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Louisiana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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A New Practice Act (99-10-53)

After 51 years, pharmacists in Louisiana have a new pharmacy law. Act 767 was passed by the Louisiana Legislature and became effective August 15, 1999. The major portion of the revision involved R.S. 37:1161 through 1250. In addition, Chapter 14-A of Title 37, and Chapter 44 of Title 51, were repealed. The process of revision involved a number of pharmacists and other stakeholders working in collaboration with the Board for almost two years. The Board is appreciative for the thoughtful consideration received from all concerned.

There were several changes in the law, and they will be communicated to you shortly. In fact, some of them are noted in this *Newsletter*. While some of the changes were effective on August 15, other changes will become effective only after the Board has promulgated new rules. The Board has already begun the process of revising those rules that are inconsistent with the new law. Once again, the Board will seek input from all the stakeholders during the rule revision process.

As we begin making other changes and communicating them to you, it is *very important* to keep up with correspondence from the Board office. Whenever you receive revised laws and rules, please update your law book in a timely fashion.

New Law for Generic Substitution (99-10-54)

R.S. 37:1241.A.(17) relates that it is now illegal for a pharmacist to "knowingly select an equivalent drug product if the practitioner instructs otherwise, by any means, on the prescription drug order."

When a prescriber orders a medication utilizing the generic name, the pharmacist is free to select the most appropriate product for that patient. When a prescriber orders a medication utilizing a specific trade name and there is no provision granting the pharmacist the option to substitute an equivalent drug product, the pharmacist *must* dispense the product ordered.

There is no longer an exception for Medicaid or any other third-party payer insurance plan. Remember, there is no equivalent drug product for a drug efficacy study implementation (DESI) drug.

Q: *If the prescriber orders a brand name medication, then checks a box indicating "generic OK" or signs the appropriate line on a two-line form, can I substitute with a generic product?*

A: Yes.

Q: *If the prescriber orders a medication by brand name, with no authority to substitute, and the patient's insurance plan only pays for a generic product, can I substitute with the generic form?*

A: No. You must contact the prescriber to obtain a new order.

Year 2000 Registration Renewal (99-10-55)

The Board office will begin printing pharmacist license renewals and pharmacy permit renewals on or about October 15. Any address changes submitted to our office on or after October 15 will not be reflected on your renewal application. We will mail all pharmacist and pharmacy renewal applications on October 27.

If you do not receive your renewal application on or before November 15, it is *your* responsibility to pursue obtaining a renewal application. Applications have been provided to all pharmacists-in-charge (PICs) for placement in the law book. Pharmacists should refer to page 336.9, and the PIC should use page 336.10. We suggest you make a copy of the form, and then return the original form to the book for future use.

Pharmacist License Renewal

- Completed application and $75 fee due in Board office on or before December 1.
- License expires December 31; pharmacists may not practice with expired license.
- There is no more "grace period." *(NEW!)*
- Expired license will incur a 100 percent penalty as well as a lapsed license fee, resulting in a total charge of $350. *(NEW!)*

Pharmacy Permit Renewal

- Completed application and $100 permit fee (and $25 for controlled dangerous substance (CDS) permit fee, if needed) due in Board office on or before December 1.
- Permit expires December 31; pharmacies may not operate with expired permits.
- After January 15, an expired permit will incur a 50 percent penalty, resulting in a total charge of $150 (and $37.50 CDS permit, if needed).

Continuing Pharmaceutical Education (99-10-56)

In order to qualify for relicensure in the year 2000, pharmacists are required to report a minimum of 15 hours of continuing education approved by the American Council on Pharmaceutical Education (ACPE). There are no restrictions on the subject matter of the ACPE-approved courses.

In order to report a continuing education credit, you must be in actual physical possession of a certificate giving you credit for the course. While you do not send the certificate (unless requested to do so by the Board office), you must possess the certificate when you report the credit. Notations on the pharmacist renewal application to the effect of "pending receipt," "mailed," or any-

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NABP Awards First VIPPS™ Seals to On-Line Pharmacies

NABP awarded its first Verified Internet Pharmacy Practice Sites (VIPPS™) seals on September 15, 1999, to three on-line pharmacies, planetRx, Merck-Medco Rx Services, and drugstore.com, each of which is now authorized to display the VIPPS seal on their Web site and maintain a link from the seal to NABP's VIPPS Web site.

"Each of these three on-line pharmacy operations were able to satisfy VIPPS' rigorous 17-point Internet pharmacy practice criteria, demonstrate appropriate licensure, and pass an on-site visit from VIPPS inspection teams at the applicants' headquarters and fulfillment centers to review and verify compliance with VIPPS criteria," said NABP President Dyke Anderson. "These pharmacies have demonstrated consumers can use their Internet services with confidence."

The VIPPS certification process begins with the submission of a completed VIPPS Application Form and supporting documentation. Submitted materials include essential information such as the applicant's business name, ownership, address and phone number, Web site address, and documentation of adherence to VIPPS criteria. Such criteria include maintaining and following written policies and procedures for drug utilization review, patient counseling, patient confidentiality, and quality improvement programs.

After an evaluation of the applicant's submitted materials, a written evaluation is issued to the applicant, and a site inspection is scheduled.

During a site inspection, VIPPS inspectors:

- Investigate issues arising from the evaluation of the applicant's submitted information;
- Confirm that policies and procedures reviewed during evaluation of the VIPPS application are available to, and used by, members of the on-line pharmacy staff, and that staff members are trained to use them;
- Collect new, revised, or additional policies and procedures supporting VIPPS criteria;
- Probe and test problem resolution and contingency plans; and
- Identify strong and weak areas or departments for internal monitoring.

Upon completion of the site visit, inspectors submit a report of their findings to NABP, including deficiencies and recommended corrective actions. A written report is then issued to the applicant. If deficiencies are noted, the report includes recommendations for VIPPS criteria compliance. If the review is satisfactory, the report confirms VIPPS certification.

"VIPPS applications continue to be received at NABP headquarters," said NABP Executive Director Carmen A. Catizone.

PlanetRx, is headquartered in South San Francisco, California. Merck-Medco is based in Las Vegas, Nevada. Drugstore.com, inc. is located in Bellevue, Washington.

ISMP Survey Reveals Pharmacy Computer System Flaws

Concerns regarding the ability of computerized pharmacy systems to detect and correct prescription errors were brought to the forefront when the results of a recent computer field test and survey performed by the Institute for Safe Medication Practices (ISMP) were published earlier this year.

The ISMP tested pharmacy computer systems with specific questions to assess their ability to detect serious or fatal errors, including serious drug interactions, and found that many systems performed poorly.

A majority of the computer systems were unable to detect orders that exceeded a set maximum dose. Only 38 percent of systems detected lethal overdoses of both cisplatin and vincristine, 34 percent detected lethal colchicine doses, and 87 percent did not detect an excessive tobramycin dose for a patient with renal impairment. Although 88 percent detected a ketorolac and aspirin cross-allergy, and 85 percent a drug interaction between ketoconazole and cisapride, only 35 percent detected a drug ingredient duplication with acetaminophen and Percocet, and only 39 percent detected a problem with an oral suspension ordered intravenously.

The survey also revealed that only 42 percent of the respondents' systems are linked between the pharmacy and laboratory. Of those with linked systems, only 41 percent automatically screen orders against current laboratory values.

"Standards of care, and most board laws, require pharmacists to perform prospective drug utilization reviews when filling prescriptions," said Kevin E. Kinkade, Chairman of the Executive Committee for the National Association of Boards of Pharmacy (NABP). "With the vast majority of pharmacists using computerized systems to assist them in performing these reviews, the boards of pharmacy have reason to be concerned about the results of this study."

ISMP recommends that pharmacists not rely on pharmacy computer systems alone to support effective drug therapy monitoring.

"Vendors may market systems by promoting the detection of unsafe orders. Yet it is clear that, in practice, complex self-programming and the unrealistic time commitment necessary to achieve desired results may prohibit full use of the sys-

ce o a particular state or jurisdiction should not be assumed
e la such state or jurisdiction.)

tems' capabilities," the ISMP report states. "Thus, such vendor claims are meaningless unless the system applications are user friendly, allow maximum capabilities to easily be achieved, and are not cost prohibitive."

ISMP plans to use the results of its survey to promote improved pharmacy computer technology for more effective recognition of drug therapy problems. The complete results of this survey can be found on ISMP's web site at www.ismp.org/ISMP/MSAarticles/Computer.html.

Y2K Guidance for Rx Medication Users Issued

In response to concerns about the possible effects of the Year 2000 (Y2K) transition on the nation's prescription drug supply, the President's Council on Year 2000 Conversion recently released a guidance for users of prescription drugs to follow when refilling medications as the country approaches the new year.

The guidance was developed by a working group composed of manufacturers, wholesalers, distributors, retailers, hospitals, health care professionals, health maintenance organizations, insurance companies, patient advocate organizations, and government agencies, who reviewed pharmaceutical supply system operations and efforts to ensure the system is equipped to handle the Y2K transition.

The guidance assures consumers a continued supply of medications, and maintains companies within the medication distribution system are testing critical computer systems and refining contingency plans. The guidance confirms that local pharmacists will be within easy access of a substantial supply of pharmaceuticals, since the industry typically operates with a 90-day inventory on hand and maintains readiness for emergencies. It is recommended that patients refill prescriptions when they have a five to seven day supply of medication remaining.

For further information, visit the President's Council on Year 2000 Conversion Web site at www.y2k.gov.

DEA Publishes Methamphetamine Control Act Special Surveillance List

Pursuant to a mandate by the Comprehensive Methamphetamine Control Act of 1996 (CMCA), which broadened controls on products used in the production of methamphetamine and other controlled substances, the US Drug Enforcement Administration (DEA) published its "Special Surveillance List," a list of "laboratory supplies" subject to CMCA controls. The CMCA makes it unlawful to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical with reckless disregard for the illegal uses to which such laboratory supply will be put. Violations of this provision can result in fines of up to $250,000.

The Special Surveillance List, which was published in the May 13, 1999 *Federal Register*, includes all listed chemicals found in Title 21 of the Code of Federal Regulations, Section 1310.02(a) or (b) (those which, in addition to having legitimate uses, are used in the illegal manufacturing of controlled substances), other chemicals such as ammonia gas, formic acid, and lithium and sodium metals, and equipment, such as tableting machines and 22-liter heating mantles.

The complete list can be viewed on the DEA home page at www.usdoj.gov/dea/. For further information, contact Frank Sapienza, chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, 202/307-7183.

DEA Takes Action on Ketamine, Marinol®

Recent actions by the US Drug Enforcement Administration (DEA) have placed ketamine (Ketalar®) into Schedule III, and have transferred synthetic dronabinol (Marinol®) from Schedule II to Schedule III of the federal Controlled Substances Act (CSA).

As of July 2, 1999, prescriptions for Marinol, used for the treatment of nausea and vomiting associated with cancer chemotherapy, and anorexia associated with weight loss in patients with AIDS, were subject to the less stringent recordkeeping requirements and distribution restrictions of those drugs included in Schedule III, including the allowance of up to five refills within six months. This action was taken based upon the DEA finding that Marinol has less potential for abuse than other drugs in Schedule II. The final rule announcing this change was published in the July 2, 1999 *Federal Register*.

August 12, 1999, was the effective date for increased restrictions on ketamine, a general anesthetic indicated for both human and veterinary use. DEA findings of a wide geographic distribution and prevalence of diversion and abuse, and the spreading notoriety among teenagers and young adults of ketamine as a party drug, resulted in the DEA's decision to make ketamine a Schedule III drug. The final rule announcing this change was published in the July 13, 1999 *Federal Register*.

For further information, contact Frank Sapienza, chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, 202/307-7183.

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thing else indicating a lack of possession of the certificate will cause the renewal application to be returned to you.

Because some continuing pharmaceutical education (CPE) vendors are slow to transmit certificates near the end of the calendar year, you may wish to reconsider waiting until the last month to obtain your necessary CPE credits.

Pharmacists – Students – Technicians (99-10-57)

If you are a pharmacist-in-charge (PIC), you must at all times ensure that all personnel you allow to function in your prescription department performing pharmacist functions are properly licensed, certified, or possess a valid work permit (student pharmacist or technician-in-training). The only exception would be student pharmacists in the pharmacy school's training program in conjunction with the pharmacy curriculum.

If you are a staff or relief pharmacist, it is your obligation to ensure that the employees assisting you in the prescription dispensing process are legally able to perform their duties during your shift. If an inspection or investigation occurs while you are on duty and unqualified persons are performing duties under your supervision, you will then be responsible to the Board in the investigative report filed by the inspector.

Technician News (99-10-58)

The new practice act made some changes with respect to certified technicians. R.S. 37:1212 provides for a change in the ratio of certified technicians allowed per pharmacist on duty. Pharmacists are now permitted to have up to two certified pharmacy technicians on duty at any given time; this ratio does not include pharmacy interns, pharmacy technician candidates, or other pharmacy support personnel.

Another change within the same section of the law provides that certified pharmacy technicians may assist the pharmacist in all aspects of pharmacy practice, except patient counseling, while under the pharmacist's direct and immediate supervision.

In all cases, a pharmacist must verify the accuracy of a prescription before the drug or device is released to a patient or patient's agent.

Disposal of Confidential Information (99-10-59)

A recent investigation by a national news organization revealed that unauthorized individuals have access to patient information that has been discarded in dumpsters as a result of the trash disposal procedures employed by some pharmacies. The following procedures are suggested to prevent the inadvertent release of confidential information:

- Shred all paper documents and black out information on prescription container labels prior to placing in the garbage.
- Give empty prescription containers back to patients.
- Implement a system whereby pharmacy garbage is held in a secure area until transferred to a disposal firm for incineration or other method of destruction.

On a Personal Note (99-10-60)

It is an honor to have been selected by the Louisiana Board of Pharmacy as its new executive director, and I am grateful for the privilege of serving the pharmacists and citizens of Louisiana. This is truly an exciting time for the profession of pharmacy, and I look forward to working with all of you as we strive to be the best we can be.

I am deeply indebted to my predecessor, Mr. Fred H. Mills, Jr., for his inspirational leadership and insightful guidance. Freddie, please accept our thanks for a job well done and best wishes for your future endeavors.

Lagniappe (99-10-61)

"Even if you are on the right track, you will get run over if you just sit there."

-Will Rogers, humorist

Special Note (99-10-62)

The *Louisiana Board of Pharmacy News* is considered an official method of notification to pharmacists and certified technicians licensed by the Louisiana Board of Pharmacy. **These newsletters will be used in hearings as proof of notification.** Please read them carefully and keep them 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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