Maryland Board of Pharmacy news

In This Issue

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists and registering pharmacy technicians, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public.

Maryland Board of Pharmacy
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From The Executive Director's Desk

LaVerne Naesea

Summer has arrived already and the Board has been busily preparing to implement new and amended regulations (as well as new statutes from the 2010 Legislative Session), while concurrently working to refine on-going operations and preparing for FY 2011 that began July 1, 2010. Inside this newsletter edition, key legislative actions taken during the 2010 session are featured. The passage of HB 114/SB 291, helps clarify the disciplinary processes of the Health Occupation Boards (HOB), while also bringing uniformity to some of the HOBs routine practices. Among other requirements, all HOBs are required to adopt sanctioning guidelines that conform to a general framework or that incorporate a common set of elements and post all final public disciplinary orders on their HOB websites.

The wholesale distributor statute was also amended to require that out of state wholesale distributors be accredited by an accreditation organization recognized by the Board, unless they are located in a state with laws that are substantially equivalent to Maryland's laws.

One other important amendment to Maryland's pharmacy laws in 2010 pertained to the Drug Therapy Management program. A Legislative approved amendment eliminated the sunset provision, thus allowing the program to become permanent. More details about these laws are described in this issue and be sure to also check out information about the new regulatory amendments regarding continuing education requirements.

Board Staff members participated in a two-day professional development retreat this past Spring. Several objectives were met at that event including gaining a greater understanding of: the Board (and State) liability; State personnel requirements; State and federal confidentiality and privacy requirements; office protocols and team work; and most importantly, reviewing A – Z considerations for implementing new laws, programs and initiatives. Small and not so small improvements in Board operations will be coming soon, thanks to staff members and guest presenters who provided especially thoughtful contributions.

The Board is anxiously awaiting announcement from Governor O'Malley regarding new Commissioner appointments in FY 2011. The first four-year term for Commissioner Harry Finke, who occupies the Independent seat expired on April 30, 2010. Members are hopeful that he will be reappointed. The first term for Cynthia Anderson, who serves in the Home Infusion/Home Care seat, also expired April 30, 2010. Ms. Anderson is not eligible for reappointment because her current employment is no longer related to Home Infusion/Care. Commissioner Alland Leandre, who currently serves in one of Board's two Consumer Representative seats, voluntarily withdrew from consideration for reappointment due to work-related reasons (sometimes we forget that work on the Board is not considered a commissioner's real employment).

Ms. Anderson and Mr. Leandre have been extremely engaged in Board activities throughout their appointments. Cindy was no stranger when appointed in 2006, because of her prior stellar volunteer work on the Board's Sterile Compounding Task Force. She continued during her Board tenure to demonstrate excellent leadership and expertise, as

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From The Executive Director's Desk

LaVerne Naesea *continued from page 1*

a member and former Chair of the Licensing Committee, Chair of the Home Infusion Committee, and former member of the Disciplinary Committee. If I had to use one word to describe Cindy, it would be thorough. The Board has been assured that minutes, regulations and statutory proposals, and reports were appropriately prepared and concerns sufficiently addressed, because of Cynthia Anderson's thorough understanding of the issues, thorough review of written documents and thorough commitment to meeting Board goals.

In a Board newsletter article, Consumer Representative Alland Leandre once described how the "last mile," traditionally the final mile in the global logistics chain, is analogous to pharmacy dispensing and counseling that he viewed as the critical "last mile" in the patient health care chain. It was evident from important comments made during Board meetings and the review of cases presented to him as a member of the Disciplinary Committee, that Al understood how Board decisions help insure the safe completion of the health care chain that Maryland patients must travel. Al, an accomplished professional in his own right, also demonstrated leadership in working with Management Information Systems (MIS) staff members. Because of his expertise with management information systems, Al analyzed the Board's existing database systems and recommended approaches to acquiring a system that will better match the Board's increasing operational requirements. His careful guidance and participation in review of various systems and related proposals has been invaluable.

Both Cindy and Alland have served beyond the scope of expected Commissioner involvement to insure quality pharmacy services to Maryland patients and assure efficient Board operations and oversight. On behalf of the Maryland Board of Pharmacy and staff, we thank Ms. Anderson and Mr. Leandre for their dedicated service and wish them all good fortune in their future endeavors!

LaVerne G. Naesea

Board Receives a First Place Ribbon at the 2010 Flower Mart

Janet Y. Seeds, Public Information Officer

On May 7, 2010, the Board participated in the 93rd Annual Flower Mart in Baltimore, Maryland. It was a successful endeavor, thanks to the joint efforts and dedication of the Maryland Pharmacy Coalition (MPC), the University of Maryland School of Pharmacy faculty and student pharmacists, Board members and staff.

Products and literature received from various health and regulatory agencies addressed a variety of health care issues. Consumers expressed appreciation for the Board's continued outreach through the Flower Mart and many acknowledged pharmaceutical education for consumers as a very important part of the health care process.

Board and staff members as well as volunteers worked from 7:30 a.m. to 4:30 p.m., with over 700 consumers visiting the booth, to provide general safety tips and health care services. In addition to providing blood pressure monitoring and consulting on prescribed medications, information was disseminated to the public on nutrition, diabetes, cholesterol, blood pressure, smoking cessation, substance abuse, H1N1, emergency preparedness, safe use of acetaminophen, and other over-the-counter medications.

The Board's booth won the first place ribbon for the best non-profit government and wellness booth at the Flower Mart! This was the fifth consecutive year that the Board's booth has won this honor. Visit the Board's website at www.dhmh.maryland.gov/pharmacyboard and click on "Consumer Information" to view the winning booth.

To volunteer for upcoming consumer events hosted by the Board of Pharmacy please contact Janet Seeds, at 410-764-5988 or JSeeds@dhmh.state.md.us.

LICENSING CORNER

Summar J. Goodman, Manager of Licensing Unit

Revised Continuing Education (CE) Requirements for Pharmacists

COMAR 10.34.18, Continuing Education for Pharmacists, regulations were amended to include requirements that will affect renewing pharmacists, effective July 1, 2010. Specifically, renewing pharmacists licensed in Maryland will now be required to document that they have:

- Acquired 1 hour of Continuing Education (CE) on preventing medication errors; and
- Acquired 2 hours of live CE: Pharmacists may acquire 2 live CE credits for attending a Board of Pharmacy Public Meeting in its entirety (not to exceed 4 CE credits per renewal period).

In addition:

- Renewing pharmacists and pharmacy technicians who wish to request acceptance of unapproved CE must make the request for Board approval 90 days prior to license expiration; and
- All Maryland licensed, out-of-state pharmacists are now required by the amended regulations to meet all Maryland Board CE requirements.

To allow time for implementing the amended regulations, pharmacists due to renew in July 2010, August 2010, and September 2010, will be exempt from meeting these new CE requirements for this renewal period.

Renewing pharmacists that are also certified to administer vaccinations in Maryland are reminded that statu-

session require renewing pharmacists, as part of the 30 hours of approved CE requirement, to :

(a) Complete 4 hours of CE credits related to vaccinations; or

(b) If registered to administer vaccines before October 1, 2008 for the first renewal of the registration after that date, demonstrate that 4 CE credits taken include education about the herpes zoster and pneumococcal pneumonia vaccines.

This notification serves as a brief summary of amended Maryland pharmacy laws and regulations relating to license renewals. Maryland licensed pharmacists are responsible for meeting all of the state pharmacy laws and regulations that may be accessed through the Board's website at www.dhmh.maryland.gov/pharmacyboard under News Updates to review the full version of the regulations. If additional information is required, please e-mail Summar J. Goodman, Licensing Manager at sjgoodman@dhmh.state.md.us.

Wholesale Distributor Law Changes - Effective October 1, 2010

Health Occupation (HO)§ 12–6C–04 of the Wholesale Distribution Permitting and Prescription Drug Integrity Act was amended during the 2010 Maryland legislative session. The amended law includes requirements that will affect renewing out-of-state wholesale distributors. Specifically, effective October 1, 2010, out-of-state distributors will fall into one of the two categories listed below and must comply with the appropriate requirements in order to receive a renewal permit:

1. The wholesale distributor is located in a state that has requirements that are substantially equivalent to Maryland's wholesale distributor requirements (i.e. IN; ND; WY; AZ; CO; FL; GA; ID; IL; KY; NB; NV; NJ; OR; or OK—for human drugs only;) and includes requirements for pedigrees, routine inspections, operations in a commercial, non-residential facility and security measures.
   • A copy of an inspection report issued by that state's Board of Pharmacy and completed within the previous renewal period must be submitted with the renewal application; or
   • If the distributor is VAWD-accredited, indicate the VAWD accreditation number on application in lieu of above referenced inspection report.
   • All other requirements, including a surety bond and background checks for the designated representative and the designated representative's supervisor are still required.

OR

2. The wholesale distributor is out-of-state and accredited by a Board-recognized accreditation organization. Currently, the National Association of Boards of Pharmacy (NABP) is the only Board-recognized accreditation organization.
   • If the distributor is VAWD-accredited, indicate the VAWD accreditation number on the renewal application.
   • Meet all other requirements, including a surety bond.

If an applicant cannot meet # 2 above, proof of submission of an accreditation application must be submitted with the renewal application. The NABP Verified Accredited Wholesale Distributor (VAWD) accreditation process includes a physical inspection of the facility and may take six months or more to complete. Applicants are encouraged to begin the accreditation process with NABP by June 30, 2010 if planning to renew their permits during the October 2010 through December 2010 renewal period. Proof of submission of an accreditation application must be submitted with the renewal application. VAWD Program requirements may be viewed online at: http://www.nabp.net/programs/accreditation/vawd/. Failure to comply with NABP's requirements in the accreditation process, including failure to respond to requests for information, will result in denial of the application.

In addition, manufacturers distributing their own prescription drugs approved by the U.S. Food and Drug Administration may complete an abbreviated application provided the following items are submitted with their application:

- A copy of the manufacturer's most recent FDA inspection.
- Documentation of FDA registration as an establishment approved to distribute prescription drugs.

General Information for All Applicants

See the Board's website for specific instructions and applications: http://www.dhmh.state.md.us/pharmacyboard/forms/establish.htm. All distributors must complete the same form unless they are a manufacturer distributing their own prescription drugs. Answers to Frequently Asked Questions are updated regularly and can be found on the Board's website at www.dhmh.maryland.gov/pharmacyboard.

Contact NABP at vawd@nabp.net with questions relating to the wholesale distributor accreditation application. Operating without a permit is punishable by a fine not to exceed $500,000. Md. Code, Health Occ. § 12-6C-11.

If additional information is needed after reviewing the Board's website, please contact Summar Goodman, Licensing Manager, at sjgoodman@dhmh.state.md.us.

COMPLIANCE CORNER

Community Pharmacy Billing

Harry Finke, Jr., Board Commissioner

There are some people who would argue that the practice of pharmacy is the most regulated profession in the United States while being one of the most competitive at the same time. There are many different ways to compete and still comply with federal and state laws. Unfortunately, it has come to the Board's attention that some community pharmacies are discounting insurance co-pays to increase their business and formulating contracts that may deny a patient's free choice of pharmacist or pharmacy services (which is proscribed in HO 12-403 b (8)).

The Federal Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting or receiving remunerations (e.g., anything of value), either for federal health care program referrals or in exchange for purchasing or arranging for the purchase of an item or service paid for through a federal health care program. Also, there is a separate yet similar federal anti-kickback law that applies to public contracts as well as various state anti-kickback laws which apply to pharmacy businesses. Be aware that if you operate a pharmacy as either a resident or non-resident permit holder, you may be subject to sanctions by the Maryland Board of Pharmacy if these laws or regulations are violated. Please make sure your business practice follows all laws, federal and state, before creating any new programs.

Amendments to Pharmacy Security Regulations Take Effect

Lenna Israbian-Jamgochian, Board Commissioner

The Board of Pharmacy recently amended COMAR 10.34.05 Pharmacy Security Regulations .02 and .05 by adding new requirements to insure pharmacy security. These amendments take effect July 1, 2010.

Specifically, the new requirements state:

.02 Prescription Area

(1) A pharmacy shall be secure from unauthorized entry as follows:

(a) Access from outside the premises shall be:

(i) Kept to a minimum; and

(ii) Well controlled;

(b) The outside perimeter of the premises shall be well lit; and

(c) Entry into areas where prescription drugs or devices and patient records are stored shall be limited to authorized personnel.

(2) A pharmacy shall be equipped with:

(a) An alarm system to detect entry after hours;

(b) A security system that provides protection against theft and diversion;

(c) Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records;

(d) An inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting;

(e) A security system to protect the integrity and confidentiality of data and documents limited to authorized personnel; and

(f) A means to make the data and documentation required under this section readily available to the Board, an agent of the Board, the Division of Drug Control, or federal and other State law enforcement officials.

.05 Security Responsibility

The pharmacy permit holder is responsible for assuring that pharmacists, employees, and others who enter the pharmacy:

C. Report thefts of prescription drugs or devices to the:

(1) Board of Pharmacy;

(2) Local police;

(3) Division of Drug Control; and

(4) U.S. Drug Enforcement Administration.

Permit holders may submit copies of the DEA 106 form to satisfy the theft reporting requirements.

DISCIPLINARY ACTIONS

Pharmacist	Lic. #	Status	Date
Josiah Akinsoji	17292	Revoked	6/16/10
Robb Foote	12098	Probation	6/16/10
Craig Holston	09940	Suspended	4/23/10
Vidhyanand Mahase	17711	Revoked	6/01/10
Callixtus Nwaehiri	10899	Revoked	4/14/10
Adebisi Ola	15402	Suspended	7/7/10
Steven Sodipo	11532	Revoked	4/14/10
Derrick Truby	12736	Suspended	5/19/10
Lisa White	12969	Suspended	6/21/10

Pharmacist Technicians

Tech Name	Reg. #	Status	Date
Erin Anthony	T00734	Suspended	6/21/10
Dwayne Drake	applicant	Denied	5/24/10
Wanda Gasque	applicant	Denied	4/27/10
Shirley Matthews	T03950	Suspended	6/21/10
Shiloh Polito	T03308	Suspended	6/23/10
Holly Roe	T04464	Suspended	4/6/10
Jacob Windsor	T00734	Suspended	6/28/10

Establishment

Name	Permit #	Status	Date
Neb 24 Distributors	D02464	Cease and Desist	5/13/10

SCHEDULING OF FIORICET – A Reminder

Katie Bales, University of Maryland School of Pharmacy, Student Pharmacist and Board of Pharmacy Intern

Although the Drug Enforcement Agency (DEA) classifies Fioricet as a non-controlled medication, it remains a CIII drug in the state of Maryland. Specifically, CR 5-404 states that "except those substances that are specifically listed in other schedules, a substance that contains any quantity of a derivative of barbituric acid, or a salt of a derivative of barbituric acid," is considered a CIII substance unless otherwise listed as a different schedule. Therefore, all prescriptions for Fioricet in the state of Maryland must follow Maryland's schedule for controlled dangerous substances (CDS). Fioricet is a combination of butalbital (a short-acting barbiturate), acetaminophen, and caffeine and is indicated for the treatment of tension headaches or headaches caused by muscle contraction.

New Pharmacy Laws

Anna Jeffers, Manager of Legislative and Regulatory Unit

SB 163/HB 868 State Board of Pharmacy – Wholesale Distributor Permitting and Prescription Drug Integrity Act – Revisions

The Wholesale Distributor Permitting and Prescription Drug Integrity Act have been in place since July 1, 2007. The Board initially required compliance with the Act for the renewals and new wholesale distributors in December 2008. As the Board began the implementation of the Act, two legislative changes have been sought. The first legislative change in the 2009 Legislative Session allowed for two surety bond amounts to relieve the financial burden on smaller wholesale distributors. Now a wholesale distributor may obtain a $50,000 surety bond instead of a $100,000 surety bond if their annual gross receipts in Maryland are less than $10,000,000.

The second legislative change, which occurred in the 2010 Legislative Session, requires an out of state wholesale distributor that wants to operate in Maryland to be 1) accredited by an accreditation organization recognized by the Board; or 2) located in a state with laws that are substantially equivalent to Maryland's laws. The Board sought this change because of the prohibitive cost of inspecting out of state wholesale distributors that were not accredited by an accreditation organization recognized by the Board or located in states with laws that are not similar to Maryland's.

SB 165/HB 600 Health Occupations – Therapy Management Contracts – Repeal of Sunset

After 8 years of hard work, implementation, promulgation of regulations, approval of various protocols, a study by the University of Maryland School of Pharmacy, two reports by the Board to the Legislature, and two sets of legislation, Drug Therapy Management is now a permanent program in Maryland! The Therapy Management Contracts legislation originally was enacted in 2002 with a Sunset date of June 1, 2008. After careful negotiation and consideration between the Board of Physicians and the Board of Pharmacy, the regulations became effective on December 11, 2003. The Board submitted a Report to the legislature in October 2006 concerning the progress and effectiveness of the program and requested that the original sunset date of June 1, 2008 be extended so that a study to be conducted by the University of Maryland School of Pharmacy could be completed. During the 2008 Legislative Session, HB 233 - Physicians and Pharmacists - Therapy Management Contracts - Extension of Law, passed extending the Sunset Date to September 30, 2010. By the end of 2009, the University of Maryland School of Pharmacy completed the mandated program study that demonstrated successful outcomes for patients which are consistent with patient outcomes across the country. The study data indicated that patients receiving care under Drug Therapy Management agreements received clinical benefits and had no major complications or hospitalizations. Further, participating patients indicated a high level of satisfaction and participating physicians and pharmacists reported that the practice protocols were adequate to meet the needs of patients. SB 165/HB 600 eliminated any future sunset dates and became effective on July 1, 2010.

The road has been long, but the process has been worth it. Drug Therapy Management is the cutting edge of pharmacy practice and is becoming more and more widely accepted around the country. Consider how Drug Therapy Management would fit into your practice and how it may be of benefit for your patients. The regulations to review are COMAR 10.34.29.01 - .11 and may be found at http://www.dsd.state.md.us/comar/searchall.aspx . Please be advised to enter all eight numbers in the box provided on the COMAR page: 10.34.29.01 and so forth.

The Interim DEA Rule on Electronic Prescribing of Controlled Dangerous Substances

On March 31, 2010, the Drug Enforcement Agency (DEA) published an Interim Final Rule (IFR) that allows for the electronic transmission of controlled substance prescriptions. The DEA accepted public comments on the IFR until May 31, 2010 and it became effective June 1, 2010. The IFR allows prescribers the option of electronic prescribing for controlled drugs prescriptions. It also outlines procedures for pharmacies to receive, dispense and store these prescriptions. The revised regulations address system and process requirements and appropriate access to electronic prescription applications.

<u>Requirements for Providers, Pharmacies, and Other Applicants</u>

Before any pharmacy computer system can be used for electronic prescribing of controlled substances, it must be audited or certified by a third party and found to be in compliance with DEA requirements for recording, signing, storing and transmitting information. There are currently no third parties approved to perform such certification. In addition, there are also major processes and system changes that must be in place before prescriber and pharmacy applications can be used for electronic prescribing of controlled substances. These include:

LEGISLATIVE/REGULATIONS UPDATE
con tinued

- Requiring two-factor authentication at signing (e.g., password and either use of a token or fingerprint verification);
- Developing signature and record keeping protocols;
- Enhancing reporting and auditing functionality;
- "Identity proofing," whereby providers must be authorized by a federally approved credentialing body to electronically prescribe controlled substances;
- Developing policies and procedures to address data entry, access control and other aspects of the IFR requirements.

Current Status

Most prescribers and pharmacies in the United States are not positioned to currently meet the intricate requirements of the IFR. Pharmacies should begin reviewing their current and planned systems and software applications with the anticipation of the IFR full implementation. More details on the IFR can be found on the DEA Diversion Control website at http://www.deadiversion.usdoj.gov/.

UPCOMING BOARD EVENTS

"Expansion of the Pharmacist's Role" CE Opportunity

Sunday, October 3, 2010
8:00 am – 11:00 am
Radisson Hotel at Cross Keys
Baltimore, Maryland
Limited Seating

"Emerging Roles for Pharmacists in Emergency Situations" Volunteers Training

Sunday, November 21, 2010
8:00 am – 12:00 pm
BWI Westin, Baltimore, Maryland
Limited Seating

For both events, contact Janet Seeds at 410-764-5988
or jseeds@dhmh.state.md.us to register.

The Department of Health and Mental Hygiene (DHMH), acting on a directive from the Governor of Maryland, is making a change to insure that all DHMH program units consistently use 'dhmh.state.md.gov' in their website addresses. Therefore, the Maryland Board of Pharmacy's website address has changed to www.dhmh.maryland.gov/pharmacyboard. Consistency is a good thing! Consistency is important in our work output, our policies and procedures, our client relationships, our business partnerships, AND our websites.

The Board of Pharmacy's former website will be available for a limited time. Please update your computer's bookmarks, favorite's pages and contact information for the Board of Pharmacy, as soon a possible, to reflect the new website address.

Reminder:

The Maryland Board of Pharmacy website address has changed.

Make a Note!!!

www.dhmh.maryland.gov/pharmacyboard

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Maryland Board of Pharmacy

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ADMIBISTRATION • 410-764-5929	
Patricia Gaither, Administration & Public Support Manager; Janet Seeds, Public Information Officer; Anasha Page, Office Secretary; Nikki Dupye, Secretary/Receptionist	Responds to inquiries regarding Fiscal, Budget, Procurement, Travel, Personnel and Public Information
LEGISLATION AND REGULATIONS • 410-764-4794	
Anna Jeffers, Legislation and Regulations Manager	Responds to inquiries regarding Legislation and Regulations and Pharmacy Practice Committee
COMPLIANCe • 410-764-5988	
Kimberly France, Pharmacist Compliance Officer; Emory Lin, Pharmacist Inspector; Nancy Richard, Lead Inspector; Vacant, Inspector; Jeannelle McKnight, Inspector; Shanelle Young, Inspector; Steven Kreindler, Compliance Coordinator; Colin Eversley, Compliance Investigator; Vanessa Thomas Gray, Compliance Secretary	Responds to inquiries regarding Complaints, Pharmacy Practice, Disciplinary, Inspections, Investigations and Pharmacists Rehabilitation
LICENSING • 410-764-4756	
Summer Goodman, Licensing Manager; Doris James, Licensing Specialist; Fannie Yorkman, Licensing Specialist; Vacant, Licensing Secretary; Keisha Wise, Licensing Clerk	Responds to inquiries regarding Licensing, Permits, and Registration, Reciprocity, and Scores
MANAGEMENT INFORMATION SERVICES • 410-764-5929	
Tamarra Banks, MIS Manager; Michelle Xu, Database Officer	Responds to inquiries regarding Computer, Database and Website and On-line Renewals

BOARD COMMISSIONERS

President: Michael Souanis
Secretary: Rodney Taylor
Treasurer: Lenna Israbian-Jamgochian
Cynthia Anderson
Lynette Bradley-Baker
David Chason
Harry Finke, Jr.
Mayer Handelman
Alland Leandre
Richard W. Matens
Donald Taylor
Reid Zimmer

BOARD COUNSEL

Linda Bethman, AAG
Francesca Gibbs

BOARD MEETINGS

The Pharmacy Board meetings are held the third Wednesday of each month and are open to the public from 9:00 a.m. – 12 noon at 4201 Patterson Avenue, Baltimore Maryland 21215.

The Board encourages all interested parties to attend the monthly Board Meetings.

2010 PUBLIC BOARD MEETING DATES

Third Wednesday of each month
9:00 am – 12:00 pm

July 21,2010
September 15, 2010

August 18, 2010
October 20, 2010

COMMITTEE MEETING	
Executive Committee Meetings First Wednesday of each month 10:00 am-12:00 pm	Licensing Committee Meetings** Fourth Wednesday of each month 9:30 am-12:00 pm
Disciplinary Committee Meetings First Wednesday of each month 1:00 pm-4:30 pm	Practice Committee Meetings** Fourth Wednesday of each month 1:00 pm-4:30 pm
Emergency Preparedness Committee Meetings* Second Wednesday of each month 9:00 am-12:00 pm	Public Relations Committee* Second Wednesday of each month 11:00 am-12:30 pm
*Meetings that are open to the public	