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Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Have You Submitted Your CE Report Form?

If your pharmacist number begins with 03-1, this is the year that you are required to submit proof of your continuing pharmacy education (CPE). By the time this *Newsletter* arrives, you will probably be near the reporting deadline of May 15. Please be sure that you submit your CPE Report Form on time. If your report form is received in the Ohio State Board of Pharmacy office by May 15, you may use CPE certificates dated on or after March 1, 2004. If the report form is received after May 15, your CPE certificates will have to be dated within the three-year period immediately preceding the date the CPE form arrives in the office (eg, if the form arrives on May 28, 2007, then only certificates dated on or after May 28, 2004, will be acceptable). Obviously, it is to your benefit to submit the CPE Report Form on time. Please also note that your CPE Report Form must be cleared by the Board before you will be sent a license renewal application.

Attention: Pharmacists Dispensing IV Admixtures

You probably know that your pharmacy's name and address are required on labels for IVs dispensed to outpatients pursuant to rules 4729-5-16 and 4729-31-03. In addition, the name and address of the pharmacy is also required on labels for all IV admixtures dispensed to inpatients in an institutional facility pursuant to rule 4729-17-10(C)(5). Are your labels in compliance?

Before the computer era, pharmacies usually met this requirement with preprinted labels. As technology is changing pharmacy operations, it is likely that your pharmacy's label information is now printed to standard, blank labels from software instructions in the computer's label set-up. Although it is probable that your pharmacy's IV labels have far more information than the mandatory minimum of these rules, please look at your present label set-up to verify that the required information is included.

Physician Assistant Prescribing Is Imminent

Last year, the Ohio General Assembly passed Senate Bill 154, which significantly changed the scope of practice for physician assistants (PAs). A major change that will affect pharmacists the most is the addition of prescribing privileges for the PAs. Unlike the advanced practice nurse (APN) prescribing laws, which state that an APN can write for a 24-hour supply of a Schedule II controlled substance under very restrictive conditions, PAs will not be able to write any Schedule II controlled substance prescriptions at all. They will, however, be able to prescribe most other Schedule III-V and non-controlled substance drugs similar to prescribing APNs, as long as their supervising physicians permit it and they are

properly licensed. Just like the APNs, a PA will have to register with Drug Enforcement Administration (DEA) before writing any controlled substance prescriptions. They will be registered as a mid-level practitioner, so their DEA numbers should begin with an M. Any PA prescriptions bearing only the PA's signature and a DEA number that begins with an A or B should make it obvious to the pharmacist that the PA is using the doctor's DEA number instead of the PA's. That is not legal.

By the time this *Newsletter* is received, the State Medical Board of Ohio will probably have promulgated the required rules regarding PAs or be very close to doing so. Since the final Medical Board rules may become effective before another *Newsletter* is published, pharmacists need to be aware that PA prescribing is imminent. The rules will be published on the Medical Board's Web site at www.med.ohio.gov and should be reviewed if there are any questions. Until the rules are published and effective, no PA in Ohio is permitted to issue a prescription. If you have any questions about PA prescribing, please call the Board office for further information.

Does the Prescriber Really Need to Sign that Piece of Paper?

Due to the number of pharmacists and prescribers calling the Board office about prescription format, signatures on written prescriptions, and the actual content of the prescriptions, it is time to review the requirements for a legal prescription. The requirements may be found on the Board's Web site, www.pharmacy.ohio.gov by clicking on the box labeled "Laws & Rules" and, on the next screen, clicking on "Administrative Code Rules." If you are printing out the rules to send to a physician's office, the two most important rules are 4729-5-13 – Prescription format, and 4729-5-30 – Manner of issuance of a prescription. If you are looking for the rule relating to the duties of the pharmacist when filling a prescription, the rule to review is 4729-5-21 – Manner of processing a prescription. All three of these rules contain requirements that, if followed, will improve the communication between the prescriber and the pharmacist, will improve the safety of the patient, and will help to ensure the security of the transaction. In addition, if these rules are followed, there should be less need for telephone conversations between prescribers and pharmacists. With the workload in many pharmacies and prescribers' offices, anything that reduces time spent on the telephone should be welcomed by all parties.

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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/CDER-Learn/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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One of the most frequent questions received in the Board office deals with the signature of the prescriber. Rule 4729-5-30, paragraph B(14), says:

For prescriptions issued to a patient by a prescriber, be:

(a) *Manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document.*

(b) *Issued in compliance with rule 4729-5-13 of the Administrative Code.*

The rule requires that written prescriptions given to the patient be “manually signed...by the prescriber.” That means the prescriber takes pen in hand and physically signs the prescription. Rubber stamps, signature by a nurse or other office personnel for the prescriber, and computer-generated signatures are all examples of illegal signatures. A hard copy prescription given to the patient that is “signed” in one of these ways is an illegal prescription and may not be filled as presented. If the prescription is for anything except a Schedule II controlled substance, the pharmacist may, of course, take a verbal order from the prescriber. Under no circumstances should a prescription presented to the pharmacist by a patient that has one of the illegal signatures above be filled without contacting the prescriber for a valid authorization. A Schedule II prescription with an illegal signature is not valid and must be rewritten by the prescriber. This signature requirement applies to all paper prescriptions given to a patient or written and then faxed to the pharmacy by a prescriber, whether handwritten, typed, or computer generated. The prescriber must physically sign these prescriptions.

On the other hand, prescriptions that are generated by a Board of Pharmacy-approved electronic prescribing system and are transmitted from the prescriber’s computer to the pharmacy fax machine or computer will not have a manual signature. No paper prescription is generated by the prescriber, so there is nothing to sign. Depending on the Board-approved prescribing system used by the prescriber, the electronic prescriptions may have a computer-generated signature, a statement that no signature is required, or a printed name where the signature would be. The pharmacist needs to know that the electronic prescription has been issued from a Board-approved system or the electronic prescription is not valid and may not be filled without a valid prescriber’s signature.

The other requirement in rule 4729-5-30 (B)(14) is that the prescription is issued in compliance with rule 4729-5-13. That means, among other things, that paper prescriptions issued to a patient may contain no more than three (3) prescriptions on a blank for non-controlled substances and no more than one (1) prescription

on a blank for controlled substance prescriptions; that controlled substances and non-controlled substances are not written on the same blank; that a preprinted prescription form that has multiple drug names and strengths listed has only one choice selected; and that the quantity on a controlled substance prescription is written alpha and numeric (eg, 10 – ten). Please note that these requirements are not necessary for Board-approved electronic prescribing systems since the patient has no opportunity to manipulate the prescription.

For a list of Board-approved electronic prescribing systems, please visit the Board’s Web site, click on the box labeled “Frequently Asked Questions” and then click on the document titled “Electronic Prescription Transmission Systems.” The list is at the bottom of the article. This list is revised each time a new system is approved by the Board.

Disciplinary Actions

Anyone with a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, www.dental.ohio.gov

State Medical Board – 614/466-3934, www.med.ohio.gov

State Nursing Board – 614/466-3947, www.nursing.ohio.gov

State Optometry Board – 614/466-5115, www.optometry.ohio.gov

State Pharmacy Board – 614/466-4143, www.pharmacy.ohio.gov

State Veterinary Medical Board – 614/644-5281,

www.ovmlb.ohio.gov

Drug Enforcement Administration – 1-800/230-6844,

www.deadiversion.usdoj.gov

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