderson recommended the addition of language indicating that the regulations cannot deviate from the current Law as written.</p>	<p>iv. Board Action: The motion was not voted on. The Motion was tabled for return to the Practice Committee for additional review.</p> <p>v. Board Action: The Board voted to approve the motion.</p>

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		<p>(continued from previous page) repackaging, delivery, control, bar coding, transaction records, dispensation records, labeling, and accountability for all medications in the system.” Therefore, the regulation may not deviate from the law as written. Also, keep in mind that .04C will be moved under the new Regulation .06 Additional Usage Requirements for Remote Automated Medication Systems.</p> <p><u>.04D</u> You had asked if this section allows only one drug product to be accessed at a time. This section was drafted to allow for access to multiple drugs prescribed for a specific patient. Access to multiple non-patient specific medications is not allowed. You had also asked that “Does not impede timely access to ordered medications” be added to this section. You indicated that there may be lag time between when the order is written and when it is recorded into the dispensing system, especially if the facility relies on paper records. .04D is exclusively for remote or decentralized automated medication systems. These systems were developed to eliminate lag time so this phrase would not need to be added. Keep in mind that Section .04D, which limits simultaneous access, will be moved and repeated in both the .05 decentralized and .06 remote regulations, since it applies to both.</p> <p><u>.05A(1)</u> You had asked that other examples of positive drug identification be added to this subsection to exemplify that other technologies are permitted. The Board feels that this subsection does allow for other forms of positive drug identification technology since it uses the words “such as” to mean that bar code technology is one of the options available. Keep in mind that this regulation will be renumbered to be .06.</p> <p><u>.09B and .10B(5)</u> You had asked for clarification of a testing program requiring “daily activity” or “daily accuracy sampling” and indicated that it may be a burden. “Daily inspection of the integrity of the system” is required to be included in a quality assurance program for remote automated medication systems. See Health Occupations Article, 12-605(e) (2) (ii), Annotated Code of Maryland. The Board included a daily accuracy sampling because the Board maintains that a pharmacist can not do an integrated test of the device without entering an order and verifying that the right result occurred, which would be sampling what is dispensed from the machine. Keep in mind that this regulation will be renumbered.</p> <p><u>.10B</u> Regulation .10 set forth the record keeping requirements for all automated medication systems. One of the requirements is documentation of patient outcomes resulting from system failures. You had requested further clarification concerning what may constitute a system failure. Since there may be a myriad of reasons for system failures which have the potential to impact patient care, the Board feels that this definition should be open ended to include any known or unknown system failure that may occur. Keep in mind that this regulation will be renumbered.</p>		

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		<p>.11A The regulations set forth that the responsible pharmacist shall insure the security of the automated medication system because that responsibility is given to the pharmacist in two places in the statute. See Health Occupations Article, 12-605(b) and (f), Annotated Code of Maryland. Keep in mind that this regulation will be renumbered.</p> <p>.11B(3) You had commented that requiring the system database to be updated daily to remove inactive passwords may be burden over the weekend. The Board feels that daily updates of the system database are essential since someone with password access may be fired or leave a position over the weekend or on a holiday. Furthermore, the statute requires that the health care facility where the system is located shall have at least technical assistance regarding operation of the system available 24 hours per day. See Health Occupations Article, 12-605(d) (3) (ii), Annotated Code of Maryland. Keep in mind that this regulation will be renumbered.”</p> <p>2. COMAR 10.34.25 Delivery of Prescriptions, submitted November 10, 2008. Secretary Colmers requested a briefing and explanation of the Board position. A letter was submitted to Secretary Colmers in response to his concerns on December 3, 2008. Board ratification was requested.</p> <p>3. Status Update:</p> <p style="padding-left: 40px;">a. COMAR 10.34.17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties, submitted to DHMH November 19, 2008 and moving through approval process within the DHMH.</p> <p style="padding-left: 40px;">b. COMAR 10.34.19 Sterile Pharmaceutical Compounding, Published December 5, 2008. COMAR 10.34.19 Md R 120508. Subject to a 30 day comment period.</p> <p style="padding-left: 40px;">c. COMAR 10.34.32 Pharmacist Administration of Vaccinations, Published December 5, 2008. COMAR 10.34.32 Md R 120508. Subject to a 30 day comment period.</p> <p style="padding-left: 40px;">d. COMAR 10.27.04 Dispensing in Methadone Clinics. Published October 24, 2008 and no further action taken at this time.</p>	<p>2. Motion: H. Finke made a motion to ratify the letter as presented.</p> <p>M. Souranis seconded the motion.</p>	<p>2. Board Action: The Board voted to approve the motion.</p>

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		<p>e. COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee, submitted to DHMH November 20, 2008.</p> <p>Pre-Submission Comments were received from the Boards of Physicians, Podiatrists (2), Dentists and M. Souranis.</p> <p>Post-Submission Comments were received from the Boards of Physicians (2), Podiatrists and the Division of Drug Control (DDC).</p> <p>The Joint Response to comments for 10.13.01 – Returned to A. Jeffers and Executive Committee to make revisions that detail in the letter includes preliminary reports from D.D.C inspections and direct references to the Statute and references to the recommendations of the American Medical Association. M. Souranis was recused.</p> <p>4. Legislative Reports – Board approval requested for required legislative reports:</p> <p>a. A. Jeffers presented the draft <u>Annual Report on Monitoring the Experience of Remote Automated Medication Systems in Nursing Homes in Maryland</u></p> <p>b. Jeffers presented the draft <u>Second Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the “Act”) as required by Health Occupations Article, Subtitle 6C, Annotated Code of Maryland.</u></p> <p>5. Legislation</p> <p>a. A. Jeffers reported that she and D. Taylor, D. Chason, H. Finke met with Delegate Montgomery. Linda Stahr and Elaine Flanagan participated in the discussion on December 16, 2008, to provide information on the implementation of electronic track and trace technology in Maryland and other pharmacy issues for the 2009 session.</p>	<p>e. Motion: L. Israbian-Jamgochian made a motion to approve the response as presented.</p> <p>R. Taylor seconded the motion.</p> <p>Motion: C. Anderson made a motion to return the letter to the Executive Committee for approval of the revisions.</p> <p>R. Zimmer seconded the motion.</p> <p>a. Motion: M. Souranis made a motion to approve the report for submission to the Legislature and return to the Executive Committee for final approval of the report.</p> <p>D. Chason seconded the motion.</p> <p>b. Motion: M. Souranis made a motion to approve the report for submission to the Legislature.</p> <p>L. Israbian-Jamgochian seconded the motion.</p>	<p>e. Board Action: The motion was not voted on.</p> <p>Board Action: The Motion was tabled for return to the Executive Committee for additional review. Board Action: The Board voted to approve the motion.</p> <p>a. Board Action: The Board voted to approve the motion.</p> <p>b. Board Action: The Board voted to approve the motion.</p>

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		<p>b. A. Jeffers announced that she would be speaking at the MD-ASCP/MSHP CE program. The presentation will be entitled "2009 Legislative Issues - Pharmacists Can Make a Difference" on Wednesday February 4, 2009.</p> <p>c. A. Jeffers provided a brief summary of the symposium she recently attended entitled "NABP 2008 Symposium on Counterfeit Drugs and Behind-the-Counter Class of Drugs." The program included information on actions being taken by the banking industry including VISA, MasterCard, and American Express to monitor for the legitimacy of pharmaceutical websites with the goal of withdrawing credit cards as a payment method if the websites are not legitimate sites.</p>		
VIII. Administration & Public Support	Patricia Gaither, Administration and Public Support Manager	<p>1. P. Gaither reported that there is one (1) one permanent position awaiting approval for an Administrative Officer that will be an Inspector position. A request has been submitted for a temporary position to replace L. Simmons during her absence.</p> <p>2. P. Gaither reported that the reimbursement for mileage will be reduced from \$0.58 per mile to \$0.50 per mile beginning January 1, 2009.</p> <p>3. P. Gaiter reported that the Towson University software development contract has been modified to extend the completion date until February 27, 2009. There will be no additional cost to the Board for the extension which allows for testing and final approval of the software.</p>		
IX. Public Relations Committee Report	Summar Goodman, Public Information Officer	<p>1. S. Goodman presented the draft Board of Pharmacy Public Sessions Calendar for review. Commissioners asked that a version of the calendar be placed on the Board website in PDF form for use by the public and whether a format was available to allow the schedule to be electronically transferred to personal electronic devices.</p> <p>2. S. Goodman reported on attendance at a recent conference in North Carolina. An advertising company has offered to print and mail a newsletter to Maryland pharmacists at minimal cost for mailing in exchange for the opportunity to sell advertising. The newsletter would be larger and more sophisticated and would have a four (4) week turnaround time. D. Taylor requested that the Public relations Committee research the issue and develop a proposal for review by the full Board.</p>		<p>1. Action Item: S. Goodman to work with T. Banks to add the calendar to the website and determine if an electronic version could be available for download.</p> <p>2. Action Item: a. L. Bethman to contact the Ethics Board for approval of the program. b. P. Gaither to research the Maryland purchasing policies regarding similar contracts. c. Public Relations Committee to develop a proposal for Board review.</p>

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		<p>3. S. Goodman reported that the Acetaminophen Workgroup has set a deadline for submission of the names of members of December 19, 2008. The first meeting is scheduled for Wednesday, February 11, 2009 at 1 P.M.</p>		
<p>X. Management Information Services</p>	<p>Tamarra Banks, MIS Manager</p>	<p>1. T. Banks presented the MIS statistical report for November 2008. See Attachment 1, Section F.</p> <p>2. T. Banks reported that work on the Towson (MOU) is progressing and is currently on schedule to be completed by the end of February 2009. The project has been extended to permit final testing of the system. Live testing will begin in January. There will not be any additional cost for the extension.</p> <p>3. T. Banks reported the results of a review of the comments regarding the pharmacist online renewal process. Of the 82 comments, 42 were complimentary. The 40 complaints were mostly focused on the requirement for posting continuing education credits and the limitations on payment methods.</p> <p>4. T. Banks reported that Maryland Medicaid has been reviewing a printout of the Board's online status reports of active pharmacy licenses as part of claims adjudication. The use of those printouts has resulted in incomplete or incorrect information and resulting disciplinary actions by Medicaid for failure to maintain a license, because Medicaid personnel were using outdated printouts instead of current Board information.</p> <p>5. T. Banks reported that new features will be added to the Inspection software to permit Inspectors to see the status of technicians and pharmacists while on site at an inspection. The inspectors will be able to sort information for each review.</p> <p>6. T. Banks reported that the Disaster Recovery training for the staff did not occur in November due to staffing availability. A summary training sheet and slides have been developed and distributed to the staff. The training will be rescheduled for February 2009.</p> <p>5. T. Banks reported that she has received two (2) new ports in the new office area to improve network connectivity. Two (2) additional ports have been requested for Board use.</p> <p>6. T. Banks reported that the website cleanup is continuing and that the files have been reduced from 3477 to 3113. D. Taylor asked that all records be maintained on the website for at least four (4) years before being archived.</p>		<p>4. Action Item: T. Banks to work with Maryland Medicaid to provide access to the new Board database for up to date information on licensee status.</p> <p>6. T. Banks to provide schedule for staff training.</p>

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XI. Practice Committee	Reid Zimmer, Chair	<p>1. A. Jeffers presented the draft <u>Annual Report on Monitoring the Experience of Remote Automated Medication Systems in Nursing Homes in Maryland</u></p> <p>2. Reid Zimmer reported on the activities of the Practice Committee. The following regulations are currently undergoing revision.</p> <p>a. The revisions to COMAR 10.34.20 Format of Prescription Transmission are awaiting additional input from D. Sharp, Executive Director of M.H.C.C. at the January Practice Committee meeting.</p> <p>b. The revisions to COMAR 10.34.23 Pharmaceutical Services to Residents in Long-Term Care Facilities will be presented at the January Practice Committee meeting. The recommendation was made to change the name of the regulations to "Comprehensive Care Facilities."</p> <p>c. COMAR 10.34.28 Automated Medication Systems</p> <p>3. R. Zimmer presented the proposed response to Delegate Hecht concerning proposed legislation for a drug take back program to prevent drugs from contaminating the water supply. <u>Fred County Proposed Pharmaceutical Take-back Program</u> <u>SMARxT Disposal - Delegate Sue Hecht</u> <u>SMARxT Disposal 030508</u> <u>DRAFT Response-Drug Take-Back-Delegate Hecht</u></p> <p>Board approved:</p> <p>"Maryland has a Prescription Drug Repository Program that is intended to provide a mechanism for the acceptance of prescription drugs and medical supplies donated by individuals and entities for the purpose of dispensing to needy individuals. The Program consists of three key components: 1) administrative oversight by the Board of Pharmacy (regulatory agency); 2) establishment of repositories that will accept, dispense and/or dispose of drugs that do not meet the criteria for the Program; and 3) establishment of drop-off sites that may receive and will forward donated drugs to a Board approved repository.</p> <p>There is one Repository/Drop-Off Site approved at this time: Harlem Gardens, located in Baltimore City.</p> <p>Unfortunately, there are a few prescription drugs or medical supplies that may not be accepted for re-dispensing. Those exceptions listed in the legislation apply to prescription drugs or medical supplies that:</p>	<p>1. Motion: R. Zimmer made a motion to approve the report for submission to the Legislature.</p> <p>L. Israbian-Jamgochian seconded the motion.</p> <p>3. Motion: L. Israbian-Jamgochian made motion to approve the report for submission to the Legislature.</p> <p>M. Souranis seconded the motion.</p>	<p>1. Board Action: The Board voted to approve the motion.</p> <p>Action Item: A. Jeffers to provide a copy of the full report to all Commissioners.</p> <p>3. Board Action: The Board voted to approve the motion.</p>

Subject	Responsible Party	Discussion	Motion	Action/Results
		<p>(continued for previous page)</p> <p>(a) Bear an expiration date that is less than 90 days from the date the drug is donated to ensure the potency and quality of the prescription drugs or medical supplies;</p> <p>(b) Have been adulterated, according to the standards of Health-General Article, §21-216, Annotated Code of Maryland, because adulterated prescription drugs or medical supplies have been determined to be a threat to public health;</p> <p>(c) Are designated controlled dangerous substances by the U.S. Drug Enforcement Administration which has determined that controlled dangerous substances may not be donated under a repository program;</p> <p>(d) Require refrigeration because the potency and quality may not be guaranteed; or</p> <p>(e) Have been previously compounded because compounded prescription drugs are patient specific. See COMAR 10.34.33.03If an individual donates any of the above items; the repository is required to dispose of them. Repositories, which would also be pharmacies, often use reverse distributors for disposal of most drugs.</p> <p>Some states treat unused, expired or adulterated drugs as infectious waste and disposal is regulated under that state’s waste management program. Two examples are California and Delaware. Their take-back programs are not regulated by their health department, but by their waste management department.</p> <p>The Board believes that individuals should first consider donating their unused medications through the Prescription Drug Repository Program. Since some unused medications are not acceptable for that program, Maryland should consider providing a mechanism for individuals to drop off their unused drugs to be disposed of as infectious waste.”</p> <p>4. R. Zimmer presented the proposed Board response to Public Inquiries.</p> <p>Question: For a pharmacist currently licensed to give influenza vaccinations in Maryland, will additional training be required in order to be able to administer Zostavax? Zostavax Administration Response: DRAFT - Zostavax administration – Jason Katcof</p> <p>RESPONSE: “Once the revised COMAR 10.34.32 Pharmacists Administration of Vaccinations becomes effective, a pharmacist registered to administer influenza vaccinations may also administer herpes zoster and pneumococcal pneumonia vaccines. Please be advised that it would be prudent for any pharmacist who is registered to administer influenza vaccinations to begin taking the continuing education courses that will be required for the administration of herpes zoster and pneumococcal pneumonia vaccines. Upon renewal, pharmacists previously registered to administer influenza vaccinations will be required to obtain 4 continuing education credits that include Advisory Committee on Immunization Practices and Centers for Disease Control guidelines for herpes zoster, influenza and pneumococcal pneumonia vaccines.</p>		

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		<p>(continued from previous page) For your information, the proposed COMAR 10.34.32 Pharmacists Administration of Vaccinations, was published in the Maryland Register on December 5, 2008. After a 30 day comment period passes, and if there are no comments, the Notice of Final Action could be published in January or February. See www.dsd.state.md.us to view the proposal.”</p>		
XII. Licensing Committee	Cynthia Anderson, Chair	<p>1. C. Anderson presented the Licensing Committee statistics for November 2008. See Attachment 1, Section A and E.</p> <p>2. C. Anderson reported that the deadline for registration by distributors is December 16, 2008 and that the Board staff has received a large number of inquires and questions that have put the staff well behind schedule. The Licensing Committee has scheduled an additional meeting on January 8, 2009 to review questions and expedite approval of applications. L. Bethman has agreed to attend.</p> <p>3. C. Anderson presented the Technician Training Program Update with the Committee’s recommendation that the Walgreen’s program be approved.</p> <p>4. C. Anderson presented the Technician Training Program Update with the Committee’s recommendation that the Your Community Pharmacy program be approved.</p>	<p>3. Motion: Motion by the Licensing Committee to approve the training program developed by Walgreen’s Pharmacy.</p> <p>D. Chason seconded the motion.</p> <p>4. Motion: Motion by the Licensing Committee to approve the training program developed by Your Community Pharmacy.</p> <p>R. Zimmer seconded the motion.</p>	<p>3. Board Action: The Board voted to approve the motion.</p> <p>4. Board Action: The Board voted to approve the motion.</p> <p>Action Item: Licensing Committee to post names of approved programs on the Board’s website.</p>
XIV. Disciplinary Committee	Rodney Taylor, Chair	<p>R. Taylor presented the Disciplinary Committee’s monthly statistics for November 2008. See Attachment 1, Sections A and C.</p> <p>2. A. Taylor presented the draft Wholesale Distributor Inspection Form for approval by the board.</p>	<p>2. Motion: L. Israbian-Jamgochian made a motion to approve the Wholesaler Distributor Inspection form.</p> <p>M. Souranis seconded the motion.</p>	<p>2. Board Action: The Board voted to approve the motion.</p> <p>Action Item: Commissioners to provide A. Taylor with comments</p>

Subject	Responsible Party	Discussion	Motion	Action/Results
				within thirty days.
XV. Long Term Care Committee	Mayer Handelman, Chair	<p>1. M. Handelman reported that the new Comprehensive Care Facility regulations have been completed by the Workgroup and will be submitted to the Practice Committee in January 2009. The December meeting of the Taskforce was cancelled.</p> <p>2. M. Handelman reported that the Assisted Living Facilities Regulations were approved and published by the Office of Health Care Quality (O.H.C.Q.). Enforcement will be delayed until the list of available pharmacists has been published. There will be a training session held on January 16, 2009, sponsored by Lifespan. M. Handelman noted that Medicare Part D will pay for patient assessments.</p>		2. Action Item. S. Goodman to post notification of the training session on the Board's website.
XVI. New Business	M. Souranis, Treasurer	M. Souranis presented the proposed Income and Expense estimates through Fiscal Year 2013 with the recommendation from the Executive Committee to raise fees to provide adequate reserves in the Board funds through Fiscal Year 2012.	<p>Motion: M. Handelman made a motion to approve the recommendation for fee increases.</p> <p>R. Zimmer seconded the motion.</p>	<p>Board Action: The Board voted to approve the motion.</p> <p>Action Item: A. Jeffers to prepare proposed regulations for the fee increases.</p>
XVII. Adjournment	Donald Taylor, Board President	<p>1. D. Taylor asked for a motion to close the Public Meeting and open a Closed Public Session for the purpose of engaging in medical review committee deliberations of confidential matters contained in technician applications in accordance with State Government, Sect. 10-508(a)(13).</p> <p>The Public Meeting was adjourned at 12:16 P.M.</p> <p>2. At 12:21P.M. Donald Taylor convened a Closed Public Session to conduct a medical review of technician applications.</p> <p>3. The Closed Public Session was adjourned at 1:47P.M. Immediately thereafter, Donald Taylor convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.</p>	<p>1. Motion: L. Israbian-Jamgochian made a motion to close the Public Meeting and open a Closed Public Session.</p> <p>R. Taylor seconded the motion.</p> <p>3. Motion: R. Matens made a motion to adjourn the Closed Public Session. H. Finke seconded the motion.</p>	<p>1. Board Action: The Board voted to approve closing the Public Meeting and opening a Closed Public Session.</p> <p>3. Board Action: The Board voted unanimously to adjourn the Closed Public Session.</p>

BOARD / STATE STATISTICS

Attachment 1 Sections A through F.

MARYLAND BOARD OF PHARMACY STATISTICS

Attachment 1 Sections A through F.

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Number of Current Licensees	20,361	21,219	21,984	22,896	22,953	23,075
Number of Active Licensees	11,598	12,426	12,491	14,112	14,267	14,367
Number of Inactive Licensees	519	520	551	493	356	364
Number of Pharmacist Licensees	14,045	14,138	14,159	14,102	14,251	14,278
Number of Pharmacy Establishment Licenses	3,169	3,175	3,179	3,208	3,222	3,241
Number of Distributor Licenses	2,052	2,062	2,077	2,094	2,109	2,120
Number of Pharmacy Technician Licensees	1,095	1,844	2,569	3,452	3,371	3,436
Number of New Applications Received	1,174	982	895	228	152	

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
						101
Number Out-of-State Applications Received	108	112	71	-	55	58
Number of Out-of-State Applicants Approved	55	84	35	-	80	38
Number of Foreign Applications Received	8	13	14	-	15	8
Number of Foreign Applicants Approved	73	94	6	8	5	1
Number of License Renewals Current	310	339	333	344	352	1,155
Number of Formerly Inactive or Reinstated Licenses	10	17	17	18	10	11
SECTION B-DISCIPLINARY COMMITTEE						
Complaints--Summary						
Number of Complaints Received	13	7	14	5	11	13
Boundaries (Harassment)	1	0	0	0	0	0
Drugs/Alcohol	2	1	-	1	-	1
Fraud	2	1	2	0	0	0
Standard of Care	7	3	6	1	6	5

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Other	1	2	6	1	5	7
Number of Complaints Closed Administratively	-	-	-	-	-	0
Number of Investigations Initiated	13	7	14	5	11	13
Number of Investigations Pending	16	23	17	9	7	15
Number of Complaints Adjudicated by the Board	12	10	7	13	13	5
Number of Complaints where Board investigated complaint and took no formal or informal action	-	0	0	0	0	0
Number of Complaints where Board referred the case for prosecution	8	6	2	3	-	0
Number of Complaints Adjudicated within Goal	12	10	7	7	9	5
Number of Complaints Pending Action by the Board (unresolved)	2	-	2	2	2	1
Number of Complaints Referred by Board to another agency	2	1	-	-	-	0
Attorney General's Office						
Number of Complaints Awaiting Action from Board Counsel	-	-	-	-	-	0
Number of Complaints Awaiting Action for more than 30 days	-	-	-	-	-	0
Number of Complaints Awaiting Action for more than 60 days	-	-	-	-	-	0
Number of Complaints Awaiting Action for more than 90 days	-	-	-	-	-	0
Number of Complaints Awaiting Action for more than 120 days	-	-	-	-	-	0

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
	-	-	-	-	-	
Number of Complaints Awaiting Action from Board Prosecutor	3	1	8	5	4	1
Number of Complaints Awaiting Action for more than 30 days	-	-	-	0	0	0
Number of Complaints Awaiting Action for more than 60 days	-	-	-	0	0	0
Number of Complaints Awaiting Action for more than 90 days	-	-	-	0	0	0
Number of Complaints Awaiting Action for more than 120 days	1	1	1	1	1	1
Audit/Quality Assurance						
Number of Licensees Reviewed	32	38	37	35	37	
Number of Patient Records Reviewed	-	-	-	-	-	
Number of Inspections/surveys conducted	82	79	70	83	85	60
Disciplinary Action--Summary						
Formal Actions Taken by Board	3	5	5	2	3	5
Number of Fines	-	2	2	2	1	2
\$ Amount of Fines	-	3,000	1,000	10,000	3,000	7500
Number of Probations	1	-	-	-	-	1

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Number of Suspensions	-	3	3	1	1	0
Number of Licenses Revoked	2	1	-	-	-	0
Number of Letters of Reprimand	-	-	-	-	-	1
Informal Actions Taken by Board	6	-	3	10	7	3
Number of Cease and Desist Letters	-	-	1	2	-	0
Number of Letters of Admonishment	3	2	-	3	1	0
Number of Letters of Education	3	2	2	2	2	2
Other	-	-	2	3	4	0
Post Adjudicatory Compliance						
Number of Cases under Supervision	13	12	12	12	12	12
SECTION C-COMPLIANCE						
Board Statistics						
Inspection Report						

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Regular Inspections						
Retail/Community				67	51	52
Long Term Care				1	-	1
Hospital				2	-	0
Waivered				1	-	1
Distributor				-	-	0
Opening Inspections						
Retail/Community				6	5	2
Long Term Care				-	-	0
Hospital				-	1	1
Waivered				2	6	1
Distributor				-	-	1
Closing Inspections						

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Retail/Community				-	4	
Long Term Care				-	-	
Hospital				-	-	
Waivered				-	-	
Distributor				-	-	
Special Investigations				-	3	1
Self Referred Pharmacists	13	13	14	15	24	26
Self Referred technicians	1	-	2	2	2	2
Referred Pharmacy Students	2	2	2	2	2	1
Self Referred transferred to Board of Pharmacy	-	-	-	-	0	0
Board Cases Requesting PEAC Assistance	8	6	6	6	6	6
New Cases This Month	1	1	2	1	1	2
Pharmacist						

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Student	-	-	-	-		
Technician	-	-	-	-		
Client Discharges	-	-	-	-	1	0
Drug Tests Ordered	44	42	46	42	44	46
Number of Positive Results	-	-	-	1	1	1
Total Combined Cases Being Monitored by PEAC	24	21	24	25	24	26
Cases under Board Monitoring	13	12	12	12	12	12
Drug Tests Ordered	30	30	30	30	27	22
Number of Positive Results	-	-	-	1	0	0
SECTION E LICENSING COMMITTEE REPORT(CONTINUED)						
Reinstatements						
Less then 2 Years	16	8	17	17		

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
					10	11
2 to 5 Years	1	-	-	1	-	-
5 + Years	-	-	-	-	-	-
Vaccine Certifications						
Received To Date	278	278	334	385	461	481
Renewed This Month	13	13	13	13	8	15
Certified This Month	7	7	26	77	47	36
Pending This Month	12	12	42	16	45	25
Total Certified To Date	246	266	292	369	416	462
Pharmacy Technicians						
Applications for Grandfathered Status	1,409	1,409	1,489	1,527	1,548	1567
Applications for Nationally Certified	2,028	2,028	2,088	2,216	2,286	2338

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Applications for Student Exemption	196	196	241	251	256	258
Applications received	3,633	3,633	3,818	3,994	4,090	4163
Registered To Date		2,080	2,569	3,122	3,371	3512
Registrations Pending		1,553	1,249	872	719	651
Technician Training Programs						
Total Programs Submitted	21	N/A	21	N/A	23	23
Total Programs Approved	7	N/A		N/A		14
Total Under Review	11	N/A	4	N/A	11	-
Total Under Re-work						8
Total Pending Review						1?
New Pharmacies						

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
New In State	2	2	3	4	2	6
New Out of State	2	2	8	6	9	4
New Waiver	-	0	0	2	-	0
Total; New Pharmacies	4	4	11	12	11	10
Closed Pharmacies						
Closed In State	1	1	4	5	1	0
Closed Out of State	-	0	2	2	1	2
Closed Waiver	-	0	1	-	-	0
Total Closed Pharmacies	1	1	7	7	2	2
Total In State Pharmacies	1,134	1,133	1,132	1,133	1,133	1,139

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Total Out of State Pharmacies	367	373	377	385	385	387
Total Waivered Pharmacies	103	102	104	104	104	104
Total Pharmacy permits	1,604	1,608	1,613	1,622	1,622	1,630
Distributors						
New in State	1	1	-	6	1	3
New Out of State	8	8	15	7	12	6
Total New Distributors	9	9	15	13	13	9
Closed Distributors						
Closed In State	-	-	-	1	-	0
Closed Out of State	-	-	-	1	-	2

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Total In State Distributors	167	187	187	192	193	196
Total Out of State Distributors	726	726	741	748	760	764
Total Distributors	893	913	928	940	953	960
Rx Repository Program						
Applications received	-	5	6	7	7	7
Applications Approved	-	-	-	-	2	2
Applications Pending	-	3	4	4	3	3
Applications Withdrawn	-	2	2	2	2	2
Total Repositories	-	-		-	3	3
Drop Off Sites					2	2
Drug Therapy Management Protocols						

StateStat Statistics	Reporting Period					
	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08
SECTION A -LICENSING COMMITTEE						
Total Applications Received	-	-	8	8	8	8
Applications Approved	-	-	4	4	4	4
Applications Not Approved	-	-	3	3	3	3
Applications pending	1	-	1	1	1	1
SECTION F-MANAGEMENT INFORMATION SYSTEMS REPORT						
Number of e-mails received	505	494	333	285	398	437
Number of website visitors	18,180	15,281	12,832	12,707	13,688	6,628*
** November web visitors period is Nov 17-30th only						

