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News

New Jersey State Board of Pharmacy

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Documentation of Quantity Dispensed

The New Jersey State Board of Pharmacy wishes to remind pharmacists of the importance of documentation when dispensing a lesser quantity of medication than that prescribed. N.J.A.C. 13:39-6.2(f)2 reads, "Accurate records of all prescription medication received and dispensed are maintained" and N.J.A.C. 13:39-6.2(f)3 reads, "Policies are in place regarding accurate dispensing and labeling of prescriptions and that such policies are followed." The Board continues to receive complaints from consumers regarding the dispensing of inaccurate or incomplete prescriptions. To avoid confusion when the quantity in stock is less than that required to fill a prescription the pharmacist should clearly describe the situation to the patient with complete instructions regarding when to return to the pharmacy to receive the remaining quantity. As an important follow-up to avoid any issues should the pharmacy be inspected by the Board, the pharmacist should add a concise yet clear description of the incident to the back of the prescription or in the computerized prescription record, which should be updated once the remainder of the prescription is dispensed.

e-Prescribing in New Jersey

The requirements for filling e-prescriptions in New Jersey are set forth in Board of Pharmacy Rule N.J.A.C. 13:39-7.11. Under the rule, a pharmacist may accept for dispensing an electronic prescription – defined as a prescription transmitted by a computer device in a secure manner, including computer-to-computer and computer-to-facsimile transmissions – for any prescription legend drug. However, under the rule, a pharmacist may only accept an electronic prescription for Schedule II, III, IV, and V controlled dangerous substances (CDS), if permitted by federal law.

On March 31, 2010, the federal Drug Enforcement Administration amended its regulations to provide prescribers with the option of issuing electronic prescriptions for CDS and permitting pharmacies to receive, dispense, and archive electronic prescriptions. New Jersey's Controlled Dangerous Substances regulations set forth at N.J.A.C. 13:45H, however, have not been updated to allow for electronic prescriptions for CDS and, therefore, are inconsistent with Board of Pharmacy Rule N.J.A.C. 13:39-7.11. Authority to amend the state CDS regulations rests with the director of the Division of Consumer Affairs. The division intends to propose amendments to the state CDS regulations in the near future in order to authorize prescribers to transmit, and pharmacists to fill, electronic prescriptions for CDS.

Disciplinary Actions

The actions listed below include only those where the individual's license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist's license may be obtained either at the Division of Consumer Affairs Web site or by calling the License Verification Line at 973/273-8090.

Surrender of License

Michael Tomasul, RPh – The Board received information that respondent was arrested and charged with obtaining or possessing CDS not directly obtained from a practitioner or under a valid prescription. Furthermore he was charged with possession with the intent to distribute. As of November 10, 2010, an interim consent order surrender of license was filed. Respondent entered this agreement voluntarily to surrender his license without making admissions. **Ordered** – Respondent is hereby granted leave and shall immediately surrender his license to practice pharmacy in the state of New Jersey pending disposition of the criminal charges and until further order from the Board.

License Suspensions

Yaritza E. Carreras, Pharmacy Technician – The Board received information that respondent was terminated from her employment and arrested by the police for allegedly stealing CDS while employed as a pharmacy technician. The Board requested that respondent submit

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Rethink the Vial

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 an 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.*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid prescriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request *Parents' Guide to Understanding Prescription Drug Abuse* brochures for distribution to your patients, visit *www.SafeguardMyMeds.org.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* Abbott advises that anyone who has the counterfeit ver-

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at *www.safemedicines.org/resources-for-healthcare-professionals.html*. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm.* Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm.* Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_X$E® Web site at *www.awarerx.org/informedSiteMap.php.*

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_X$E Web site at *www.awarerx.org/OTCMedUse.php.* The AWAR$_X$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

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a written statement under oath regarding this allegation. No response was received. A provisional order of discipline was issued, and again no reply was received. As of November 10, 2010, a final order of discipline was filed. **Ordered** – Respondent's certificate to practice as a pharmacy technician be suspended until such time as respondent cooperates with the Board's investigation by providing the requested information.

Colleen M. Rauh, Pharmacy Technician – The Board received information that respondent was arrested for theft of medication. Respondent admitted to police that the pills were for her own use. As of December 9, 2010, a final order of discipline was filed. **Ordered** – Respondent's certificate to practice as a pharmacy technician in the state of New Jersey is suspended for five (5) years.

Alfredo Balleras, RPh – The Board received information that respondent, while acting as a pharmacist-in-charge for an Internet pharmacy in New Jersey, filled more than 400 prescriptions for CDS that were faxed from various Web sites acting as middlemen, without verifying the source or validity of the prescriptions. Respondent admitted never asking for the original prescriptions from the practitioners and instead chose to rely on the facsimile versions received. As of December 9, 2010, a consent order was filed. **Ordered** – Respondent's license to practice pharmacy in the state of New Jersey shall be suspended for four (4) years retroactive to October 1, 2010, and until further order of the Board. After successful completion of the two (2)-year active suspension, respondent may petition the Board to convert the remaining two (2) years of suspension to be stayed and served as a term of probation.

Victor H. Fakondo, RPh – As of December 30, 2010, a consent order was filed. The Board received information that respondent was convicted of one count of claim for payment/reimbursement or other benefits and sentenced by the Superior Court of New Jersey, Union County to serve 180 days in jail, provide restitution in the amount of $229,000, and a five (5)-year period of probation. Respondent, while employed as a pharmacist, generated prescriptions for medications that were never dispensed, printed invoices, and then deleted the records from the computer. Respondent then submitted the false claims to the insurance company for reimbursement. **Ordered** – Respondent's license to practice pharmacy in the state of New Jersey shall be suspended for five (5) years to run concurrently with the period of his criminal probation. The first three (3) years of which shall be served as a period of active suspension and the remaining two (2) years shall be stayed and served as a term of probation.

License Reinstatement

Christopher Elias, RPh – As of November 30, 2010, an order of reinstatement was filed. This matter was opened to the Board upon receipt of respondent's reinstatement application. Respondent practiced pharmacy for 18 months with an expired license and misrepresented to his employer that his license was renewed and not due to expire. Respondent entered an incorrect expiration date in the database that is used for the verification of internal licensing at his place of employment. **Ordered** – Respondent is to successfully complete all reinstatement application requirements, successfully complete six (6) hours of continuing education in pharmacy law, and provide proof of all monthly installments toward the civil penalty incurred ($10,000). Once all of the above is provided his license will be reinstated. Upon reinstatement, respondent's license will be suspended for six (6) months, all stayed and to be served as a period of probation.

Alan Kay, RPh – As of December 8, 2010, a consent order of reinstatement of license with conditions and monitoring was filed. This matter was most recently opened to the Board upon receipt of respondent's application to reinstatement. Respondent was arrested and charged with unlawful possession of CDS and prescription legend drugs. On December 9, 2009, the Board filed a consent order, respondent voluntarily surrendered his license with no reinstatement to be made until the completion of his term of conditional discharge. **Ordered** – Upon successful completion of all requirements on the reinstatement application and documentation of completion of the continuing education requirements respondent's license to practice pharmacy in the state of New Jersey shall be reinstated subject to a two (2)-year probation and monitoring conditions.

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