January 2010

News

North Carolina Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Item 2193 – Pharmacy Employers Must Review the Federal Excluded Individuals List

Editor's note: Thank you to Jim Wilson, a Durham-based attorney, who frequently represents pharmacists before the North Carolina Board of Pharmacy and other venues, for submitting this news item.

Before hiring pharmacy personnel, be sure to check the federal Excluded Individuals List, *http://exclusions.oig.hhs.gov/*. Failure to do so can lead to severe problems.

Under federal law, persons found to have committed certain violations of law can be excluded from participation in federal health care programs. State law usually prohibits such persons from participating in state health care programs too. Exclusion from participation means these people cannot be paid with government money for any health care or related services (they still can, if otherwise eligible, be covered as patients by governmental payers).

The federal government takes the position that this means such persons cannot be paid if they "input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs reimbursed, directly or indirectly, by any Federal health care program."

It seems not to be widely known that this prohibition extends to employers of excluded individuals. The Office of Inspector General (OIG) of the US Department of Health and Human Services explains it as follows:

"Thus, a provider or entity that receives Federal health care funding may only employ an excluded individual in limited situations. Those situations would include instances where the provider is both able to pay the individual exclusively with private funds or from other non-federal funding sources, and where the services furnished by the excluded individual relate solely to non-federal program patients. In many instances, the practical effect of an OIG exclusion is to preclude employment of an excluded individual in any capacity by a health care provider that receives reimbursement, indirectly or directly, from any Federal health care program."

Consequences of hiring an excluded individual can be severe. In addition to having to pay back the entire amount received for a service provided by an excluded individual, it is possible for the government to add penalties of up to three times the original amount plus thousands of dollars per claim. The government takes the position that employers have a duty to check the Excluded Individuals List.

As of the writing of this article, there were about 18 pharmacists from North Carolina on the Excluded Individuals List.

Item 2194 – Armed Forces Personnel License Renewal

During the 2009 legislative session, the General Assembly enacted S.L. 2009-458, which requires occupational licensing boards to pass rules to postpone or waive conditions of licensure renewal for members of the armed forces whose licenses are in good standing and who are eligible for an extension of time in which to file an income tax return under federal and North Carolina law (chiefly, armed services personnel deployed overseas for combat and certain other operations). The Board of Pharmacy has long allowed postponements or waivers in these circumstances for members of the armed forces.

The Board of Pharmacy has passed a rule to implement this statute, which will be codified at 21 NCAC 46.1613. At the time of this writing, the rule was awaiting final clearance from the North Carolina Rules Review Commission. The text of the rule may

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FDA and ISMP Warn of Potential Medication Errors for Dosing and Emergency Compounding of Tamiflu

Food and Drug Administration (FDA) issued a Public Health Alert regarding potential dosing errors with Tamiflu® (oseltamivir) for oral suspension. While United States prescriptions for liquid medicines are generally written in milliliters or teaspoons, Tamiflu is dosed in milligrams and packaged with a dispenser marked in milligram dosages. Errors where dosing instructions for the patient do not match the dosing dispenser have been reported to FDA. FDA advises that providers should write doses in milligrams if the dosing dispenser with the drug is in milligrams. Pharmacists should ensure that prescription instructions and the dosing device use the same unit of measure. More information can be accessed at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.*

The Institute for Safe Medication Practices (ISMP) issued an alert to all health care professionals regarding a risk of dosing errors related to the concentration of pharmacy-compounded Tamiflu (oseltamivir phosphate) oral suspension being dispensed due to shortages of the manufacturer's oral suspension. The base concentration for the commercially manufactured Tamiflu oral suspension is 12 mg/mL. The directions for emergency compounding of Tamiflu oral suspension from Tamiflu powder capsules result in a 15 mg/mL oseltamivir base concentration. Incidents have occurred resulting in too large of a dose being dispensed to children. ISMP advises that prescribers communicate suspension doses in milligrams rather than by volume, and that, if experiencing shortages of commercial Tamiflu oral suspension, pharmacists communicate with area medical practices regarding the dosage error risk. More information may be found at the ISMP Web site at *www.ismp.org/safetyalerts/20091015-Tamiflu.asp*.

FDA Authorization for Use of Outdated Tamiflu Products Remains in Effect until April 2010

On October 30, 2009, FDA issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for oral suspension as part of the federal government's response to the 2009 H1N1 influenza public health emergency. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless it is terminated earlier, or extended. The authorized lots of Tamiflu for oral suspension, which were tested through the federal government's Shelf-Life Extension Program, are part of the Strategic National Stockpile and are listed on the FDA Web site at *www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm*. Additional information for health care professionals and the EUA letter are also available on the FDA Web site.

HIPAA and Quality – The Seven-Year Itch

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

On April 24, 2003, an article in the *Wall Street Journal* noted that many health care providers "are going overboard to avoid violations" of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which took effect on April 14 of that year. In fact, initial concern was that the rule might actually slow the transfer of protected health information and place patients at risk for harm, certainly the opposite of HIPAA's intended goal.

One particularly troubling area of confusion is whether listing the drug's intended purpose on a prescription violates the privacy rule. Initially, numerous organizations reported that physicians were reluctant to include this crucial information on prescriptions. But according to the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription does not violate the privacy rule. Although a patient's diagnosis or purpose for using a medication would qualify as protected health information, communicating this information on a prescription does not require separate, special authorization because the information is used for the purposes of treating the patient. A violation would occur only if the prescription form was then used for a purpose not defined by the HIPAA privacy rule, such as copying it for a marketing company.

Concerns were also raised that listing a purpose on prescriptions did not meet qualifications of providing only the minimum amount of information necessary to treat the patient. However, the "minimum necessary" rule does not apply when protected health information is disclosed between providers treating the same patient. ISMP firmly believes that the drug's intended purpose should be part of the "minimum amount of information necessary" on a patient's prescription. Pharmacists should never be expected to dispense a medication without knowing its intended use, which is typically the case in many community pharmacies. Knowing the

medication's purpose helps pharmacists avoid confusion between products with look-alike names, as most products with similar names are used for different purposes. It also allows a double check to occur because the pharmacist is able to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use.

The same arguments hold true for medication reconciliation. It is not a violation of the HIPAA privacy rules for community pharmacies to share patient information for the purposes of reconciling a patient's medication profile with hospitals because the minimum necessary rule does not apply when protected health information is disclosed between providers treating the same patient.

Seven years later, the best advice is still to use common sense when applying the HIPAA rules so that patient privacy and safety are not compromised.

USP Standards for Heparin Products May Require Dosage Adjustments

Heparin products using new standards began shipping on October 8, 2009, and may require that dosages are adjusted to achieve consistent potency, according to a FDA alert. New manufacturing controls issued by United States Pharmacopeia (USP) were adopted for heparin to guard against potential contamination. Included in the new controls were changes in the unit dose, making heparin about 10% less potent than the former unit used. More information can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm*.

FDA Issues Alert, Seeks Assistance in Tracking Stolen Tylenol Arthritis and Tylenol PM Caplets

FDA has issued an alert regarding stolen Tylenol® Arthritis and Tylenol® PM products. Pharmacists should be wary of the following Tylenol products:

- Tylenol Arthritis Pain Caplet 150 count bottles with the following identifying information: UPC number 30300450838155, code number 8381500, and lot number 09XMC112.
- Tylenol PM 2-caplet packets with the following identifying information: UPC number 30300450482304, code number 4823000, and lot number 09XMC110.

The theft took place at a cargo terminal at the Jacksonville Port Authority in Jacksonville, FL on September 25, 2009.

FDA seeks assistance in tracking this theft and is asking pharmaceutical drug distributors and pharmacies that may receive offers for the stolen drug products, or that may have been sold stolen product, to contact FDA's Office of Criminal Investigations (OCI) by phone at 800/551-3989 or on the OCI Web site at *www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm*. Pharmacists should verify pedigrees they receive with any wholesale drug purchases. News regarding the alert can be found at *www.fda.gov/ICECI/CriminalInvestigations/ucm186269.htm*.

FDA Warns Companies to Stop Marketing Unapproved Codeine Sulfate Tablets

On October 13, 2009, FDA warned four companies to stop marketing unapproved codeine sulfate tablets. The manufacturers and distributors that received warning letters are as follows:

- Lehigh Valley Technologies Inc in Allentown, PA
- Cerovene Inc in Valley Cottage, NY
- Dava International Inc in Fort Lee, NJ
- Glenmark Generics Inc USA in Mahwah, NJ

FDA regulations allow manufacturers 90 days to cease manufacturing of new product, and distributors 180 days to cease further shipment of existing products. Previously manufactured unapproved products may still be found on pharmacy shelves for a period of time. FDA advises that Roxane Laboratories markets FDA-approved codeine sulfate tablets and is able to meet the demand for the drug. For additional information about the warning letters, visit *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm*.

2010 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2010 *Survey of Pharmacy Law* is now available.

The *Survey*, produced as a CD, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, "Wholesale Distributor Licensure Requirements," asks whether or not states license or register manufacturers separately from wholesalers.

Updates for the *Survey* were graciously provided by the state boards of pharmacy. In addition to the state boards of pharmacy's support, this year NABP requested data from numerous outside organizations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25.

The *Survey* can be purchased for $195 by visiting the publications section of the NABP Web site at *www.nabp.net*, downloading the publications order form, and mailing it to NABP Headquarters with a check or money order made payable to NABP. Credit card payments are accepted by phone.

All final-year pharmacy students receive the *Survey* free of charge through the generous sponsorship of Purdue Pharma L.P.

For more information on the *Survey*, please contact customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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be found on page 555 of the October 15, 2009 issue of *North Carolina Register* at *www.oah.state.nc.us/rules/register/Volume24Issue08October152009.pdf*.

Any pharmacist, technician, dispensing physician, dispensing nurse practitioner, or dispensing physician who is a serving member of the armed forces and has any question about renewal issues should feel free to call Board staff.

Item 2195 – Drug Donation Statute and Implementing Regulations

During the 2009 legislative session, the General Assembly enacted S.L. 2009-423, An Act to Establish the Drug, Supplies, and Medical Device Repository Program in the North Carolina Board of Pharmacy. This statute charges the Board to establish and administer rules that allow the donation of prescription drugs and devices within certain statutory (and to-be-established rule-based) parameters. This statute, which provides long-needed guidance on donation and redispensing of prescription drugs, devices, and medical supplies, was primarily sponsored by Representative Randy Stewart of Nash County, a physical therapist and former member of the North Carolina Board of Physical Therapy Examiners. The text of the statute may be found at *www.ncleg.net/Sessions/2009/Bills/House/PDF/H1296v5.pdf*.

The Board convened a working group to draft rules to implement the donation statute, and Board staff anticipates that draft rules will be presented to the Board members at the January 19 meeting. If the draft is approved, the proposed rules will be published for commentary and a public hearing will be held at a date to be determined. The proposed rules will appear both in the *North Carolina Register* and on the Board Web site, *www.ncbop.org*.

Board staff encourages pharmacists, particularly those who provide services through free and charitable clinics, to provide comments on the proposed rules.

Item 2196 – Proposed Rulemaking Concerning Advanced Pharmacy Technicians in the Hospital Practice Setting

At the November 17, 2009 meeting, the Board members approved for publication a proposed rule to create an "Advanced Pharmacy Technician" classification in the acute-care inpatient hospital practice setting. This proposed rule follows on the Board's support of associate degree programs in pharmacy technology currently implemented at a handful of North Carolina community colleges, as well as the results of Rule .2510 pilot programs conducted at Broughton State Hospital and Wake Forest University Baptist Medical Center.

By the time of this *Newsletter's* publication, the proposed rule will have been published for commentary in the *North Carolina Register* and on the Board's Web site, *www.ncbop.org*. The thrust of the rule would be to allow technicians who are registered, certified, and holders of an associate degree in pharmacy technology to, in the acute-care inpatient hospital practice setting, validate certain stock-filling and unit-dose prepackaging tasks performed by other technicians. In addition to specifying the qualifications necessary for the advanced pharmacy technician credential, the proposed rule spells out training and supervision requirements for pharmacist managers, as well as certain documentation responsibilities.

Board staff strongly encourages pharmacists, particularly those practicing in the acute-care inpatient hospital setting, to review the proposed rule and provide timely comments.

Item 2197 – Renewal Season Is in Full Swing

Pharmacists, pharmacy permits, technicians, dispensing physicians, dispensing nurse practitioners, and dispensing physician assistants are reminded that the renewal period for licenses, registrations, and permits began November 1, 2009. By the time of this *Newsletter's* publication, any non-renewing licensee, registrant, or permittee will have entered the 60-day so-called grace period for renewal. Anyone who fails to renew by the end of February is deemed by North Carolina law to be engaged in the unlicensed practice of pharmacy. See NCGS §90-85.17.

The online renewal process should be familiar to all licensees, registrants, and permittees. As a reminder, all renewals must be completed online. No paper renewals will be accepted.

The *North Carolina Board of Pharmacy News* is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote 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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