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North Carolina Board of Pharmacy

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Item 2165 – Prescriptions for Methadone at 40 mg Strengths

A number of pharmacists have contacted North Carolina Board of Pharmacy staff to ask whether it is legal to fill a prescription for methadone at a 40 mg strength for treatment of pain. Confusion on this issue is understandable.

On January 1, 2008, manufacturers of 40 mg methadone hydrochloride tablets voluntarily agreed with the Drug Enforcement Administration to distribute these tablets only to facilities authorized to conduct detoxification and maintenance treatment for opioid addiction, and to hospitals. More information on this voluntary distribution restriction is at *www.deadiversion.usdoj.gov/pubs/pressrel/methadone_advisory.htm*.

Community pharmacists have reported receiving prescriptions directing the patient to take a total 40 mg dose of methadone for treatment of pain using, for example, four 10 mg strength methadone tablets. Board staff is aware of no absolute legal prohibition on the filling of such prescriptions. Again, the voluntary distribution restriction is directed to the 40 mg strength tablet. Board staff is aware of no statute or rule flatly prohibiting the use of a 40 mg dosage of methadone to treat pain. Of course, pharmacists must – as with all prescriptions for controlled substances – be mindful of their corresponding responsibility to ensure that a prescription for any controlled substance is written for a legitimate medical purpose in the ordinary course of practice.

Moreover, press reports have focused on an upswing in methadone-related overdose deaths, particularly in North Carolina. Accordingly, pharmacists must be vigilant in conferring with patients and prescribers to ensure that a patient-appropriate dose of methadone is being prescribed and administered.

Item 2166 – Technician Diversion and Pharmacist Manager Responsibility

Board staff continues to receive and investigate numerous complaints involving the diversion of controlled substances by technicians. In some cases, the sheer number of controlled substance dosage units diverted is staggering.

Pharmacist managers are reminded that they are the "person who **accepts responsibility** for the operation of a pharmacy in conformance with all statutes and regulations pertinent to the practice of pharmacy and distribution of drugs by signing the permit application, its renewal or addenda thereto." 21 NCAC 46.1317(25). Among those responsibilities is adequate security of the pharmacy. In cases where the pharmacist manager knew, or reasonably should have known, of technician diversion, but took inadequate steps to discover the source of the theft and/or halt further theft, the pharmacist manager's license is subject to discipline.

Likewise, Board staff again reminds pharmacist managers of their responsibility to ensure that technicians are registered with the Board. Often an investigation into technician diversion reveals that the responsible technicians were not registered. Employing unregistered technicians is a separate ground for discipline of a pharmacist manager's license.

Item 2167 – Pharmacist to Technician Ratios

Board staff reminds pharmacist managers that the Pharmacy Practice Act states that the permissible ratio of pharmacists to technicians is 1:2. NCGS §90-85.15A(c). That ratio may be increased if "the additional pharmacy technicians have passed a nationally recognized pharmacy technician certification board exam" **and** the ratio increase is approved **in advance** by the Board. *Id.*

Board inspections continue frequently to reveal that pharmacies exceed the permissible ratio, oftentimes doing so even after being warned in a previous inspection to remedy the issue. Board staff members have been, and will continue to be, vigilant in enforcing this requirement and, where appropriate, disciplining pharmacist manager licenses and/or pharmacy permits for violations. The statutory ratio is a public safety measure.

Board staff has noticed as well that some applications for a pharmacist to technician ratio increase indicate that only a minimal number (including, sometimes, zero) technicians are certified. The technician statute plainly states that **all** additional technicians above the 1:2 pharmacist to technician ratio must be certified. Board staff has denied, and will continue to deny, applications for a ratio increase where it is clear that pharmacy shifts cannot possibly be covered by an adequate number of **certified** technicians as specified in the statute.

Item 2168 – Changes to ACPE Numbering System

The Accreditation Council for Pharmacy Education (ACPE) continues to make changes to the substantive and procedural aspects of its continuing pharmacy education (CPE) standards. ACPE now requires a CPE program be plainly designated as targeted to pharmacists, pharmacy technicians, or both. A new numbering scheme is designed to indicate the intended audience.

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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.

Table 1: Examples of FDA Actions Regarding Unapproved Drugs
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.

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Target audience designator: P – Pharmacist; T – Pharmacy Technician.

If a CPE activity's target audience is exclusively pharmacists, then the designator "P" will be used as follows:

- 01-P Disease state management/drug therapy
- 02-P AIDS therapy
- 03-P Law (related to pharmacy practice)
- 04-P General pharmacy
- 05-P Patient safety

If a CPE activity's target audience is exclusively pharmacy technicians, then the designator "T" will be used as follows:

- 01-T Disease state management/drug therapy
- 02-T AIDS therapy
- 03-T Law (related to pharmacy practice)
- 04-T General pharmacy
- 05-T Patient safety

A CPE activity intended for both pharmacists and pharmacy technicians will have the same Universal Program Number with respect to the provider identification number, cosponsor designation, year of release, sequence number, and format. The topic designator in the number, however, will be specific to each audience. For example:

- 197-000-06-001-L05-P (program number to be used for pharmacists)
- 197-000-06-001-L05-T (program number to be used for pharmacy technicians)

Pharmacists should be aware of the new designations when selecting and reporting CPE hours for license renewal.

Item 2169 – Licensees, Permittees, and Registrants Should Provide the Board with a Valid E-mail Address

Licensees, permittees, and registrants are aware that the Board is shifting more of its operations to a "paperless" environment. As part of that shift, Board staff will no longer send paper-based renewal reminders. Accordingly, any licensee, permittee, or registrant who wishes to receive these reminders must provide the Board with a valid e-mail address. In addition to renewal reminders, Board staff use the e-mail listserve to send emergency notifications and solicit input on various issues from practitioners. Please note that the Board does not share e-mail addresses with other entities.

Item 2170 – Pharmacist Administration of the Zoster Vaccine

Rule .2507 governing pharmacist-administered vaccines was amended effective February 1, 2008, to allow pharmacists to administer the zoster vaccine (presently marketed under the name Zostavax®). As with the pneumococcal vaccine, a pharmacist must consult with the patient's primary care provider before administering the zoster vaccine. Pharmacists may not administer the zoster vaccine to a patient who does not have a primary care provider.

Some pharmacists have asked whether a prescription is required to administer the zoster vaccine. The answer is no. The amended rule requires documentation that the primary care physician approved administration of the zoster vaccine. A written prescription certainly will suffice as that documentation. But other documentation, such as a notation in the patient's profile also suffices.

Item 2171 – Board Staff Available for Presentations

Board staff members are often asked by various pharmacy organizations to make presentations on various law-related topics. When possible, staff accommodates these requests. Any organization that would like a Board staff member to present on a particular topic or set of topics should contact the Board office.

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