

NEWS

Louisiana Board of Pharmacy

5615 Corporate Blvd, Suite 8E, Baton Rouge, LA 70808-2537
www.labp.com

Published to promote voluntary compliance of pharmacy and drug law.

License and Permit Renewals for 2008 – New Procedures (07-10-276)

The renewal cycle for pharmacists and pharmacies will open on November 1, 2007. The Louisiana Board of Pharmacy will no longer automatically mail renewal applications; instead, the Board office will send a reminder postcard to all pharmacists and pharmacies just prior to November 1. The postcard will remind you of the three options you have to renew your credentials: (1) visit the Board's Web site at www.labp.com and renew the credentials online using a credit card; (2) visit the Board's Web site and print a renewal application, then mail it with the appropriate fee to the Board office; or (3) send a written notice to the Board office (mail, fax, or e-mail) with your name, address, and credential number requesting the Board to mail an application to you. For those credentials renewed online, we will mail those renewals within one to two business days; for those credentials renewed with paper applications, we will mail those renewals within two to four weeks, depending on the volume of paper applications received.

Any address changes submitted to the office after October 10, 2007, will not be reflected on your reminder postcard. If you do not receive your reminder postcard by November 15, 2007, it is **your** responsibility to obtain a renewal application or renew your credential online.

The online renewal feature of the Web site will only be accessible from November 1, 2007 through December 31, 2007. While the Board makes every effort to maintain the online convenience during the renewal period, our service provider may experience weather-related or other unforeseen technical difficulties from time to time – as they did on the last day of the summer renewal cycle earlier this year. You have 60 days to renew your credentials; if you choose to wait until the last day and the Web site is unavailable, then you will be responsible for the consequences of your failure to renew your credential in a timely manner. Why take a chance? Please do not wait until the last minute.

Pharmacist License Renewal

- ◆ Pharmacist licenses expire December 31, 2007; there is no grace period, and a pharmacist shall not practice with an expired license.
- ◆ If you elect to use a paper application and you need a current renewal on or before January 1, 2008, we suggest you submit your completed application and \$100 fee to the Board office on or before December 1, 2007. Do not forget to date and sign the application and answer the questions at the bottom of the application – if they are not all answered, or if there is no supporting information with positive responses, the application will be returned to you as an incomplete application.
- ◆ The renewal of an expired license will incur a 50% penalty as well as a lapsed license reinstatement fee, resulting in a total charge of \$350.
- ◆ If it is important for you to know when your paper application is received at the Board office, we suggest you use a mailing service with tracking options (United States Postal Service, United Parcel Service, FedEx, etc).

Pharmacy Permit Renewal

- ◆ Pharmacy permits expire December 31, 2007; there is no grace period, and a pharmacy shall not operate with an expired permit.
- ◆ If you elect to use a paper application and you need a current renewal on or before January 1, 2008, we suggest you submit your completed application and appropriate fee to the Board office on or before December 1, 2007. Do not forget to answer all questions and sign the application; incomplete applications will be returned to you unprocessed.
- ◆ Please note the presence of a new fee this year: a \$25 service fee for the Prescription Monitoring Program (PMP). This fee was authorized by Act 676 of the 2006 Louisiana Legislature. This fee will be collected from all pharmacies licensed by the Board (with the exception of those few pharmacies exempt from all other fees), as well

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Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at www.fda.gov/cder/meeting/medication_guides_200706.htm.

Reporting Makes a Difference



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**[®] **Community/Ambulatory Edition** by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System*, and *Identifying and Preventing Medication Errors*, the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- ◆ Losec[®] (error reports indicating mistaken as Lasix[®]) to Prilosec[®],
- ◆ Levoxine (error reports indicating mistaken as Lanoxin[®]) to Levoxyl[®],
- ◆ Reminyl[®] (error reports indicating mistaken as Amaryl[®]) to Razadyne[™] (and unfortunately new error reports show Razadyne being mistaken as Rozerem[™])



◆ and the most recent, Omacor[®] (error reports indicating mistaken as Amicar[®]) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit www.ismp.org and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "inherently unsafe practice." FDA also encourages consumers to review www.fda.gov for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

- ◆ inadequate labeling for safe use;
- ◆ inappropriate packaging and, therefore, uncertain product integrity;
- ◆ possible previous withdrawal from the US market for safety or efficacy reasons;
- ◆ drug-specific risks requiring initial screening and/or periodic patient monitoring;
- ◆ potential harm or abuse, such as with the use of controlled substances; and
- ◆ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites[™] program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at www.fda.gov/dockets/ecomments.

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at www.cfsan.fda.gov/~dms/dscgmps7.html and a fact sheet at www.cfsan.fda.gov/~dms/dscgmps6.html.

More information is available on the FDA Unapproved Drugs Web site at www.fda.gov/cder/drug/unapproved_drugs/default.htm.

as those practitioners authorized to prescribe controlled substances (CS) for humans. We did not collect the fee for the 2007 renewal, but since we intend to implement the program before the 2009 renewal, we are collecting the service fee for the 2008 renewal.

- ◆ The renewal of an expired pharmacy permit will incur a 50% penalty as well as a lapsed permit reinstatement fee, resulting in a total charge of \$412.50, which includes the PMP fee.
- ◆ The renewal of an expired controlled dangerous substance (CDS) permit will incur a 50% penalty as well as a lapsed reinstatement fee, resulting in a total charge of \$237.50.
- ◆ If it is important for you to know when your paper application is received at the Board office, we suggest you use a mailing service with tracking options.

Pharmacists, Interns, Technicians, and Technician Candidates (07-10-277)

If you are a pharmacist-in-charge (PIC), you must – at all times – ensure that all personnel allowed to perform professional functions in your prescription department are properly licensed, registered, or certified. If you are a staff pharmacist or relief pharmacist, it is your responsibility to ensure that the employees assisting you in the prescription dispensing process are properly credentialed to perform their duties during your presence. If a compliance officer discovers persons performing professional functions without the necessary credentials, you will be identified as the responsible person in the investigative report filed by the compliance officer.

Inappropriate Marketing Practice (07-10-278)

We are aware of a marketing practice used primarily by pharmacies servicing the long-term care provider market, eg, nursing homes. To demonstrate to their potential clients how the pharmacy packages patients' medications, some pharmacies have been packaging candy in blister packaging to resemble prescription medications. Typically, pharmacies will distribute these promotional items at trade shows and other similar events. One of these promotional candy packages was recently found in the hallway of an elementary school. The school nurse reported some of that school's students receive prescription medication packaged in a similar manner, and questioned the propriety of packaging candy to resemble prescription medication. Given the potential for serious harm to a student or anyone else, we concur with that concern.

We trust that pharmacists and pharmacies understand the potential for a serious medication error, and further, that all pharmacies will cease and desist those promotional activities that package candy to resemble prescription medications.

New Regulations (07-10-279)

All of our licensees should have received *Bulletin No. 07-01* on or about August 15, 2007. If you did not, or if you have misplaced your copy, you can also view that document on

the Board's Web site at www.labp.com. The bulletin identified the changes in the regulations that became effective this past June and July. We have received requests for additional information about some of the changes, and the following information is presented in response.

The requirements for continuing education (CE) for pharmacists were modified to require at least three hours of live CE per year, as designated by Accreditation Council for Pharmacy Education (ACPE). If you are not sure whether an ACPE-accredited CE program is considered a live presentation, examine the program identification number: if the third character from the end is an "L," then it is considered a live presentation. For those pharmacists who are unable or unwilling to acquire at least three hours of live CE, the Board has authorized those pharmacists to fulfill their requirements with the acquisition of an additional five hours, over and above the 15 hours already required. This new rule becomes effective on January 1, 2008. During the 2008 calendar year, pharmacists will need to earn at least 15 hours of ACPE-accredited CE, of which at least three hours must be earned in live presentations, as designated by ACPE. If a pharmacist is unable or unwilling to acquire live CE, then the pharmacist will need at least 20 hours of ACPE-accredited CE. The requirement of this modified rule in Section 507 will become enforceable with the 2009 renewal.

Collaborative drug therapy management between pharmacists and physicians in Louisiana is now permitted, subject to the requirements found in Section 523 of the Board's rules. If you have an interest in this topic, we encourage you to review the requirements, procedures, and standards of practice identified in the rule.

Section 705 of the rules was modified to clarify that pharmacy interns may not practice in pharmacies where the permit is on probation with the Board, nor shall they practice under the supervision of a pharmacist whose license is on probation with the Board.

Section 1143 of the Board's rules now permits a Louisiana-based pharmacy to acquire remote prescription processing services from another Louisiana-based pharmacy. Similarly, Section 1525 permits a Louisiana-based hospital pharmacy to acquire remote medical order processing services from another Louisiana-based pharmacy. Those pharmacies seeking to implement such services should review the requirements of those sections.

Finally, the Board has published a Final Rule for the new PMP. At this time, we are working on the administrative aspects of the program. As soon as we have the details in place, we will inform all the prescribers and dispensers of CS. We anticipate starting the program near the end of this year or in the beginning of next year.

All of these new rules, as well as all other changes, can be viewed on the Board's Web site: www.labp.com → Laws & Regulations → Title 46 – Administrative Code.

Disciplinary Actions (07-10-280)

Although every effort is made to ensure the information is correct, you should call the Board office at 225/925-6496 to verify the accuracy of any listing before making any decision based on this information.

During its May 10, 2007 administrative hearing, the Board took action in the following matters:

Steve Patrick Michel (Pharmacist License No. 11999) re Complaint No. 06-0235, Formal Hearing: License suspended for five years, and further, respondent assessed \$25,000 plus investigative, administrative, and hearing costs; and further, acceptance of application for reinstatement conditioned upon payment of all fines and costs in all prior proceedings. *Charges*: four counts, including continuing to practice with a suspended license. The respondent has appealed the decision of the Board; nevertheless, the Board's order is in effect while the appeal is pending.

Med South Rx, LLC (Applicant for Pharmacy Permit) re Complaint No. 06-0221, Formal Hearing: Applicant assessed investigative, administrative, and hearing costs; and further, conditioned any further consideration of application upon payment of all assessments. *Charges*: two counts, including false advertising.

Brenda Bester Butler (Technician Certificate No. 6336) re Complaint No. 06-0234, Formal Hearing: Certificate revoked, and further, respondent assessed \$5,000 plus investigative, administrative, and hearing costs. *Charges*: seven counts, including unlawful possession of CDS in Schedules IV and V.

Gary Vincent Schexnayder (Technician Certificate No. 7242) re Complaint No. 06-0229, Formal Hearing: Certificate revoked, and further, respondent assessed \$5,000 plus investigative, administrative, and hearing costs. *Charges*: six counts, including failure to maintain current mailing address with the Board, failure to provide information legally requested by the Board, and failure to submit to medical evaluation when directed by the Board.

During its August 9, 2007 administrative hearing, the Board took final action in the following matters:

Medsource Pharmacy Services (Pharmacy Permit No. 5070) re Complaint No. 07-0069, Voluntary Consent Agreement: Permit placed on probation for five years, beginning June 30, 2007, and further permit owner assessed \$25,000 plus investigative and administrative costs. *Charges*: 18 counts, including operation of a pharmacy with multiple technicians and no pharmacists, improper packaging and labeling of prescription medications, and improper reuse of previously dispensed prescription medication.

Leo Gerard Riche (Pharmacist License No. 14961) re Complaint No. 07-0070, Voluntary Consent Agreement: License placed on probation for five years, beginning

June 30, 2007, and further respondent assessed \$1,000 plus administrative costs. *Charges*: 19 counts, including accountability as PIC for improper operation of Medsource Pharmacy Services, failure to properly supervise pharmacy technicians, improper packaging and labeling of prescription medications, and improper reuse of previously dispensed prescription medications.

Rachel Iles Bailey (Technician Certificate No. 5580) re Complaint No. 07-0071, Voluntary Consent Agreement: Certificate placed on probation for 18 months, beginning June 30, 2007, and further respondent assessed \$250 plus administrative costs. *Charges*: five counts, including practicing beyond lawful scope of practice at Medsource Pharmacy Services.

Adriel Peter Joseph (Pharmacist License No. 17298) re Complaint No. 07-0025, Voluntary Consent Agreement: License suspended for seven years, beginning June 30, 2007, and further respondent assessed \$10,000 plus investigative and administrative costs; and further, the acceptance of any future reinstatement application conditioned upon certain terms as identified in the agreement, including the mandatory service of at least 18 months on active suspension. *Charges*: 19 counts, including dispensing fraudulent prescriptions for CS in Schedules III and IV for himself, conviction of a felony, and acquisition of a license by fraud due to his failure to report that conviction to the Board on a renewal application.

Scotty Paul Broussard (Pharmacist License No. 15681) re Complaint No. 06-0170, Voluntary Consent Agreement: License placed on probation for three years, beginning on June 30, 2007, subject to certain terms as enumerated in the agreement. *Charges*: five counts, including acquisition of a license by fraud due to his failure to report prior arrests by law enforcement to the Board on a renewal application.

Thomas J. Jasso (Technician Certificate No. 4166) re Complaint No. 07-0019, Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on application for reinstatement. *Charges*: five counts, including unlawful acquisition of a CS by fraud, theft, or forgery.

Thomas Earl Mattern (Technician Certificate No. 5770) re Complaint No. 07-0115, Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on application for reinstatement. *Charges*: five counts, including unlawful possession of a CS in Schedule III.

Makesha Graves Singleton (Technician Certificate No. 6016) re Complaint No. 07-0130, Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on application for reinstatement. *Charges*: five counts, including unlawful acquisition of a CS by fraud, theft, or forgery.

Nicole Marie Venable (Technician Certificate No. 7586) re Complaint No. 07-0127, Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on application for reinstatement. *Charges*: five counts, including unlawful acquisition of a CS in Schedule III by fraud, theft, or forgery.

Amanda Valyce Fulcher (Technician Certificate No. 6982) re Complaint No. 07-0124, Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on application for reinstatement. *Charges*: five counts, including unlawful acquisition of a CS in Schedule III by fraud, theft, or forgery.

Angela Knight Leggett (Technician Certificate No. 6502) re Complaint No. 07-0140, Voluntary Consent Agreement: Certificate was revoked, with permanent prohibition on application for reinstatement. *Charges*: five counts, including unlawful possession of a CS in Schedule III by fraud, theft, or forgery, and failure to notify Board within 10 days of change in location of pharmacy employment.

Joseph Todd Plauche (Pharmacist License No. 15534) re Complaint No. 07-0117, Voluntary Surrender: License was suspended for an indefinite period of time.

Joyce Renee Jones (Technician Certificate No. 7153) re Complaint No. 07-0139, Voluntary Surrender: Certificate was suspended for an indefinite period of time.

On this same date, the Board also issued Letters of Warning to five pharmacy permit holders, as well as Letters of Reprimand to one pharmacy permit holder, two pharmacists, and five pharmacy technician candidates. The Board granted two requests for modification of probationary terms – from one pharmacist and one intern. With respect to impaired practitioners, the Board accepted the voluntary surrender of credentials from one pharmacist and one technician, granted requests for probated reinstatement from two pharmacists, one intern, and one technician, and placed two practitioners on probation – one pharmacist and one intern.

Calendar Notes (07-10-281)

The next Board meeting and administrative hearing will be November 14-15, 2007, at the Board office. The office will be closed November 22-23 in observance of Thanksgiving, December 25 in observance of Christmas Day, and December 31 in observance of New Year’s Day.

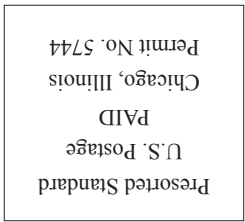
Special Note (07-10-282)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read them carefully. We encourage you to keep them in the back of the *Louisiana Pharmacy Law Book* for future reference.

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LOUISIANA BOARD OF PHARMACY
National Association of Boards of Pharmacy Foundation, Inc
1600 Fehamville Drive
Mount Prospect, IL 60056