July 2005

Louisiana Board of Pharmacy

NEWS

Published to promote voluntary compliance of pharmacy and drug law.

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

Proposed Changes to Pharmacy Technician Regulation (05-07-218)

During its May 11, 2005 meeting, the Louisiana Board of Pharmacy voted to begin the process of revising the pharmacy technician regulation – more particularly, the section that describes the scope of practice and ratio of technicians to pharmacists. Section 907 of the Board's regulations dictates the limitations on the scope of practice for both pharmacy technicians and pharmacy technician candidates. There are no proposed changes for pharmacy technician candidates. The Board's proposal would remove the restrictions that prevent technicians from accepting original verbal prescriptions and from giving or receiving verbal transfers of prescriptions. The proposal further provides that when a technician accepts a verbal prescription, the order must then be reduced to written form and both the receiving technician and supervising pharmacist must initial the hard copy of the prescription. The Board also proposes some flexibility in the technician ratio. Currently, one pharmacist on duty may supervise a maximum of two pharmacy technicians plus one pharmacy technician candidate as well as other types of personnel. The proposal would allow a pharmacist to supervise a maximum of three pharmacy technicians whenever there are no pharmacy technician candidates present. Finally, the Board's proposal offers a clarification of the restriction on the interpretation of a prescription. The current regulation does not prevent technicians or technician candidates from translating abbreviations and other phrases into patient-oriented language as they enter prescriptions into a dispensing software system. The "interpretation" of a prescription is a professional activity performed by a pharmacist; it includes the analysis of a new prescription order in light of all other information about that patient including the drug utilization review procedures. The proposal adds clarifying language specifically permitting technicians and technician candidates to translate prescription orders.

The Board will convene a public hearing at 9 AM on Wednesday, July 27, 2005, at the Board office to receive oral and written testimony on the Board's Notice of Intent. You may access a copy of the proposal in the June 2005 issue of the *Louisiana Register*; that document is available – free of charge – at www.doa.state.la.us/osr. You may also access a copy of the proposal from the Board's Web site at www.labp.com. The deadline for receipt of all comments is July 27. The Board will analyze and respond to all comments received. If the analysis of the comments warrants further changes, then the Board may conduct another public hearing on that proposal. If the analysis does not warrant further changes, then the Board will file a report with the legislature. If there is no objection from the legislature, then the Board may publish the proposal as a Final Rule in the *Louisiana Register*. The proposal will become effective on the date of publication of the Final Rule; at this point, the earliest possible effective date is September 20, 2005.

When there is any change in this – or any – regulation, we will notify you. Until then, the current rules for pharmacy technicians may be found in Chapter 9, which begins on page 89 of the *Louisiana Pharmacy Law Book*.

Pharmacies – Are You Obtaining Drugs from a Legitimate Distributor? (05-07-219)

The Louisiana Board of Wholesale Drug Distributors maintains a Web site at www.lsbwdd.org; you can verify the credentials of any distributor licensed to conduct business in this state. We encourage you to minimize your risk of counterfeit or diverted drugs. Make sure your distributor is licensed to conduct business in Louisiana.

Live Continuing Education (05-07-220)

During its May 11, 2005 meeting, the Board discussed a proposal to require that some portion of the continuing education required for renewal of licensure be obtained via live presentations. While there was support for the concept, the members did not reach a consensus on the number of hours. They agreed to discuss the proposal again during their next meeting on August 17. If you have any thoughts you wish to share with the members, we encourage you to contact them directly. Their contact information can be found in the member directory on the Board's Web site at www.labp.com.

Disciplinary Actions (05-07-221)

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 11 meeting, the Board took final action in the following matters:

Juliana Jenese Lanns (Technician Certificate No. 6190), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on reinstatement. *Charges:* (1) unlawful possession with intent to distribute a Schedule II controlled substance, (2) unlawful acquisition of a Schedule II controlled substance, and (3) unlawful possession and dispensation of a prescription drug.

Sondra Fay Johnson (Technician Certificate No. 4168), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on reinstatement. *Charges:* (1) unlawful acquisition and possession of prescription drugs, and (2) failure to conform to the minimal standards of acceptable and prevailing pharmacy practice, whether or not actual injury to a patient has occurred.

Louis Oliver Lenfant, Jr (Pharmacist License No. 10793), The Board accepted the voluntary surrender of the license, resulting in the indefinite suspension of the license, effective May 12, 2005.

Continued on page 4

New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.

Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

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.

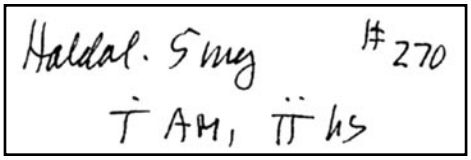
Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for

the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as "phenobarbital 32.400MG tablet." The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily. The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.



Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- Always include a leading zero for dosage strengths or concentrations less than one.
- Never follow a whole number with a decimal point and a zero (trailing zero).
- Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to "fax noise." Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

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Jennifer Mary Russo (Technician Certificate No. 5636), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on reinstatement. *Charges:* (1) unlawful acquisition of a Schedule III controlled substance, and (2) unlawful possession with intent to distribute a Schedule III controlled substance.

Walgreen Pharmacy No. 032-2262 (Pharmacy Permit No. 2385), Voluntary Consent Agreement: Permit owner assessed $1,000 plus administrative and investigative costs. *Charge:* has engaged, or aided and abetted, a person to assist in the practice of pharmacy with an expired registration.

Medicap Pharmacy No. 338 (Pharmacy Permit No. 5253), Voluntary Consent Agreement: Permit owner assessed $1,000 plus administrative and investigative costs. *Charge:* has engaged, or aided and abetted, a person to assist in the practice of pharmacy with an expired certificate.

American Diversified Pharmacies (Pharmacy Permit No. 5349), Voluntary Consent Agreement: Permit owner assessed $5,000 plus administrative and investigative costs. *Charge:* operation of a pharmacy without a pharmacy permit.

Lutresca Turette Stumon (Technician Certificate No. 5296), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on reinstatement. *Charges:* (1) unlawful acquisition of a Schedule III controlled substance, and (2) has been convicted of a felony.

Dana Cecile Galliano (Pharmacist License No. 14375), Voluntary Consent Agreement: License suspended for three years, execution thereof stayed, then placed on probation for three years, beginning March 31, 2005, subject to certain terms. Respondent also assessed $2,750 plus administrative costs. *Charges:* (1) has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, whether or not actual injury to a patient has occurred, (2) has evaded, or assisted another person in evading, any local, state, or federal laws or regulations pertaining to the practice of pharmacy, (3) accountable for shortages of controlled substances, and (4) failure to discharge responsibilities as pharmacist-in-charge.

Safescript Pharmacy New Orleans – Elmwood [aka QVL Pharmacy No. 223] (Pharmacy Permit No. 5447), Voluntary Consent Agreement: Permit suspended for one year, execution thereof stayed, then placed on probation for one year, beginning March 31, 2005, subject to certain terms. The permit owner was also assessed $20,000 plus administrative and investigative costs. *Charges:* (1) has divulged or revealed confidential information or personally identifiable information to a person other than as authorized by law or regulations, and (2) failure to provide adequate security to prevent indiscriminate or unauthorized access to confidential information.

The Board also issued Letters of Reprimand to two pharmacists, two pharmacy technicians, and one pharmacy permit; it also issued Letters of Warning to three pharmacy permits. With respect to the reinstatement of lapsed licenses, the Board granted requests from two pharmacists, subject to the completion of certain prerequisites; the Board also granted the request of one pharmacy intern, and placed the registration on probation for one year. With respect to impaired practitioners, the Board accepted the voluntary surrender of license from one pharmacist and granted requests for reinstatement from two pharmacists and one pharmacy intern.

Calendar Notes (05-07-222)

The office will be closed on July 4 for Independence Day, as well as September 5 for Labor Day. The next Board meeting will be held August 17-18 at the Board office in Baton Rouge.

Lagniappe (05-07-223)

"Don't fight a battle if you don't gain anything by winning."
– George Patton

Special Note (05-07-224)

The *Louisiana Board of Pharmacy News* 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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