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Nevada State Board of Pharmacy News

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Board Members

Delivery of Prescriptions

Judging from recent inquiries regarding the delivery of prescriptions, a review of the Nevada State Board of Pharmacy's regulations on that subject is probably in order. The Board refers you to NAC 639.710, which clearly addresses the delivery of prescription drugs. Please note:

- The person delivering the drug must be a **bona fide employee** of the licensee; must be at least 16 years old; and must not have been convicted of any drug-related crime.
- The prescribed drug must be delivered directly to the patient; to a person at the patient's residence; or to staff of a medical facility where the patient resides.
- The person accepting the medication must sign for it; security within the delivery process must be maintained; and records of this activity must be maintained by the licensee.
- Authorized, non-compensated agents of the patient (ie, neighbor, friend, relative) may pick up a prescription for a patient.

So the obvious questions emerge:

Q. Is it ok for a taxi driver to pick up a patient's medication?
A. No, the taxi driver is compensated.
Q. Is it ok to hire a "delivery service" to deliver for a pharmacy?
A. No, a delivery service is not a bona fide employee of the licensee.
Q. Who constitutes an "authorized agent" of the patient?
A. Verbal or written authorization to the pharmacist from the patient.
Q. Can a "common carrier" such as United Parcel Service or the United States Postal Service deliver a prescription?
A. Yes.
Q. How long should delivery records be kept?
A. Two years, as are all pharmacy records.
Q. Can a compounding pharmacy deliver a prescription for a patient to that patient's doctor's office?
A. Yes, under two conditions:

- That the patient is the person billed for the medication, not the doctor.
- That the prescription is for **administration** to the patient in the doctor's office.

Q. How is counseling on new prescriptions accomplished if they are being delivered to the patient?
A. The pharmacist must counsel the patient either by calling him or her or providing a 24/7 800 number for the patient to use to contact a pharmacist.

Unlicensed Practice

Many of you are aware of the ongoing battle facing all of the health care boards in not only Nevada, but around the nation, with respect to the unlicensed practice of a heath care profession. Examples abound in Nevada alone:

- The botched surgical procedure performed in the back room of a convenience store in Las Vegas, NV.
- The discovery of a literal "pharmacy" in that same back room, with the vast majority of drugs being administered and dispensed illegally imported from Mexico.
- The administration of construction grade silicone to a patient at a medical spa in Las Vegas (resulting in death of the patient).
- The administration of all sorts of drugs in medical spas by people who have no authority to possess, administer, or dispense those drugs (Botox®, Juviderm®, Latisse®, HCG), many times injuring the patient (visual problems, drooping, and disfiguration).
- The discovery of a "dentist" working on children out of a motel room for cash.

As a result, the Board is participating with the Boards of Nursing, Medicine, Cosmetology, Osteopathic Medicine, and Dentistry in a unified approach to addressing these issues. Through the efforts of former Attorney General Frankie Sue Del Papa, on behalf of the Nevada State Health Division, and in a coordinated approach with the University of Nevada Latino Research Center, outreach education, information, enhanced efforts in enforcement, and legislative initiatives are currently being developed.

Manufacturing vs Compounding

Given the recent sad developments across our nation as the result of poor compounding practices by the New England Compounding Center (NECC) in Massachusetts (39 deaths at the time of this writing), the Board once again reminds all of you of the basic differences between compounding and manufacturing. Pharmacies are licensed and inspected by the Board to **fill prescriptions.** That is what pharmacies do. Manufacturers are licensed and inspected by Food and Drug Administration (FDA) to **manufacture drugs.** That is what they do. How a pharmacy, such as NECC, feels it has the legal authority to compound (manufacture) and ship bulk product to medical facilities without the scrutiny of FDA through a proper license is beyond comprehension. The results are obvious. Many of you have or will have opportunity to buy product from compounding pharmacies throughout the nation. Heed the warning: you can only buy pursuant to a patient-specific prescription!

NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

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.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

DEA Update

A recent Drug Enforcement Administration (DEA) ruling relating to the faxing of refill requests has confused many. In a nutshell, a pharmacist cannot send a reminder letter (fax) that is partially or fully pre-populated for the prescriber to simply sign, claiming that the pharmacist would then be acting as an agent of the prescriber. Any reminder letters (faxes) cannot look like a prescription. Pharmacies need to work with their software vendors to ensure that their refill forms comply with this ruling. **Note: this only applies to prescriptions for controlled substances.**

Bowl of Hygeia

The Bowl of Hygeia Committee has selected Mr Joseph R. Kellogg as the recipient of the 2012 Bowl of Hygeia Award, one of pharmacy's most prestigious awards, recognizing an outstanding pharmacist who also gives back to his community. Joe, a resident of Henderson, NV, is a 1967 graduate of North Dakota State University, where he administers two scholarships to pharmacy students. Joe served for a number of years on the Nevada Board, presiding over the Board for two years. He has always been active in pharmacy associations, as well as in community associations, and is currently a pharmacy manager for Smith's Food and Drug. Joe not only "flies high" as a private pilot, but also in the minds of all who know him as an outstanding gentleman and exceptional pharmacist. Congratulations, Joe!!

Updates on Prescription Drug Disposal

By: Liz Altmiller, PharmD Candidate 2013

Prescription medications not only lose their efficacy after expiration, but also can be very unsafe when used in the wrong manner. The old method of "Crush and Flush" is no longer considered an acceptable method of disposal for unused or expired medications. When addressing patients' concerns with eliminating unwanted prescriptions, pharmacists should educate patients on discarding in a safe manner. One option is using a sealable plastic bag with a small amount of water to dissolve the pills, then adding kitty litter or coffee grounds, and placing with the household waste out of the reach of children or pets. SMARxT Disposal is a safe drug disposal Web site with a step-by-step video for proper disposal and has current updates on DEA's National Prescription Drug Take-Back Initiative. For your convenience, the Web site is easily converted to Spanish for your Spanish-speaking patients. Please visit their Web site for more information at *www.smarxtdisposal.net.*

Semi-annual National Prescription Drug Take-Back Days are organized by DEA and the locations and organizations involved vary, based on the region of Nevada. For more information on the National Prescription Drug Take-Back Initiative, please visit DEA's drug diversion Web site at *www.deadiversion.usdoj.gov/drug_disposal/index.html.*

Northern Nevada

Drug Abuse Prevention Coordinator Stacy Shamblin, of the Reno Police Department stated that the difference between the permanent drop boxes and the Prescription Drug Round Up in Northern Nevada is that all medications, syringes, liquids, and more are accepted at the Prescription Drug Round Up, which is coordinated with DEA's National Prescription Drug Take-Back Initiative. Release dates for the Drug Take-Back Initiative are usually released one to two months prior to the event. Join Together Northern Nevada is a useful resource for substance abuse prevention, and their Web site is kept up to date with information about Northern Nevada's drug disposal locations, dates, and times. Please visit their Web site for more information at *www.JTNN.org/committees/prescriptiondrug.html* or *www.facebook.com/pages/Join-Together-Northern-Nevada/171403951769.*

Southern Nevada

According to Coordinator Jason Roth, Operation Medicine Cabinet started in February 2010 as a partnership between the College of Pharmacy of Roseman University of Health Sciences in Las Vegas and the Las Vegas Metropolitan Police Department. This program has collected over 10 million doses in Clark County alone, helping to protect the public against accidental ingestion of prescription medications. This program is unique in Nevada in the fact that they serve the military and the Paiute Indian Tribe located north of Las Vegas. Operation Medicine Cabinet now joins DEA in their semi-annual National Prescription Drug Take-Back collection events every spring and fall. For more information about Southern Nevada's drug disposal locations, dates, and times, or for the latest updates in drug abuse, please visit *www.OperationMedicineCabinetLV.org* or *www.facebook.com/operationmedicinecabinetlv.*

Year-Round Prescription Drug Drop Boxes

Permanent drop boxes are located in select law enforcement departments of Nevada. Special considerations for dropping off medications at the permanent drop boxes are that needles, syringes, liquids, inhalers, powders, or loose pills are not allowed. All medication must be in a sealed bag or container. Remind patients that the drop box is strictly confidential with no questions asked. Removal of personal information from the bottle prior to dropping off the medication is recommended, however, it is not necessary. The drop box locations vary in times of operation.

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