

Louisiana Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Common Myths and Questions (08-07-299)

Based upon the communications the Louisiana Board of Pharmacy has with pharmacists and technicians across the state, we have compiled a list of topics that seem to create the most misunderstanding.

- ◆ *“My district supervisor said it was acceptable to dispense a quantity higher than the amount prescribed if a patient wanted it.”*

The typical scenario involves a prescription for a month supply of medication with multiple refills authorized; the request comes from a patient wanting more than one month supply for extended travel or other reasons. A pharmacist shall not dispense any medication in a quantity greater than the amount prescribed for each filling. When a greater quantity is desired, the pharmacist shall contact the prescriber. If the prescriber authorizes the same medication with a higher quantity, then the pharmacist shall record that new prescription for processing. A pharmacist may not simply re-write a prescription for a greater quantity without obtaining authorization from the prescriber, nor may a pharmacist dispense a quantity higher than the amount prescribed for each filling.

- ◆ *“My employer said that we could now accept electronic signatures for Schedule III-V prescriptions.”*

The United States Drug Enforcement Administration (DEA) is working on regulations to allow the use of electronic signatures for controlled substance prescriptions. Until those regulations are released, electronic signatures for prescriptions are **not** permitted for **any** controlled substances in **any** schedules. When a pharmacist receives a facsimile document purporting to be prescription for a controlled substance bearing an electronic signature that is not manually signed, he or she should recognize the prescription is not valid. The pharmacist should contact the prescriber and verify the prescription; that verification results in a new prescription that may then be processed.

- ◆ *“One of our patients now resides in an assisted living facility, and they want us to repackage their prescription medications.”*

When a patient in a health care facility receives medication from another pharmacy and either the patient or facility personnel request that you repackage their medication into unit-dose packaging, your pharmacy permit does not authorize you to perform that service. To legally perform this service, you must first register with the US Food and Drug Administration (FDA) as a repacker and comply with all the federal rules for that class of business. One pharmacy may not repackage medications dispensed on prescription by another pharmacy – to do so would result in the dispensing of misbranded medication, a violation of federal and state laws and rules. If you wish to repackage medications into unit dose and then sell those medications to another pharmacy, then you must be registered with the FDA as both a repacker and a distributor. If you wish to repackage bulk medications you acquired from a distributor into unit dose and then dispense those medications to your patients on receipt of a prescription, then your pharmacy permit allows you to do so.

- ◆ *“One of our patients owes us money from previous prescriptions we dispensed to her – do we have to transfer her refills to another pharmacy?”*

A patient's debt to a pharmacist shall never justify the “hostage” of a patient's medication. When a pharmacist elects to discontinue a business relationship, the pharmacist shall release any unfilled prescriptions desired by the patient. If the pharmacist has unfilled prescriptions on file, those shall be returned to the patient. If there are refills remaining on any original prescriptions, the pharmacist shall either transfer the refills to the patient's new pharmacy, or in the alternative, shall provide an information copy of the prescription directly to the patient. An information copy is a record of all the relevant prescription data elements that may be given to the patient. The patient may take the information copy to another pharmacist, who may then

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A Community Pharmacy Technician's Role in Medication Reduction Strategies



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 Food and Drug Administration (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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs

with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.



Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at www.fda.gov/cder/guidance/6911fnl.pdf) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- ◆ Drugs with potential safety concerns
- ◆ Drugs that lack evidence of effectiveness
- ◆ Fraudulent drugs
- ◆ Drugs with formulation changes made as a pretext to avoid enforcement
- ◆ Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: www.fda.gov/cder/drug/unapproved_drugs/.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at www.rxpatrol.com/videos.asp and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

use the data elements to contact the prescriber and obtain a new prescription.

♦ *“If the prescriber does not write “brand necessary” on a prescription written for a branded product, then we can dispense a generic drug.”*

When a prescription is written for a branded product, two levels of approval are required in order to interchange (substitute) and dispense a generic drug product – the prescriber and the patient. (1) When the prescriber wishes to prohibit generic interchange, the prescriber must handwrite a mark inside a check box labeled “Dispense as Written” if the prescription is in written form, or the equivalent thereof if the prescription is in electronic form. If the prescription is reimbursable by Louisiana Medicaid, then the check box is insufficient and the prescriber must handwrite the words “brand necessary” (or “brand medically necessary”) in order to prevent generic interchange. If the prescriber has prohibited generic interchange in the proper manner, then the pharmacist shall not dispense a generic product, even if desired by the patient or strongly suggested by a third-party payor. If economics suggests the need for a generic product, then the pharmacist may contact the prescriber to obtain a new order permitting the use of a generic product. (2) When the prescriber has not prohibited generic interchange in the proper manner, then the pharmacist may dispense a generic product, but only if the patient is aware of – **and consents to** – the cost-saving interchange. Since a patient must approve generic interchange prior to the act of dispensing, a patient should never be surprised at finding a generic product in their medication container.

♦ *“When FDA approves a generic drug product for commercial use, it may be used as a substitute for the brand name product.”*

FDA approval for any drug product addresses quality concerns for the manufacturing process of that particular product. The question of whether a product may be used as a generic equivalent of a branded product is dependent on the rating of the branded product. When FDA (in its *Orange Book*, available online free at www.fda.gov/cder/orange) has rated the branded product with an AB rating, then the generic product may be interchanged for that branded product. However, if the branded product is not rated AB, then no generic products on the market may be interchanged for that branded product. Again, the presence of a generic drug product on the market does not automatically qualify it to be dispensed as an equivalent drug product to the branded product.

The Board continues to receive reports of inappropriate interchange using generic drug products of branded products that are not AB rated by FDA. In particular, we have commonly found large pharmacy organizations such as chain store pharmacies and hospital pharmacies that inserted generic drug products into the master drug file of their dispensing software system and tagged them as generic equivalents to branded products that are not

AB rated. When the non-AB rated branded product is entered in the system for prescription processing, the system will also display a generic drug product. Pharmacists and technicians are commonly misled to believe the listed generic drug product is a generic equivalent to the branded product. The result is the dispensing of a mis-branded product, and it is the dispensing pharmacist who is accountable for that violation of federal and state laws and rules. There are no generic equivalents for non-AB rated branded products. When a non-AB rated branded product is prescribed, the dispensing of a generic product requires prescriber authorization, which then creates a new prescription for processing.

♦ *“I know we cannot take any previously dispensed prescription medication back into the pharmacy for redispensing. Does that also mean no refunds?”*

The restriction on accepting the return of a prescription medication for redispensing is a matter of law. However, the question of whether or not to issue a refund – full or partial – for that return is a matter of business, not a matter of law. If you practice pharmacy long enough, life may present you more than one opportunity to not only discard a medication you bought, but also to give the patient a full refund. The restriction on the return does not prevent the issuance of a refund.

♦ *“All Accreditation Council for Pharmacy Education (ACPE)-accredited continuing education (CE) certificates must have the “P” or “T” suffix on the program identification number.”*

All ACPE-accredited CE approved after January 1, 2008, must have the new suffixes on the program identification numbers. However, there are still some valid CE programs that were approved prior to 2008 that are not required to have the new suffixes. In most cases, correspondence CE programs remain valid for up to three years after the initial release date or approval date. We will rely on the approval date listed on the certificate; if it predates 2008, then no suffix is required, but if it was approved on or after January 1, 2008, then the suffix is required.

Regulatory Proposal for Controlled Dangerous Substances (08-07-300)

The 2006 Louisiana Legislature transferred the responsibility for the issuance of all controlled dangerous substance (CDS) licenses in the state from the Department of Health and Hospitals to the Board of Pharmacy. The Board has recently completed the drafting of a completely new chapter of rules for controlled substances. The new chapter will contain the current rules applicable to pharmacies as well as all the rules necessary for all other CDS licensees. You may access a copy of the proposed rule and monitor the promulgation process by visiting our Web site at www.labp.com (Meetings & Notices).

Disciplinary Actions (08-07-301)

Although every effort is made to ensure this 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 February 22, 2008 administrative hearing, the Board took action in the following matters:

Caleb Lamar Cox (Intern Registration No. 41143), Formal Hearing: Registration suspended for five years; further, assessed \$5,000 plus administrative, investigative, and hearing costs. *Charges*: three counts, including failure to comply with terms of previous agreement with the Board.

Tammy Lynn Nicholas Scott (Technician Certificate No. 5130), Formal Hearing: Certificate revoked; further, assessed \$5,000 plus administrative, investigative, and hearing costs. *Charges*: seven counts, including failure to report criminal conviction on renewal application.

Bettina Renee Brown (Applicant for Pharmacy Technician Candidate Registration), Formal Hearing: Application denied; refused to issue registration, and further, assessed administrative hearing cost. *Basis*: three counts, including attempted acquisition of credential by fraud or misrepresentation.

Charlotte Larette Wyatt (Applicant for Pharmacy Technician Candidate Registration), Formal Hearing: Application denied; refused to issue registration, and further, assessed administrative hearing cost. *Basis*: two counts, including substantial prior criminal history.

During its May 7, 2008 meeting, the Board took final action in the following matters:

Rhonda LaCheryl Jackson (Applicant for Pharmacy Technician Candidate Registration): Board denied the application and refused to issue the registration.

Kuriel Anthony Breaux (Applicant for Pharmacy Technician Candidate Registration): Board denied the application and refused to issue the registration.

Constance Ann Edwards (Technician Certificate No. 7561), Voluntary Consent Agreement: Certificate suspended for an indefinite period of time. *Charges*: four counts, including practicing with an expired certificate for several months in multiple pharmacies.

Lacey Husser Fleming (Technician Certificate No. 6207): Board accepted voluntary surrender of the credential, resulting in suspension of the certificate for an indefinite period of time, effective March 25, 2008.

Raynotte Ann Rideau (Technician Candidate Registration No. 11902): Board accepted voluntary surrender of the credential, resulting in suspension of the registration for an indefinite period of time, effective March 6, 2008.

Scotty Paul Broussard (Pharmacist License No. 15681), Voluntary Consent Agreement: License placed

on probation for 10 years, beginning March 31, 2008, subject to certain terms as enumerated in the agreement; further, assessed \$2,500 plus administrative and investigative costs. *Charges*: three counts, including failure to provide information legally requested by the Board and failure to notify the Board of a change in mailing address.

Lakeisha Shawanda Stanley (Technician Certificate No. 7352), Voluntary Consent Agreement: Certificate revoked with permanent prohibition on any future application. *Charges*: seven counts, including breach of confidential patient information for personal gain.

Michael Anthony Joplin (Pharmacist License No. 11329): Board accepted voluntary surrender of the credential, resulting in suspension of the license for an indefinite period of time, effective March 4, 2008.

Wade Randall Veillon (Pharmacist License No. 11709): Board accepted voluntary surrender of the credential, resulting in suspension of the license for an indefinite period of time, effective May 1, 2008.

Ronald Yancy LaFitte (Pharmacist License No. 10882): Board denied request for early termination of probation; term of probation continues to November 9, 2010.

James Robert Lang (Pharmacist License No. 10884): Board denied request for early termination of probation; term of probation continues to January 1, 2012.

Cheryl Ann Batiste (Pharmacist License No. 10442), Voluntary Consent Agreement: Board granted request for reinstatement of the previously suspended license; placed reinstated license on probation for five years, beginning May 7, 2008, subject to certain terms as enumerated in the agreement.

Rodney Joseph Krumm, Jr (Pharmacist License No. 16050), Voluntary Consent Agreement: Board granted request for reinstatement of the previously suspended license; placed reinstated license on probation for five years, beginning May 7, 2008, subject to certain terms as enumerated in the agreement; further, assessed \$2,500 plus administrative costs.

Aurdie Kent Bellard (Pharmacist License No. 14340), Voluntary Consent Agreement: Board granted request for modification of probationary terms.

Kerry Michael Finney (Pharmacist License No. 13535), Voluntary Consent Agreement: Board granted request for modification of probationary terms.

Fyona Meshelle Daenen (Technician Certificate No. 7335), Voluntary Consent Agreement: Board granted request for reinstatement of previously suspended certificate, and then required compliance with certain terms as enumerated in the agreement.

Glenn Samuel Warciski (Pharmacist License No. 16387), Voluntary Consent Agreement: Board granted request for reinstatement of the expired license.

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Steve Patrick Michel (Pharmacist License No. 11999), Voluntary Consent Agreement: Board granted request for reinstatement of the previously suspended license; placed reinstated license on probation for five years, beginning May 7, 2008, subject to certain terms as enumerated in the agreement.

Patricia B. Hogan (Technician Certificate No. 1158): Board accepted voluntary surrender of the credential, resulting in the suspension of the certificate for an indefinite period of time, effective March 11, 2008.

Scarlett Francine Sumrall (Technician Certificate No. 7519): Board accepted voluntary surrender of the credential, resulting in the suspension of the certificate for an indefinite period of time, effective March 31, 2008.

Kenneth Delbert Knowlton (Pharmacist License No. 10881): Board accepted voluntary surrender of the credential, resulting in the suspension of the license for an indefinite period of time, effective April 4, 2008.

Donald Peter Auzine, II, MD (CDS License No. 28735): Board accepted voluntary surrender of the credential, resulting in the suspension of the CDS license for an indefinite period of time, effective April 15, 2008.

Holli Gay Palmer (Technician Certificate No. 7851), Voluntary Consent Agreement: Certificate revoked with permanent prohibition on any future application. *Charges*: six counts, including forgery of prescriptions for Schedule III controlled substances.

James Claude McGee (Pharmacist License No. 16890): Board accepted voluntary surrender of the credential resulting in the suspension of the license for an indefinite period of time, effective May 7, 2008.

On this same date, the Board also issued Letters of Warning to four pharmacy permit owners and two pharmacists, as well as Letters of Reprimand to two pharmacy permit owners and one pharmacist. Finally, they accepted a voluntary surrender of certificate from a technician, tendered for medical reasons.

Calendar Notes (08-07-302)

The next Board meeting and administrative hearing will be August 6-7, 2008, at the Board office. The office will be closed July 4 in observance of Independence Day and September 1 in observance of Labor Day.

Special Note (08-07-303)

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.

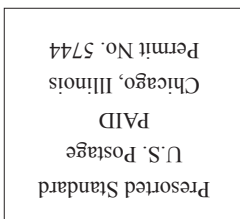
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