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Louisiana Board of Pharmacy

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Medication Errors (99-04-41)

Have you ever dispensed the wrong drug or the incorrect strength of a drug? Have you ever typed the wrong directions for use on the prescription label? Have you ever misinterpreted a prescription? Do you work in a practice setting that impedes your ability to deliver patient care?

Courts have cited long-standing language that a pharmacist should not only be skillful when dispensing medications, but should also be exceedingly cautious and prudent in view of the terrific consequences that may occur because of a medication error. The profession of pharmacy filled more than two billion prescriptions last year, and literally more than a million of them had potential to harm. This month's newsletter will review actual dispensing error complaints recently received by the Board and possible ways to avoid these errors.

Wrong Drug or Strength

A common error reported to the Board involves prescriptions filled with either the wrong drug or the correct drug but an incorrect strength. One such example involved a written prescription calling for Lescol 20mg, which was actually filled with Zestril 20mg. The patient took the incorrect medication and suffered adverse effects. How could this error have been prevented?

- Institute the "triple check plus two" method into your dispensing pattern. Check the strength of the drug when taking the drug off the shelf, check the name and strength of the drug prior to counting/pouring the drug into the dispensing container, and check the name and strength of the drug after affixing the label to the container. Then check the NDC number of the stock bottle against the NDC number on the computer screen or printout. Finally, take the prescription out of the bag and visually review it while discussing the prescription with the patient.
- Separate drugs that are similar in name and strength. Put drugs such as Prilosec and Prozac on different shelves or in different parts of the prescription department.

Wrong Directions for Use

A new written prescription for Zantac liquid was entered into the pharmacy's computer with the directions of "4cc given by mouth twice daily." The prescription was for a one-month old infant and the prescriber's instructions were "0.4cc given by mouth twice daily." In addition, the complainant alleged that the pharmacist did not provide verbal counseling when the prescription was picked up. The infant was hospitalized, long-term adverse effects are questionable, the mother had to discontinue breast feeding, and potential litigation is pending.

Labeling prescriptions with incorrect directions for use is another common error reported to the Board. How can these types of errors be prevented?

- Check the directions on the actual prescription against the directions on the computer-generated label. If pharmacy technicians are used to enter prescriptions, or to perform any other nonjudgmental functions in the pharmacy, the pharmacist must carefully check the technician's work at all times, since pharmacists are ultimately responsible for the work performed by pharmacy technicians.
- Be familiar with pediatric dosages. In reviewing the patient's medication record, check the patient's date of birth. Knowing that a patient is an infant/child would alert the pharmacist that the dosage might be different.
- Discuss the prescription with the patient/agent. When explaining the directions for use, a pharmacist should look at the label and also the contents and recheck the prescription for any errors.
- Workload during a busy period can overload the judgment of a pharmacist. Long workdays can lead to fatigue, which affects the pharmacist's error detection and problem-solving skills.

Verbal Orders

A verbal prescription was received over the phone for Paxil, and the pharmacist interpreted the order for Pepcid. Miscommunication often leads to errors when receiving prescriptions over the phone. Many drug names sound similar when a person does not speak clearly, or the drug names may look similar when not written out clearly. How can these types of errors be prevented?

- Pharmacists and technicians should have regular visual and auditory checkups. Noise levels and illumination levels affect dispensing errors.
- Repeat telephonic prescription information to the prescriber/agent to confirm the correct receipt and transcription. Repeating prescription information while writing it down may slow a prescriber/agent who is speaking too rapidly.
- Ask the prescriber/agent for the drug's intended use. Knowledge of the drug's intended use may alert the pharmacist to a potential transcription error.

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NABP to Verify Licensure of Internet Pharmacy Practice Sites

The National Association of Boards of Pharmacy (NABP) has announced its decision to develop the NABP Verified Internet Pharmacy Practice Sites (VIPPS), a new program that will verify the licensure of Internet pharmacy practice sites and inform the public of those Web sites that are licensed in good standing with the appropriate state board(s) of pharmacy or other regulatory agencies. Those Internet sites receiving NABP verification will be listed in the VIPPS database on www.nabp.net, NABP's Web site, and made accessible to the public free of charge.

Explaining the Association's decision to create the VIPPS program, NABP President Kevin E. Kinkade noted, "While a growing number of legitimate Web sites are coming on-line to dispense prescription and over-the-counter medications and provide counseling, the medium has attracted a visible band of unlicensed and unscrupulous entrepreneurs who are interested only in a quick profit, often at the patient's expense. These sites frequently operate for a short time at one Web site address before disappearing and setting up shop under another name to escape detection." Kinkade said that NABP became aware of the need for the license verification service during the past year, as several states reported consumer complaints related to Internet pharmacy practice sites.

Internet pharmacy practice sites that wish to receive NABP verification will submit a detailed application that requests information about the site and its services.

"It is our intent to have a prototype of the new NABP VIPPS database completed this spring," said Kinkade. "The site is expected to be fully operational by the end of 1999."

FDA Issues Final "MedGuide" Regulation

The Food and Drug Administration (FDA) recently issued a final regulation that requires the distribution of Medication Guides, also known as MedGuides, to patients receiving prescription drugs and biological products that, in the FDA's determination, pose a serious and significant public health concern. Medication Guides, according to the FDA, will contain FDA-approved drug information and will improve public health by providing information necessary for patients to use their medications safely and effectively.

MedGuides must meet numerous specified conditions, including that they must be written in non-technical, understandable English, and must be non-promotional in tone or content. In addition, MedGuides must convey to patients specific information, including the drug product's indications and safe use, as well as the particular serious and significant public health concerns that created the need for the MedGuide.

The regulation requires that MedGuides be provided to patients if the FDA determines: 1) The drug product is one for which patient labeling could help prevent serious adverse effects; 2) The drug product is one that has serious risks (relative to benefits) of which patients should be made aware because information concerning the risks could affect patients' decision to use, or to continue to use, the product; or 3) The drug product is important to patient health and adherence to directions for use is crucial to the drug's effectiveness. The FDA anticipates that no more than five to 10 products per year will require MedGuide distribution.

The new rule takes effect on June 1, 1999. For further information, contact Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD-40), FDA, 5600 Fishers Lane, Rockville, MD 20857, 301/827-2828, Ostrove@CDER.FDA.GOV.

NABP Finalizes Confidentiality Guidelines for Patient Compliance/Intervention Programs

In his State of the Union address this past January, President Clinton underscored the importance of assuring the privacy of patients' medical records, particularly with the increased use of electronic access and storage mechanisms.

Announcing his intention to confront the issue in 1999, Clinton said, "As more of our medical records are stored electronically, the threats to our privacy increase. Because Congress has given me the authority to act if it does not do so by August, one way or another, we will protect the privacy of medical records this year."

The National Association of Boards of Pharmacy (NABP) has already begun its own effort to protect the confidentiality of patients' medical information, and to prohibit inappropriate and potentially detrimental patient contact by patient compliance and patient intervention programs whose intent is to promote improved medication use behaviors. In February, NABP's Executive Committee approved "Guidelines for the Confidentiality of Patient Health Care Information as It Relates to Patient Compliance and Patient Intervention Programs," which respond to concerns raised about the practices of some of these programs.

"We want to ensure that patient compliance and patient intervention programs promote compliance with medication therapy without coercing patients to switch medications or jeopardizing the confidentiality of the patient's medical information," said NABP President Kevin E. Kinkade. "The Guidelines are meant to provide appropriate direction and information regarding the design and implementation of, and participation in, such programs."

An initial version of the Guidelines was drafted by NABP with assistance from Massachusetts-based Elensys Care Services, Inc., a company that works with pharmacy operators to develop prescription drug compliance programs to improve patient compliance with medication therapies. That version was released for comment in June 1998, and was subsequently reviewed by NABP's Task Force on Patient Compliance and Intervention Programs.

"NABP received numerous comments regarding the Guidelines," said NABP Executive Director/Secretary Carmen A. Catizone. "Our Task Force reviewed those comments and incorporated what it felt was necessary to protect the public."

Specifically, the Task Force on Patient Compliance and Intervention Programs sought to: 1) prevent the unauthorized release of confidential patient information; 2) give patients the option to participate in or withdraw from such programs at any time; and

3) protect patients from programs that may have as their sole focus economic gain or incentives to switch medications.

The complete text of the Guidelines can be viewed on NABP's Web site at www.nabp.net.

New Law Reduces Potential for Excessive DEA Fines

A recent amendment to the federal Controlled Substances Act (CSA) now makes it less likely that the Drug Enforcement Administration (DEA) will be able to impose significant fines on pharmacies found to have unintentionally violated CSA record-keeping provisions. Signed into law last October, the amendment changes the legal standard for civil violations of record-keeping requirements for control of licit drugs from "strict liability" to "negligence," and reduces the maximum penalty from $25,000 to $10,000. The provision is in response to publicity and concern over the DEA's imposition of significant civil penalties against community pharmacies for minor record-keeping violations.

The accompanying report directs the Attorney General to consider the following when assessing whether to impose civil penalties and determining appropriate fines:

- whether diversion actually occurred or if the record-keeping violations are of such a nature that it cannot be determined whether diversion occurred;
- whether actual or potential harm to the public resulted;
- whether the violations were intentional or negligent in nature;
- whether the violations were a first-time offense;
- time intervals between inspections in which any serious or no violations were found;
- whether the violations were multiple occurrences of the same type of violation;
- whether and to what extent the defendant profited from the illegal activity; and
- the financial capacity of the defendant to pay the fine assessed.

The Attorney General may take into account whether the defendant has taken immediate and effective corrective actions.

FDA Releases Draft Compounding MOU for Interstate Distribution

The Food and Drug Administration (FDA) has released for comment a draft standard memorandum of understanding (MOU) for use by states seeking to comply with the pharmacy compounding provisions of the FDA Modernization Act of 1997 (FDAMA). Developed in consultation with the National Association of Boards of Pharmacy (NABP), the "Memorandum of Understanding on Interstate Distribution of Compounded Drug Products" describes the responsibilities of the states and the FDA in investigating and responding to complaints related to compounded drug products distributed interstate, and addresses the interstate distribution of inordinate amounts of compounded drug products.

The FDAMA's provisions exempt compounded drug products from certain Federal Food, Drug and Cosmetic Act requirements, provided the compounding is conducted under either of the following conditions: 1) the state in which the drug is compounded has entered into an MOU with the FDA "which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside such state;" or 2) the state in which the drug is compounded has not entered into such an MOU and a licensed pharmacist, pharmacy, or physician "distributes (or causes to be distributed) compounded drug products out of the state in which they are compounded in quantities that do not exceed five percent of the total prescription orders dispensed or distributed by such pharmacy or physician."

The draft standard MOU, published in the January 21, 1999 *Federal Register*, can be viewed on the FDA Web site at www.fda.gov.

Until at least 90 days after the standard MOU is finalized and made available to the states for their consideration and signature, the FDA intends to exercise its enforcement discretion. This means the FDA will not normally take regulatory action regarding the requirement that a licensed pharmacist, pharmacy, or physician may not distribute, or cause to be distributed, in interstate commerce compounded drug products constituting more than five percent of the total prescription orders dispensed or distributed.

Pharmacy Manpower Shortage Seen

A recent survey conducted by the National Association of Chain Drug Stores (NACDS) seems to contradict the widely disseminated projections of the 1995 report of the Pew Health Professions Commission that there would be too many pharmacists for the jobs available in the future. The NACDS survey found manpower shortages in almost every state, with a total of 3,510 open pharmacy positions as of August 1998. NACDS predicts that demand for full-time pharmacists in chain community retail pharmacy practice will increase more than 25 percent during the next two years.

The manpower shortage is also a concern in hospital practice settings. A recent issue of *Hospital Pharmacist Report* states that by 2006, government sources predict a 7.4 percent increase in the number of hospital pharmacy jobs, including staff and management positions. Hospital recruiters note that while they face stiff competition from retail pharmacies that may offer more attractive salary and benefit packages, the hospital setting continues to attract pharmacists who enjoy performing more clinical tasks.

Fueling the pharmacy manpower shortage is a decrease in the number of pharmacy school graduates. The American Association of Colleges of Pharmacy (AACP) estimates that the number of pharmacy graduates peaked at 8,003 in 1996 before dropping to 7,772 in 1997, the most recent year for which statistics are available. Early indications from the colleges of pharmacy to the National Association of Boards of Pharmacy (NABP) point to even lower numbers in 1998 and 1999.

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- Verbally counsel the patient/agent about the medication. Discussing the name of the drug, what the drug is supposed to do, how and when to take the drug, and for how long also helps to avoid potential errors.

Working Conditions

A common complaint the Board receives concerns horror stories from pharmacists about their working conditions and the impact on patient care. A recent survey of pharmacists revealed the following:

- 63 percent polled do not have sufficient time to fulfill OBRA '90 counseling requirements.
- 92 percent of surveyed pharmacists agree that the increase in third-party payers has added disproportionately to the time it takes to fill prescriptions. Furthermore, only one-quarter of the pharmacists report that their employers consider the workload effects when taking on new third-party contracts.
- 65 percent of the pharmacists surveyed said they ***would not*** choose to become a pharmacist if they had to begin college today.

What is the solution to all of these concerns and how can the public best be protected?

The proud profession of pharmacy must finally say enough! As a professional, you alone must make difficult decisions when patient care is at risk, when stress levels are dangerously affecting your judgment, when you must work at a rate that clouds your judgment, when staffing levels are dangerously low, when you have not had a lunch break and your energy level is low, and when you know things just are not correct. You are a professional; command that respect.

Boards of pharmacy cannot provide all the answers. The North Carolina Board of Pharmacy approved a proposed rule that would mandate a pharmacist's maximum number of work hours and the availability of meal and rest breaks. The proposed rule was turned down by the state Rules Review Commission on December 17, 1998. The commission felt the Board of Pharmacy did not have statutory authority, and that implementing the rule would be difficult.

The Louisiana Board of Pharmacy will continue to explore avenues that prevent medication errors and solutions that improve pharmacists' working conditions. Your comments and suggestions are essential. If you have solutions or ideas, do not hesitate to write the Louisiana Board of Pharmacy.

A special thanks to the Texas State Board of Pharmacy for assisting with this article.

Annual Pharmacy Technician Renewal (99-04-42)

The Board will mail a renewal application to all Louisiana Certified Pharmacy Technicians holding a current certificate no later than May 1, 1999. The properly completed renewal application and fee must be mailed to the Board office by May 30, 1999. The current renewal will be valid until June 30, 1999. Please get your renewal in early!

Pharmacy Preceptor (99-04-43)

To participate in the Pharmacists Preceptor Training Program, applications for preceptor and preceptor site are no longer required to be completed and submitted to the Board office for approval. All pharmacists and pharmacies will automatically be approved unless said license and/or permit is currently on probation. If the license and/or permit is on probation, the application for the work permit will not be issued.

Lagniappe (99-04-44)

Take care of your reputation. It is your most valuable asset.

Special Note (99-04-45)

The *Louisiana Board of Pharmacy News* is considered an official method of notification to pharmacists 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.

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