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Nevada State Board of Pharmacy News

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Pharmacy Compounding Update

In an effort to keep you in the loop regarding the national tragedy that has unfolded as a result of contaminated products compounded by New England Compounding Center (NECC) and concerns about their sister company (Ameridose), the Nevada State Board of Pharmacy offers the following:

- Both pharmacies were licensed in Nevada as "out-of-state pharmacies," however, the Board did not renew either license in October 2012.
- In conjunction with the Nevada Department of Health and Human Services, all pharmacies, surgery centers, hospitals, and clinics were notified of the NECC recall of all of their products, and a notification was sent to all consulting pharmacists. NECC was contacted to obtain a list of buyers in Nevada as a double check. A small number of NECC compounded products were indeed found in a Las Vegas, NV, surgery center; however, none were used, thankfully, and those vials were confiscated.
- The Board then pulled all of its investigative and inspection staff members off their regular duties and conducted inspections of all Nevada pharmacies that compound sterile products.
  - ◊ These inspections included sterility and strength testing of randomly selected products from each pharmacy.
  - ◊ Board staff accompanied Food and Drug Administration (FDA) inspectors (out of the San Francisco Bay-area regional office) and Nevada Department of Health and Human Services inspectors in conducting one Nevada pharmacy inspection.
- Note: The Board enacted comprehensive compounding regulations in 2008; has trained its entire inspecting and investigatory staff in sterile compounding; and inspects, at least annually, according to those regulations.
- Committees in both the United States Senate and the US House of Representatives have held hearings to analyze the NECC issue and to consider regulatory changes to pharmacy compounding to ensure prevention of another such incident.
- Board Executive Secretary Larry Pinson attended a meeting called by FDA on December 19, 2012, at FDA Headquarters in Maryland, to explore compounding pharmacy and its oversight.
- The National Association of Boards of Pharmacy® has developed a Compounding Action Plan in a national effort for better oversight of compounding pharmacies.

The Board reminds all pharmacists that pharmacies are licensed by boards of pharmacy to fill prescriptions, not to manufacture drugs. FDA licenses manufacturers to manufacture drugs. Purchases of drugs should only be made from Nevada-licensed, FDA-approved manufacturers or wholesalers. NECC was not licensed or overseen by FDA, yet they were clearly manufacturing, and the results are obvious and tragic.

Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

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.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ♦ Opioid-containing analgesics
  - ◊ fentanyl patches
  - ◊ hydrocodone with acetaminophen
  - ◊ oxycodone with acetaminophen
- ♦ Anticoagulants
  - ◊ warfarin
  - ◊ enoxaparin
- ♦ Antidiabetic drugs (insulin analogs)
  - ◊ Humalog® (insulin lispro)
  - ◊ NovoLog® (insulin aspart)
  - ◊ Levemir® (insulin detemir)
  - ◊ Lantus® (insulin glargine)
  - ◊ Apidra® (insulin glulisine)
- ♦ Antineoplastic drug (non-oncologic use)
  - ◊ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow,

encourage, or mandate pharmacists to substitute generics for brand-name drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, will be available in the forthcoming June-July 2013 *NABP Newsletter,* which will be accessible in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders; experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal; and the background to communicate relevant trends or issues to the patient.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders exactly as written within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements; be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system; and regularly review insurance payment information with patients, and provide unit cost information to help patients manage medication costs.

The full article regarding standards of care for hemophilia patients, including information on state implementation of such standards, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of *www.nabp.net.*

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

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Taking Control of Controlled Substance Misuse

Written by Paul Oesterman, PharmD, Associate Professor of Pharmacy Practice, Roseman University of Health Sciences College of Pharmacy, Henderson, NV

Practicing pharmacists should be aware of the continued emergence of the misuse of prescription drugs. Of special concern are the opiates, benzodiazepines, and muscle relaxants. Reasons for the misuse include ease of access, cost, product recognition, dose standardization, street value, and assurance of purity. Practicing pharmacists are challenged daily to ensure that those patients with legitimate need for narcotic analgesics are able to procure them in a timely and appropriate manner, while limiting access to those with no legitimate medical need. The latter can present fraudulent or stolen prescription blanks, phoned in orders, faxed orders, or may even use the services of a prescriber who performs a minimal assessment and writes the prescriptions.

Tips to Curtail Drug Seeking Behavior

1. Do **not** offer **price** information on controlled substances (CS) over the phone; advise the patient that your policy is to provide this information once you have possession of the prescription so you can ensure accuracy.
2. Do **not** offer **inventory** status of CS over the phone; again, advise the patient that you need to see the prescription before providing any information.
3. Obtain government-issued **photo ID** for all CS prescriptions and **retain** a copy of the ID with the prescription. This may be of value when law enforcement is looking for those who may be guilty of prescription drug misuse.
4. Establish a policy that all CS prescriptions for new or unfamiliar patients require **verification calls** to the prescribing provider. Document on the prescription the name of the person with whom you spoke. This will help to curtail the after-hours drug seeking patients from frequenting your pharmacy.
5. Make a **photocopy** of all suspicious prescriptions, and if the patient chooses to not have the prescription filled, place a note in your computer system. Save these copies in a separate alphabetic file, which again may be useful to law enforcement as they try to assist pharmacists in curtailing drug seeking behavior.
6. Utilize the **Controlled Substance Abuse Prevention Task Force Prescription Monitoring Program** information to assess frequency of fills, number of pharmacies, and number of providers being used by the patient. It is here to help you practice pharmacy the way it was intended. Visit *http://bop.nv.gov/Links/All/CSAP_Task_Force/* for more information.
7. **Report any suspicious activities** of patients or providers to the appropriate authorities. They are on our side and want to work together to make pharmacies safe and promote quality pharmacy practice.

Together, if we **all** follow these measures, we will be able to stem the tide of prescription drug misuse.

The *Nevada State Board of Pharmacy News* is published by the Nevada State 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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