

April 2007



Nevada State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

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2007 Board Meeting Schedule

April 18-19.....Reno
June 6-7.....Las Vegas
July 25-26.....Las Vegas
September 5-6.....Reno
October 24-25.....Las Vegas
December 5-6.....Reno

Valuable Resources

Just a reminder that all pharmacists and technicians have available to them two very important resources should the need arise. The first is PRN-PRN, which is a resource for the drug and/or alcohol impaired pharmacist or technician seeking help. The contact is Larry Espadero at 702/251-1377. The second and relatively new resource is Your Success Rx for the pharmacist or technician who is having practice difficulties such as repeated misfills and mistakes or who was involved in the dispensing of a prescription or chart order that resulted in harm to a patient. The contact is Katie Johnson at 775/885-0578. You will find links to both organizations on our Web site at bop.nv.gov under the "Licensee Assistance Programs" tab. Both chemical dependency and being involved in a sentinel event are devastating experiences that one need not face alone.

Reminder

Board regulations require that all pharmacists, interns, technicians, and technicians-in-training notify the Nevada State Board of Pharmacy in writing within ten (10) days of a change of address or employment. It is crucial that we have your current contact information on file at the Board. We also encourage each of you to furnish an e-mail address so

that we can contact you more efficiently and quickly should the need arise.

Generic Substitution

The subject of generic substitution seems to arise repeatedly in one form or another. With the emergence of the now infamous "\$4 generic" the scenario goes as follows: Your patient presents a prescription clearly marked "dispense as written" for a brand name drug (ie, Synthroid®). Upon learning that the pharmacy has a generic available for \$4, the patient demands the generic, even though the physician is known by the pharmacist to insist on the brand for thyroid replacement. The patient argues that it is he or she who is not only ingesting the medication, but also paying for it. Who makes the choice: the physician, the patient, or the poor pharmacist who is in the middle?

The statutes and regulations support the physician having the ultimate authority. If the pharmacist's request on behalf of the patient for a generic is denied, the patient has the choice of taking the brand name or dealing with the physician directly.

Disposal of Patient Information

In November 2006, the National Association of Boards of Pharmacy® informed the Board of the following:

It has come to our attention through the efforts of NBC Affiliate, Channel 13 Indiana reporter Bob Segall, that the problem has resurfaced or pharmacies have become lax in their management of patient data and information. Mr Segall found numerous examples in pharmacies across the country of patient information discarded with the routine trash and left unsecured in outside disposal areas. The findings were troubling and something that should have been addressed in the best interest of patient safety and confidentiality.

Please review and reassess your disposal policies and procedures with respect to protecting and maintaining patient confidentiality.

Buprenorphine (Suboxone®/Subutex®) Confusion

On June 23, 2005, a final rule was published expanding the Drug Addiction Treatment Act of 2000 to include specifically

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FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at www.fda.gov/medwatch/report/hcp.htm. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger

than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.

Changes in Medication Appearance Should Prompt Investigation

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.

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.



After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**[®] (letrozole) but instead received the estrogen replacement product **femhrt**[®] (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at www.connectlive.com/events/fdamedwatch. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at www.fda.gov/cder/learn/CDERLearn/default.htm.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at www.buprenorphine.samhsa.gov.

Deadline Approaches for Pharmacists to Use NPI Numbers

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at <https://nppes.cms.hhs.gov>.

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approved Schedule III, IV, and V medications for use in the treatment of opiate detoxification and maintenance. Currently, Suboxone® (buprenorphine and naloxone) and Subutex® (buprenorphine) are the only two drugs in this category that have been approved by Food and Drug Administration (FDA). A physician must apply for, and receive, a waiver from Drug Enforcement Administration (DEA) to prescribe these medications for detoxification or maintenance purposes. If so certified, the physician is assigned a certification DEA number in which the alpha character is replaced with an "X" in the physician's original DEA number. Prescriptions for buprenorphine for detoxification or maintenance purposes must include both the existing DEA number and the certification DEA number as it is with methadone.

The question now comes from many of you: "Can any physician prescribe buprenorphine for pain, even though it is "off-label" and the physician has not been certified by DEA to use buprenorphine for opiate addiction?" The answer is "yes"; however, the prescription must indicate on it somewhere (like in the sig) that it is being prescribed for pain, so that the pharmacist knows that it can be dispensed without the "X" DEA number. If you desire further information, please call FDA at 1-888/BUP-CSAT or visit its Web site www.buprenorphine.samhsa.gov. This Web site may also be used (by clicking on "Buprenorphine Locator") to verify a physician's status, or you may call 240/276-2716.

The Pharmacist-In-Charge

One of the many responsibilities of the managing pharmacist is to ensure the security of the drug inventory – especially the controlled drug inventory. The Board office has become aware of some interesting situations across the country that indicate the need for better vigilance on the part of the managing pharmacist:

- ◆ There was a report of a computer maintenance repairman who, while "repairing and maintaining" the computer, was stealing hydrocodone.
- ◆ There have been reports of inventory crews stealing controlled substances while conducting routine inventory.

- ◆ A "reverse distributor" company has been implicated in drug diversion while processing returns for a pharmacy.
- ◆ A high school student who was "shadowing" a pharmacist to learn more about the profession was found to be connected to drug theft.
- ◆ The Board has prosecuted several cases this past year involving staff pharmacists removing, for personal use, narcotics from either Pyxis machines or the narcotic cabinet through sophisticated diversion schemes.

The pharmacist-in-charge simply can never weaken his or her vigilance.

Check Out the Board's Web Site

Have you had a chance to peruse the Board's updated Web site lately? Here are just **some** of the things you will find on our site:

- ◆ Licensing applications and official forms
- ◆ Continuing education information
- ◆ Calendar of upcoming Board meetings and Board minutes
- ◆ The Law Book by section
- ◆ Previous *Newsletters*
- ◆ Verification of a license

Please tell us what you think by clicking on the link "What do you think of our website? Click here to Send us your comments!" located at the bottom of the home page.

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