Maryland Board of Pharmacy
Public Board Meeting

Meeting Minutes
Date: February 17, 2016

Name	Title	Present	Absent	Present	Absent
Board Committee					
Ashby, D.	Commissioner	X		2	
Bouyoukas, S.	Commissioner	X		2	
Gavgani, M. Z.	Commissioner/President		X	1	1
Jones, David H.	Commissioner/Secretary	X		2	
Peters, R.	Commissioner	X		2	
Robinson, T.	Commissioner		X	1	1
Rochester, C.	Commissioner	X		2	
Roy, S.	Commissioner	X		2	
Smith, J.	Commissioner/Treasurer	X		2	
St. Cyr, II, Z. W.	Commissioner	X		2	
Yankellow, E.	Commissioner	X		2	
Zagnit, B.	Commissioner	X		2	
Board Counsel					
Bethman, L.	Board Counsel	X			
Felter, B.	Staff Attorney	X			
Board Staff					
Speights-Napata, D.	Executive Director	X			
Ennels, S.	Deputy Director of Operations	X			
Wu, Y.	Compliance Manager	X			
Page, A.	Executive Administrative Associate	X			
Waddell, L.	Administration and Public Support Manager	X			
Jeffers, A.	Legislation/Regulations Manager	X			
Johnson, J.	MIS Manager	X			

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	**A.) M. Gavgani, Board President**	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* *The February 2016 Public Board Meeting was presided over by David Jones, in the absence of Mitra Gavgani.* **1. D. Jones called the meeting to order at 9:31 A.M.** **2. D. Jones reminded all guests to sign the guest log, indicating whether they would like continuing education credits.** **3. D. Jones requested that all Board commissioners and staff members introduce themselves and informed guests that the meeting agenda and packet materials were available for review. He advised guests that all packets must be returned at the end of the meeting.**		
	B.) D. Jones, Secretary	**4. Review and approval of January 2016 Public Meeting Minutes.** **5. D. Jones shared remarks about A. Jeffers, who retired on February 29, 2016 after 11 years of service with the Board of Pharmacy.**	4. Motion to approve January 2016 Public Meeting Minutes as prepared by D. Ashby, 2nd by C. Rochester.	4. The Board voted to approve this motion.
II. A. Executive Director Report	**D. Speights-Napata,**	**1. Operations Updates**		

<table>
<tr><th>Subject</th><th>Responsible Party</th><th>Discussion</th><th>Action Due Date (Assigned To)</th><th>Results</th></tr>
<tr><td></td><td>Executive Director</td><td>a. State Ethics Financial Disclosure Form
b. Call Canter Improvements
c. MPJE Examination
d. Josette Towles and BithGroup Contract Recommendations
e. Request From Guam BOP

2. Meetings Update</td><td>1e. Motion to approve request for shadow inspections.</td><td>1e. The Board voted to approve this motion.</td></tr>
<tr><td>B. Operations Report</td><td>S. Ennels, Deputy Director of Operations</td><td>1. APS Unit Updates

Budget Summary
Personnel Updates – L. Waddell

2. MIS Unit Updates – J. Johnson

Online Pharmacy Renewals
TORF Project
Exit Interview for IT Audit

3. Data Integrity Unit Updates</td><td></td><td></td></tr>
<tr><td>C. Licensing</td><td>Y. Wu, Compliance Manager</td><td>1. Unit Updates
2. Monthly Statistics
<table>
<tr><th>License Type</th><th>New</th><th>Renewed</th><th>Reinstated</th><th>Total</th></tr>
<tr><td>Distributor</td><td>8</td><td>9</td><td>0</td><td>1052</td></tr>
<tr><td>Pharmacy</td><td>15</td><td>0</td><td>0</td><td>2078</td></tr>
</table></td><td>2. Recommendation by J. Smith to place a reminder in the upcoming newsletter regarding Student-Intern Registration.</td><td>2. Will be discussed in the next Public Relations Committee meeting.</td></tr>
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			Pharmacist	**35**	**455**	**0**	**10900**	
			Vaccination	**33**	**60**	**0**	**4144**	
			Pharmacy Intern - Graduates	**3**	**0**	**0**	**30**	
			Pharmacy Intern - Students	**48**	**0**	**0**	**547**	
			Pharmacy Technician	**133**	**325**	**2**	**9159**	
D. Compliance	**Y. Wu, Compliance Manager**	**1. Unit Updates** **2. Monthly Statistics** **Complaints & Investigations:** New Complaints - 23 Resolved (Including Carryover) – 26 Final disciplinary actions taken – 1 Reversals – Summary Actions Taken – 1 **Inspections:** Total - 145 Annual Inspections - 133 Opening Inspections - 4 Closing Inspections - 1 Board Special Investigation Inspections – 2 Division of Drug Control Closing Inspections – 3						

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E. Legislation & Regulations	**A. Jeffers, Legislation & Regulations Manager**	**REGULATIONS:** **Effective February 1, 2016: UPDATE** **10.34.10 Pharmacist, Pharmacy Intern, and Pharmacy Technician Code of Conduct** **10.34.19 Sterile Pharmaceutical Compounding** **10.34.29 Drug Therapy Management** This chapter was revised pursuant to 2015 Legislation brought by the Maryland Pharmacy Coalition. **Published November 13, 2015. Three comments have been received and responses approved 1/20/16 and sent 1/27/16. One other response came in the Board delegated to Practice to respond. Sent 1/29/16. Waiting for the Notice of Final Action.** DTM Forms to be revised and MOU with Nursing and Podiatry Boards to be considered. **10.34.33 Prescription Drug Repository Program** This chapter was revised pursuant to Federal law and regulations. **Published December 28, 2015.** Three Comments received: **The Board approved the comments below and Linda Bethman indicated that she would make**	10.34.33 Motion by committee to approve responses as prepared with amendments by L. Bethman, 2nd by J. Smith.	10.34.33 The Board voted to approve this motion.

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		clarifying revisions to the proposal to avoid any more confusions. This may result in clarifying revisions to the Board's response to the comments although approved today. **Apple Drugs** **Wicomic Hlth Dept** **NACDS comments prescription drug repository Jan 2016** **Draft Board Response – 10.34.33 – Apple Drug** Thank you for submitting a comment concerning the proposed Code of Maryland Regulations (COMAR) 10.34.33 Prescription Drug Repository Program, as published in 42:26 Md. R. 1631 - 1633 (December 28, 2015). The Board of Pharmacy (the "Board") revised COMAR 10.34.33 to promulgate regulations for the disposal of non-controlled dangerous substances (Non-CDS) only. The Prescription Drug Repository Program has always been completely voluntary ***and there is no fee to apply.*** It was noted in Apple Drug's comment that COMAR 10.34.33.07B(4) is in conflict with federal law because it requires that a separate secure container be maintained behind the prescription counter. This requirement is not in conflict with federal law because this requirement is for Non-CDS only.		

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		The federal requirements apply to the disposal of controlled dangerous substances (CDS). If Apple Drug would like to dispose of both CDS and Non-CDS then it would follow the federal law and regulations. Apple Drug also commented on COMAR 10.34.33.06-1A and 10.34.33.07C which indicated to Apple Drug that only a pharmacist may accept donated prescription drugs (CDS and Non-CDS) and the pharmacist may not delegate this function to a pharmacy technician. The requirement that only the ultimate user in lawful possession of the CDS may transfer that substance to a collector is a federal requirement for CDS. For Non-CDS, only a pharmacist may accept donated prescription drugs and the pharmacist may not delegate this function to a pharmacy technician. Apple Drug questioned whether COMAR 10.34.33.07D is in conflict with federal law since it appears to Apple Drug that the receptacle is required to be behind the counter. 10.34.33.07D applies to both CDS and Non-CDS. If a pharmacy is commingling CDS and Non-CDS, then the pharmacy simply follows the federal law and regulations. The Board would like to thank you again for your thorough reading of, and comment to, the proposed COMAR 10.34.33 Prescription Drug Repository Program. ***In light of the confusion regarding Non-CDS receptacles and CDS***		

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		receptacles, the Board will be making minor clarifying revisions to the proposed regulations in the Notice of Final Action. The Board considered your comment at the February 17, 2016 Board Meeting and voted to adopt the regulations as proposed with minor clarifying revisions. **Draft Board Response – 10.34.33 – Wicomico Hlth** Similar response to above **Draft Board Response – 10.34.33 - NACDS** Thank you for submitting a comment concerning the proposed Code of Maryland Regulations (COMAR) 10.34.33 Prescription Drug Repository Program, as published in 42:26 Md. R. 1631 - 1633 (December 28, 2015). The Board of Pharmacy (the "Board") revised COMAR 10.34.33 to promulgate regulations for the disposal of non-controlled dangerous substances (Non-CDS) only. The Prescription Drug Repository Program has always been completely voluntary. NACDS recommended in its comment that the Board consider implementing a registration procedure instead of requiring Board approval for pharmacies operating a drug disposal program. The Board's Prescription Drug Repository Program application procedures are indeed simple		

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		registration procedures. The Board has every right to require registration even though the federal law and regulation do not. It was noted in NACDS's comment that COMAR 10.34.33.07B(4) is in conflict with federal law because it requires that a separate secure container be maintained behind the prescription counter. This requirement is not in conflict with federal law because this requirement is for Non-CDS only. The federal requirements apply to the disposal of controlled dangerous substances (CDS). If NACDS would like to dispose of both CDS and Non-CDS then it would follow the federal law and regulations. Additionally, NACDS requested that the Board revise COMAR 10.34.33.07D to read "Repositories that collect both non-controlled and controlled dangerous substances for disposal" so as avoid further potential conflicts with the DEA rule. The Board believes that the proposed regulations are clear as written and that commingling of non-controlled and controlled dangerous substances is addressed in COMAR 10.34.33.07D(3). The Board would like to thank you again for your thorough reading of, and comment to, the proposed COMAR 10.34.33 Prescription Drug Repository Program. The Board considered your comment at the February 17, 2016 Board Meeting and voted to adopt the regulations as proposed.		

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		10.34.37 Chapter 37 Pharmacy Permit Holder *Requirements* — Wholesale Distribution *and Non-Resident Pharmacy Operations* Board approval requested for the following proposed revisions. **DRAFT 10.34.37 Practice Draft 021716** **The Board approved the proposal for release for informal comments.** **10.34.39 Pharmacist Administration of Self-Administered Drugs** This chapter was revised pursuant to 2015 Legislation brought by the Maryland Pharmacy Coalition. **Published December 28, 2015.** **NACDS comments on Pharmacists Admin of Drugs Jan 2016** **Draft Board Response – 10.34.39 – NACDS** **The Board approved the following response:** Thank you for submitting a comment concerning the proposed Code of Maryland Regulations (COMAR) 10.34.39 Pharmacist Administration of Self-Administered Drugs, as published in 42:26 Md. R. 1633 - 1634 (December 28, 2015). NACDS suggested that COMAR 10.34.39.03 be revised to read:	10.34.37 Motion for revisions by Practice Committee, 2nd by J. Smith. Motion by D. Jones to release for informal comment, 2nd by D. Ashby. 10.34.39 Motion to approve prepared response by committee, 2nd by D. Ashby.	10.34.37 The Board voted to approve this motion. The Board voted to approve this motion. 10.34.39 The Board voted to approve this motion.

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		"If the pharmacist is not already registered with the Board as referenced under 10.34.32.03, the licensed pharmacist shall attest that the pharmacist has the appropriate training in administration of self-administered drugs…" The reason the Board requires attestation of training by the pharmacist is because the training for the administration of immunizations is not identical to the training for administration of many self-administered drugs. The Board made the decision to put the burden of acquiring and maintaining the appropriate training to administer self-administered drugs on the pharmacist by requiring the pharmacist to attest that he or she has the appropriate instruction in a variety of areas. Additionally, the Board included a section that a pharmacist, certified under Health Occupations Article, 12-508, is deemed to have satisfied the training requirements of the chapter. See the proposed COMAR 10.34.39.03C. The Board would like to thank you again for your thorough reading of, and comment to, the proposed COMAR 10.34.39 Pharmacist Administration of Self-Administered Drugs. The Board considered your comment at the February 17, 2016 Board Meeting and voted to adopt the regulations as proposed.		

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		LEGISLATION: **1) The Board ratified the following positions for the following bills:** **HB 117 State Board of Pharmacy - Licensure Requirements for Pharmacists - Proof of Proficiency in English** **HB117-ProficiencyinEnglish-BoPharm-SWA.docx** **Support with Amendment** **HB 15 Harford County – Suspected Overdoses – Reporting Requirement** **Letter of Concern** **2) The Legislative Committee recommends the following positions for bills with hearings Feb. 16th – 19th and the Board ratified those positions:** **SB 469 State Board of Pharmacy - Licensure Requirements for Pharmacists - Proof of Proficiency in English** **sb0469F – Support with Amendment identical to HB 117** **HB 404 End of Life Option Act** **hb0404F – No Position** **HB 437/SB537 DHMH – PDMP – Modifications**	HB 117 Motion by committee to ratify, 2nd by D. Ashby.	HB 117 The Board voted to approve this motion.

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		hb0437F – No Position **SB 614 Veterinarians, Pharmacies, and Pharmacists – Dispensing Compounded Preparations for Use by Companion Animals** **sb0614F – Letter of Concern** **SB 647 Physicians – Prescriptions Written by Physician Assistants - Preparing and Dispensing.** **sb0647F – No Position** **SB 806 State Board of Physicians – Naturopathic Doctors – Establishment of Naturopathic doctors Formulary Council and Naturopathic Formulary** **sb0806F – Letter of Concern** **3) New Bills with hearings after February 22nd:** **HB 217/SB 529 Open Meetings Act – Requirements for Providing Agendas** **hb0217F – No Position, Monitor** **HB 250/SB 528 General Provisions – Open Meetings Act – Required Training and Certificate of Compliance** **hb0250F – No Position, Monitor** **SB 382 PDMP – Revisions**		

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		sb0382F – No Position, Monitor **Email to entire Board for consideration.** **HB 413 Open Meetings Act – Video and Audio Streaming** **hb0413F – No Position** **HB 741/SB 427 Higher Education – Institutions of Postsecondary Education – Consumer Protection Provisions** **hb0741F – No Position** **SB 598/HB 823 General Provisions – Open Meetings Act – Enforcement and Training** **sb0598F – No Position, Monitor** **SB 804 State Government – Occupational Licensing of Ex-Offenders – Transfer of Statutory Provisions** **sb0804F – No Position** **HB 770/SB 712 Criminal Procedure – Nonviolent Felonies – Stet, Shielding, and Expungement** **hb0770F – No Position, Monitor** **HB 826 Prescription Drug Repository Program – Repository Inventory Requirement** **hb0826F – Follow-Up with sponsor since it does not change anything.**		

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		HB 838 Civil Immunity – Emergency Care for Drug Overdose – Protocols **hb0838F – No Position, Follow-up with sponsor.** **SB 890 Expungement – Misdemeanor Convictions** **sb0890F – No Position, Monitor** **SB 923/HB 979 Occupational Licenses – Denial for Criminal Conviction – Notice of Prohibition and Task Force** **sb0923F - Monitor** **HB 1088/SB 754 Open Meetings Act – Annual Reporting Requirement, Enforcement, and Training** **hb1088F – No Position, Monitor** **Added: HB 1362/SB 949 Crimes - Robbery, Burglary, or Theft of Property - Controlled Dangerous Substances** **Support with Amendment –** amend the penalties and referral for drug treatment section so that it is discretionary.	HB 1362/SB 949 Motion by Z. St. Cyr, II to support with amendments, 2nd by D. Ashby.	HB 1362/SB 949 The Board voted to approve this motion.
III. Committee Reports **A. Practice Committee**	**D. Jones, Chair**	1) Christine Cassetta, Quarles&Brady **Wholesale Dist - delivering to physician offices**	1) Motion by committee to approve, 2nd by J Smith.	1) The Board voted to approve this motion.

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		Draft Board Response – Wholesale Dist – delivering to Phy Office **The Board approved the following response:** Dear Ms. Cassetta: Thank you for contacting the Maryland Board of Pharmacy (the "Board") concerning a wholesale distributor delivering prescription medications to the premises listed on a physician's permit. Please see Health Occupations Article, 12-6C-09C(1), Annotated Code of Maryland where it states: (c) (1) Except as provided in paragraph (2) of this subsection, a wholesale distributor may deliver prescription drugs only to: (i) The premises listed on the recipient's license or permit; Please note that the law indicates that the wholesale distributor may deliver to the premises listed on the recipient's license or permit. It does not specifically set forth what type of license or permit. Therefore, the wholesale distributor may deliver to the premises listed on the physician's license, the physician's DEA permit, or perhaps the physician's dispensing permit which is location specific. For controlled dangerous		

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		substances, however; the shipping address must match the address on the DEA permit. Please be advised that this response was prepared with the knowledge of only the facts presented. Any person who wishes to republish or reproduce, in whole or in part, any material issued by the Board should contact the Board for prior consent. This response is not intended to be legal advice. Although references to current laws and regulations may be included in this response, keep in mind that laws may change annually and regulations may be changed at any time. Further, the information provided is based on state pharmacy laws and regulations. Federal rules and state requirements that are not included under the Maryland Pharmacy Practice Act, however, may also apply. To insure that all current applicable laws have been considered, you may want to consult with your own legal counsel. Board responses to inquiries are intended for guidance purposes only. As these positions do not necessarily reflect a discussion of all material considerations required to reach the conclusions stated, they are not intended to be rules, regulations, or official statements of the Board. Accordingly, due to their highly informal nature, these responses are not considered binding upon the Board and should not be relied on as definitive.	2) Motion by committee to approve, 2nd by D. Ashby.	2) The Board voted to approve this motion.

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		2) International Academy of Compounding Pharmacists **Compounded and Repackaged Meds for Office-Use** **Draft Board Response – Cpdg and Repkged Meds for Office Use** **The Board approved the following response:** To Whom It May Concern: Thank you for contacting the Maryland Board of Pharmacy (the "Board") concerning the implementation of the FDA's Drug Quality and Security Act (DQSA) in regards to both compounded and repackaged medications for office use. Please be advised that the Board is not introducing any legislation regarding compounding or office use compounding at this time. The Board has decided not to move forward with revisions to its laws and regulations until there is more clarity provided by the FDA. The Board will, in the meantime, be enforcing existing Maryland law. Please be advised that this response was prepared with the knowledge of only the facts presented. Any person who wishes to republish or reproduce, in whole or in part, any material issued by the Board should contact the Board for prior consent. This response is not intended to be legal advice.		

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		Although references to current laws and regulations may be included in this response, keep in mind that laws may change annually and regulations may be changed at any time. Further, the information provided is based on state pharmacy laws and regulations. Federal rules and state requirements that are not included under the Maryland Pharmacy Practice Act, however, may also apply. To insure that all current applicable laws have been considered, you may want to consult with your own legal counsel. Board responses to inquiries are intended for guidance purposes only. As these positions do not necessarily reflect a discussion of all material considerations required to reach the conclusions stated, they are not intended to be rules, regulations, or official statements of the Board. Accordingly, due to their highly informal nature, these responses are not considered binding upon the Board and should not be relied on as definitive. Thank you again for your letter. Should you have questions or additional concerns, please feel free to contact me.		

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B. Licensing Committee	**J. Smith, Chair**	**1. Review of Pharmacist Applications:** a. **J. Fama** – Applicant, a recent graduate, erroneously submitted a reciprocity application along with a fee of $300 and later sent in another new application with a $150 fee. Requesting the Board to refund $300. *Licensing Committee's recommendations:* Approve refund of $300. **2. Review of Pharmacy Intern Applications: NONE** **3. Review of Pharmacy Technician Applications:** **a. L. Sanchez –** Applicant requesting approval of Puerto Rico education in order to reciprocate her registration to Maryland. *Licensing Committee's recommendations:* Approve the request. **b. N. Inman** – Applicant has not graduated High School, but is enrolled in National Collegiate Prep. *Licensing Committee's recommendations:* Approve applicant for technician registration and upon renewal, to provide proof of graduation from high school or GED or in good standing with the high school.	1a. Motion by committee to approve, 2nd by D. Ashby. 3a. Motion by committee to approve, 2nd by C. Rochester. 3b. Motion by committee to approve, 2nd by D. Ashby.	1a. The Board voted to approve this motion. 3a. The Board voted to approve this motion. 3b. The Board voted to approve this motion.

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		c. **V. Matsos** – Applicant requesting waiver of reinstatement process, as his registration expired 07/2015 after he reinstated in April and did not receive the updated registration. *Licensing Committee's recommendations:* Deny the request **STEVE BOUYOUKAS RECUSED.** **4. Review of Distributor Applications:** *None* **5. Review of Pharmacy Applications:** *None* **6. Review of Pharmacy Technicians Training Programs:** *None* **7. New Business:** a. **Accreditation Commission for Health Care (ACHC) (Suzie Steger)** – ACHC is requesting approval from the Board to inspect sterile compounding pharmacies. It currently accredits compounding pharmacies in all 50 states through its Pharmacy compounding Accreditation Board (PCAB), which is compliant with USP 797 and UPS 795. Would like Board to accept PCAB as evidence of sterile compounding compliance. *Licensing Committee's Recommendations:* Ask ACHC to provide more detailed written perspective for Board review prior to meeting with them	3c. Motion by committee to deny request, 2nd by D. Ashby. 7a. Motion by committee to approve recommendation, 2nd by C. Rochester	3c. The Board voted to approve this motion. 7a. The Board voted to approve this motion.

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		b. Pharmacy Intern – First year Pharmacy Students are being offered position of the summer and have not actually completed their first year of school but will before they begin. Logistically, the Board does not let them apply. How can this be handled? *Licensing Committee's Recommendations:* Allow the first year pharmacy students to apply and the Board to review, process, and approve their application, but keep the status as "pending" and change to "active" around May, after they have finished the first year.	7b. Motion by committee to approve recommendation, 2nd by D. Ashby.	7b. The Board voted to approve this motion.
		c. Pharmacist and Vaccine Certification on-line renewal application – Question #12: "Do you have a Maryland Vaccination certification you wish to renew? (NOTE: You MUST complete the required 4 hours of continuing education to renew your vaccine certification)" and Question #12.1: "If you answered Yes, please provide your current CPR expiration date." *Licensing Committee's Recommendations:* Change Question #12.1 to say: "Is your CPR certification card current?" If the answer is "Yes", then proceed with the renewal of the pharmacist license and vaccination certification. If the answer is "No", then a hold will be placed on the vaccine certification renewal for	7c. Motion by committee to approve recommendation, 2nd by D. Ashby.	7c. The Board voted to approve this motion.

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		the licensing specialist to contact the licensee. In addition, to have inspectors check CPR cards upon inspection ***Late Addition*** In recent months, there have been third party inquiries regarding the status of licensure applications from services that provide application preparation services. The committee recommends that licensure applications be amended to include any persons or entities that can be given information regarding the applicant.	***Late Addition*** Motion by committee to approve this recommendation, 2nd by D. Ashby.	***Late Addition*** The Board voted to approve this motion.
C. Public Relations Committee	**B. Zagnit, Chair**	**Public Relations Committee Update** Articles for the upcoming newsletter should be submitted immediately for timely preparation of the spring edition.		
D. Disciplinary	**T. Robinson, Chair**	**Disciplinary Committee Update** *None at this time*		
E. Emergency Preparedness Task Force	**S. Roy, Chair**	**Emergency Preparedness Task Force Update** *None at this time.*		
IV. Other Business & FYI	**M. Gavgani, President**	MIS Unit Acknowledgement	Z. St. Cry, II acknowledged the diligent work of the MIS Unit staff in preparation of the upcoming pharmacy renewal period.	
V. Adjournment	**M. Gavgani, President**	**D. Jones asked for a motion to close the Public Meeting at 11:21 AM and open a Closed Public Session for the purpose of engaging in medical review committee deliberations regarding**	Motion to close Public Meeting by C. Rochester, 2nd by J. Smith.	The Board voted to approve this motion.

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		confidential information in applications in accordance with the Open Meetings Act, General Provisions Article, Section3-305 (b) (7) and (13). 11:21 **At 11:35 AM, D. Jones convened a Closed Public Session for the purpose of engaging in medical review committee deliberations regarding confidential information in applications in accordance with the Open Meetings Act, General Provisions Article, Section3-305 (b) (7) and (13).** **The Closed Public Session was adjourned at 11:57 AM and immediately thereafter, D. Jones 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.**		