NEWS

April 2005

Louisiana Board of Pharmacy

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New Board Member (05-04-211)

Governor Kathleen Blanco has appointed a new public member to the Louisiana Board of Pharmacy. Mr Alvin A. Haynes, Jr, of Opelousas was appointed on February 10, 2005, and his term will expire at the pleasure of the governor. Mr Haynes replaced Mr Jeffery Landry, who completed five years of service to the Board. The Board members and staff express their appreciation to Mr Landry for his work over the years.

Renewal of Pharmacy Technician Certificates (05-04-212)

The Board office will begin printing renewal applications during the week of April 18, 2005. Any address changes received after April 15 will not be reflected on the renewal application. We will mail the applications during the week of April 25. If you do not receive your application by May 15, it then becomes **your** responsibility to obtain a renewal application. You may download a replacement application form from our Web site at www.labp.com.

All technician renewals will expire on June 30, 2005. If you need a renewal before July 1, we suggest you mail the properly completed application and fee on or before May 30. Technicians may not practice with an expired renewal. The renewal of an expired certificate will incur an additional $200 reinstatement fee. Applications bearing a postmark of July 1 or later must be accompanied by the late fee, or they will be returned unprocessed.

Deferred Enforcement of Regulation (05-04-213)

During its February 17, 2005 meeting, the Board voted to continue to defer the enforcement of Section 1505.A of the Board's regulations.

Electronic Transmission of Prescriptions (05-04-214)

If we can rely on current estimates, approximately 20% of physicians and other prescribers utilize technology in the generation and transmission of their prescriptions. There are concerted efforts underway to increase that number. It is widely accepted that the proper use of technology may reduce the incidence of medication errors, both in the prescribing and dispensing arenas. The federal government, via the Medicare Modernization Act, has begun an intensive effort to increase the utilization of electronic prescribing as part of an electronic medical record.

Even as the federal effort seeks to establish a national uniform standard for that process, the wide variety of user capabilities on both the prescribing and dispensing sides of the transaction presents challenges to software and hardware vendors, users, and regulators.

Though the Board now requires all pharmacies to use computerized dispensing systems, there are a variety of software programs with differing capabilities and levels of sophistication. Some systems are able to receive electronically constructed and transmitted (computer to computer) prescriptions, and some cannot; the latter may accept other methods of electronic communication (computer to facsimile). On the other side of the transaction are prescription generation software programs that also exist in a variety of platforms. Some programs construct the prescription according to the same software standard used by pharmacies to receive prescriptions (ie, SCRIPT by National Council for Prescription Drug Programs), and some programs are based on the Health Level Seven standard used in some electronic medical record systems.

As prescribers attempt to connect to dispensers, the optimum scenario arises when the prescriber is able to connect directly – with no intermediate stops – to the computer in the pharmacy. More likely than not, however, the prescription will need to be transmitted through a network of one or more companies. Companies engaged in the electronic transmission of prescriptions are classified by the Board as "routing companies." These entities are prohibited from accessing or altering any information that travels through their system, and they may store that prescription information only for transmission receipt audit purposes. To do anything else with that information would be a violation of the Board's confidentiality regulation in Section 1129.

So how does the pharmacist verify the authenticity and legitimacy of an electronic prescription?

On the receipt of the first such prescription from a particular prescriber, it would be prudent to contact the prescriber to verify the method of prescription transmission.

The pharmacist should also be cognizant of the routing company. To assist you in that effort, we have placed a roster of routing companies on the Board's Web site (under Pharmacy, then E-Prescribing). While the Board is not in the business of approval of routing companies, the roster will indicate those companies who have submitted appropriate and relevant materials and documented their compliance with the Board's regulations and policies concerning the electronic transmission of prescriptions.

Disciplinary Actions (05-04-215)

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 August 19, 2004 administrative hearing, the Board took final action in the following matters:

Continued on page 4

Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

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, then publishes its recommendations. 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.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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Norman George Nasif (Pharmacist License No. 10299), Hearing: Ratified prior summary suspension of license, then revoked license; also fined $172,200 (*in solido* with Budget Saver Pharmacy) plus administrative and hearing costs. *Charges:* (1) committed repeated occasions of negligence or incompetence, (2) failed to conform to minimal standards of acceptable pharmacy practice, (3) failed to verify authenticity and legitimacy of prescriptions, (4) dispensed prescriptions based solely on electronic questionnaires, and (5) made illegal payments for referrals from another health care provider.

Budget Saver Pharmacy (Pharmacy Permit No. 1386), Hearing: Ratified prior summary suspension of permit, then revoked permit; also fined $172,200 (*in solido* with Norman George Nasif) plus administrative and hearing costs. *Charges:* (1) committed repeated occasions of negligence or incompetence, (2) failed to conform to minimal standards of acceptable pharmacy practice, (3) dispensed prescriptions based solely on electronic questionnaires, and (4) made illegal payments for referrals from another health care provider.

During its November 18, 2004 administrative hearing, the Board took final action in the following matters:

Charles N. Angle, III (Technician Certificate No. 1102), Hearing: Certificate revoked; also assessed administrative and hearing costs. *Charges:* (1) failed to furnish information legally requested by the Board, (2) failed to submit to medical evaluation as directed by the Board, (3) is habitually intemperate or is addicted to use of habit-forming drugs, and (4) failed to conform to minimal standards of acceptable pharmacy practice.

Brianne Marquis Synette Johnson (Technician Certificate No. 5172), Hearing: Certificate revoked; also assessed administrative and hearing costs. *Charges:* (1) unlawful acquisition of a controlled substance by fraud, (2) unlawful possession of a Schedule III controlled substance, and (3) unlawful possession of prescription medication.

Kelly Marie Dees (Technician Certificate No. 4135), Hearing: Certificate revoked; also assessed administrative and hearing costs. *Charges:* (1) unlawful acquisition of a controlled substance by fraud, (2) unlawful possession of a controlled substance, and (3) unlawful possession of a prescription medication.

Louis Randy Hatten (Technician Certificate No. 5105), Hearing: Certificate suspended indefinitely; also assessed administrative and hearing costs. *Charge:* (1) failed to pay costs assessed in a prior disciplinary hearing.

During its February 17, 2005 administrative hearing, the Board took final action in the following matters:

William Scott Martin (Pharmacist License No. 15752), Voluntary Consent Agreement: License suspended for 10 years, and further, reinstatement prohibited for at least three (3) years; also fined $10,000 plus administrative and investigative costs. *Charge:* felony conviction in federal court for health care fraud; sentenced to incarceration and restitution.

Michael Gerard Chidester (Technician Certificate No. 6497), Voluntary Consent Agreement: Certificate revoked. *Charges:* (1) unlawful acquisition of controlled substances, and (2) unlawful possession of prescription medication.

Kari O. Mathis (Technician Certificate No. 4559), Voluntary Consent Agreement: Certificate revoked. *Charge:* failed to conform to minimal standards of acceptable pharmacy practice.

The Board also issued Letters of Reprimand to four pharmacy technicians. With respect to the reinstatement of lapsed licenses, the Board granted a request from one pharmacist to provide additional time to comply with the terms of the reinstatement order. With respect to impaired practitioners, the Board accepted the voluntary surrender of license from six pharmacists, and the voluntary surrender of registration from two interns; denied a request for reinstatement from one pharmacist; granted requests for reinstatement from five pharmacists; and approved a non-disciplinary diagnostic monitoring contract for one technician.

Calendar Note (05-04-216)

The next Board meeting will be held May 11-12, 2005, at the Board office in Baton Rouge.

Special Note (05-04-217)

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.

The *Louisiana Board of Pharmacy News* is published by the Louisiana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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