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Nevada State Board of Pharmacy News

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Board Members

The Correct Prescriber

Recently the Nevada State Board of Pharmacy was queried by a Drug Enforcement Administration (DEA) agent prior to that agent's intent to make an arrest on a physician for prescribing controlled substances even though that physician had surrendered his DEA license. Records generated from data supplied from several pharmacies indicated several prescriptions for controlled substances dispensed under this physician's name.

Fortunately for the physician, Board staff was asked to verify some of the prescriptions in question for accuracy, only to discover that none of them had actually been written by that physician! So how does this happen?? Simple, but sad: **All of these prescriptions were entered and filled by the various pharmacies under the wrong doctor's name as the result of careless technician input and lack of attention by the verifying pharmacist.** A doctor almost went to jail due to incompetent pharmacy activity, not to mention the fact that all of those prescriptions were dispensed mislabeled.

So who is responsible for the accuracy of your prescriber information system? If you are the managing pharmacist, you are accountable for the proper maintenance of all prescription records and if you are a pharmacist, you are accountable for what goes in the record of the prescriptions you have verified. Prescribers die; prescribers lose or surrender their DEA registrations; prescribers move out of Nevada and change offices. This all must be properly maintained in your computer, and not only the Board of Pharmacy, but DEA, has authority to discipline pharmacists and pharmacies for inaccurate or improper record keeping for controlled substance prescriptions.

Bottom line: Carefully check the prescriber's name and DEA number. **It matters!**

Are You Really Counseling?

Board of Pharmacy staff is continually amazed at the number of complaints received from consumers involving missfilled prescriptions that have been documented by the pharmacist as "counseled." Often the Board wonders exactly what sort of counseling took place, if any. The following are examples, mostly from the past few Board meetings:

- Clonazepam (antianxiety) was given for clozapine (antipsychcotic)
- An unreconstituted amoxicillin suspension was dispensed to the patient
- Methadone (opiate) was given for Ritalin® for an eight-year-old
- Labetalol **125 mg BID** was dispensed
- Septra® DS **tablets** were dispensed for a two-year-old
- Tramadol (analgesic) was given for trazodone (antidepressant)
- Synthroid® (thyroid) was given for Zoloft® (antidepressant)
- Medrol® (corticosteroid) was given for Provera® (progestin)

If these prescriptions were indeed counseled as indicated on their respective counseling logs, just what do you suppose they were talking about?

Reminder On 'Office Use' Drugs

As a reminder, if a practitioner needs a drug for administration in his office, the pharmacy must make that transfer

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Pharmacists Provide Feedback at APhA: 'It's About Time! What a Great Tool'

Since the March 2011 launch of the new CPE Monitor™ service, more than 10,000 pharmacists and technicians have created their National Association of Boards of Pharmacy® (NABP®) e-Profile and obtained their permanent identification number. In its effort to educate licensees, NABP answered questions about CPE Monitor during the American Pharmacists Association (APhA) Annual Meeting and Exposition on March 25-28, 2011, in Seattle, WA, in which pharmacists shared with NABP staff positive feedback about the new service. Visitors to the booth noted that they are looking forward to using the new tool to track their continuing pharmacy education (CPE).

Beginning in the latter part of 2011, the CPE Monitor service will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credits. The service will also provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012. In the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

Pharmacists whose names have changed since the last time they interacted with NABP will need to go through the name change process before beginning their CPE Monitor registration. Name changes can be made in the licensee's NABP e-Profile by submitting a photocopy of the document granting your name change and completing the correct NABP name change form. These downloadable forms are available on the NABP Web site at *www.nabp.net/programs/cpe-monitor/cpe-monitor-service* in the frequently asked questions section. One form pertains to those who have had their name change granted by a United States government agency, and the other form pertains to those who have had their name change granted by a foreign government agency. In addition to the form, licensees must submit a photocopy of the documentation noting the name change, which includes marriage license or certificate, divorce decree, or court ordered name change document.

Pharmacists and technicians may access additional information about CPE Monitor in the Programs section on the NABP Web site at *www.nabp.net/programs* or at *www.MyCPEmonitor.net.* CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Protecting Yourself from Identity Theft

Being asked for your Social Security number (SSN) when applying for a loan or credit card, or even when setting up an account with a business for a service, is now commonplace. With this increased use of SSNs comes the increased risk of identity theft, and reputable businesses have been diligent in taking measures to implement security protocols to protect their customers.

Although some may believe that non-governmental organizations are prohibited from obtaining SSNs, in fact there is no law banning private organizations, such as NABP, from collecting this information. In recent years, a federal government task force recognized the importance of SSN use by private entities and preservation of such use. In addition, many states' laws specifically permit private entities to collect and use individual SSNs for purposes of application and enrollment processes, to confirm SSN accuracy, or for internal verification or administrative purposes.

For many decades, NABP has supported the boards of pharmacy in their licensure processes and the Association adheres to state and federal laws when collecting SSNs for purposes of internal data verification and board of pharmacy licensure processes. In addition, NABP has high security protocols and utilizes required technologies and protections, including encryption technologies, to protect sensitive information.

Some pharmacists have asked about using the National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services (CMS) as an alternative to providing their SSN. However, applying for an NPI number requires candidates to disclose their SSN to CMS, and may not address candidate concerns about providing their SSN to third parties. In addition, this excludes pharmacy technicians, who are not eligible for an NPI number.

A verification process using the SSN is the best way for organizations like NABP to help ensure the accuracy of data within its systems. NABP collects and reports data such as examination scores and continuing education records to the boards of pharmacy and having incorrect data could create serious adverse consequences for licensees. The use of the full nine-digit SSN, along with other demographic information such as license number(s), will help NABP internally verify that each profile created within its systems is unique, contains accurate information, and will match state board licensure records. The SSN is not used for any other purposes and is not shared with other entities except for the purposes of delivering requested services.

Reputable organizations use secure collection, storage, and disposal procedures, such as SSL encryption, access restriction and monitoring, firewalls, and shredding to protect customers information and thwart would-be hackers and identity thieves. Nevertheless, understanding how identity thieves steal your information will help you protect yourself from identity theft. According to the Social Security Administration thieves acquire your personal information by:

- Stealing wallets, purses, and your mail (bank and credit card statements, pre-approved credit offers, new checks, and tax information);
- Stealing personal information you provide to an unsecured site on the Internet, from business or personnel records at work, and personal information in your home;
- Rummaging through your trash, the trash of businesses, and public trash dumps for personal data;
- Posing by phone or e-mail as someone who legitimately needs information about you, such as employers or landlords; or
- Buying personal information from "inside" sources. For example, an identity thief may pay a store employee for information about you that appears on an application for goods, services, or credit.

Contaminated TPN Spurs ISMP Call for Action

In response to the infections of 19 Alabama patients by contaminated total parenteral nutrition (TPN), the Institute for Safe Medication Practices (ISMP) called upon Food and Drug Administration (FDA) to take several actions, including collaborating with boards of pharmacy in enforcing compounding standards. An investigation led by Alabama Department of Public Health and Centers for Disease Control and Prevention (CDC) determined that a failure in a step of the sterilization process for the compounded TPN most likely led to its contamination with Serratia marcescens bacteria. Of the 19 cases of infection that resulted in Birmingham, AL, area hospitals, nine were fatal. An investigation revealed that TPN produced by Meds IV was the common source of the infections and that a container and stirrer, and a tap water spigot at Meds IV are likely the sources of the bacteria. The product was recalled by Meds IV on March 24, 2011.

ISMP has expressed support for the provision of additional resources to boards of pharmacy so that boards can survey compounding pharma-

cies to enforce compliance with United States Pharmacopeia Chapter 797 standards. ISMP also calls upon FDA to work with state boards of pharmacy to support enforcement efforts. Further, ISMP calls on FDA to provide guidance documents for industry on relevant good pharmacy compounding practices. More information about ISMP's call for action is available in an April 7, 2011 article on the ISMP Web site at *www.ismp.org*.

ISMP Provides Strategies to Enhance Safety Procedures in Pharmacies

This column was prepared by 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.*

When investigating errors, look for contributing factors and then apply prevention recommendations that make sense for your organization. Use a variety of the strategies listed below to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Fail-safes and constraints involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system is integrated with the cash register and requires the patient's date of birth be asked and entered at the point of sale.

Automation and computerization of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy and robotic dispensing devices with bar coding.

Standardization creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication.

Redundancies incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

Reminders and checklists help make important information readily available. For example, prescription blanks that include prompts for important information (eg, medication indication, allergies, patient birth date).

Rules and policies are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

Education and information are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

FDA Warning: Benzocaine Use and Rare, But Serious Condition

FDA has issued a warning to consumers and health care providers regarding the use of benzocaine and its association with a rare, but serious condition, methemoglobinemia. Methemoglobinemia results in the amount of oxygen carried through the bloodstream being greatly reduced, and in the most severe cases, can result in death. Benzocaine gels and liquids are sold over-the-counter under different brand names – such as Anbesol®, Hurricaine®, Orajel®, Baby Orajel, Orabase®, and store brands – and are used to relieve pain from a variety of conditions including teething, canker sores, and irritation of the mouth and gums. Benzocaine is also sold in other forms such as lozenges and spray solutions.

FDA notes that methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, including concentrations as low as 7.5%. Further, the cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. Symptoms include pale, gray, or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate and usually appear within minutes to hours of applying benzocaine. Symptoms may occur with the first application of benzocaine or after additional use. FDA advises that if consumers or their children experience any of these symptoms after taking benzocaine, they should seek medical attention immediately. The FDA safety warning is available at *www.fda.gov*.

FDA Reminder About Pradaxa Storage/Handling

FDA issued a safety alert regarding special handling instructions for Pradaxa® due to concerns that these requirements are not commonly known. FDA advises that Pradaxa, an anticoagulant medication known as a direct thrombin inhibitor, should only be dispensed and stored in the original bottle or blister package due to the potential for product breakdown from moisture and loss of potency.

Specifically, FDA advises pharmacists that Pradaxa should only be dispensed in the original manufacturer bottle with the original dessicant cap. Pradaxa should not be repackaged. Patients should be advised to store the medication in the original container and avoid using pill boxes or other containers for storage. Also, once a bottle is opened, the product must be used within 30 days to ensure potency. The Pradaxa label and medication guide contain more information about these storage and handling requirements. The FDA safety alert is available on the FDA Web site at *www.fda.gov*.

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via invoice, which is then filed with the pharmacy's other drug disposition records. A prescription for "office use" is unacceptable and obviously to transfer a Schedule II drug requires the execution of DEA Form 222, as well as an invoice. Federal wholesale regulations allow for such "incidental sales," but require a wholesaler license for sales beyond that.

Cancer Drug Donation Program

During the 2009 Legislative Session, the Cancer Drug Donation Program was enacted. This program allows participating pharmacies to accept certain cancer medications used in the course of cancer treatment that were previously dispensed by a Nevada pharmacy. The drugs may then be redispensed to Nevada residents currently being treated for cancer. Participation by a pharmacy is voluntary and patient recipients must be approved by the Board of Pharmacy. A highlight of some of the details follows:

- The patient must be a resident of Nevada, diagnosed with cancer, who presents a prescription written by a Nevada licensed practitioner, along with written authorization for participation from the Board.
- Donated drugs must have been originally dispensed by a licensed Nevada pharmacy; must have an expiration date greater than 30 days; must be in the original, unopened, sealed package; must not be temperature sensitive; and must not be controlled substances, compounded or from a clinical study.
- A receiving/dispensing pharmacy must be approved by the Board to do so; must store the drugs in a separate area from other medications; and must dispense via a prescription with proper labeling.

Applications to participate can be found on the Board of Pharmacy Web site.

50-Year Certificates

Congratulations to **Gerald Mandel** and **Selwyn Pomerance** for achieving 50 years of continuous licensure with the Nevada State Board of Pharmacy! Your devotion and contribution to the profession are truly remarkable and you are both to be commended.

Scan Technology

Scan technology is one of the innovations that has remarkably increased accuracy in most pharmacy practices. Even with the assurance gained through this technology, the pharmacist must still remain diligent during the verification process. Two recent cases heard by the Board demonstrate this need, both involving the dispensing of a prescription containing two different drugs in the same vial, and in both cases, coming from two different stock bottles. The stock bottles were from the same manufacturer, were the same size, and had the same label color. The drugs involved both began with the same letter, and in one of the incidents, the strength was the same. Obviously a partial bottle began the fill, but did not contain enough tablets, so the bottle stocked behind the first bottle was pulled and used to complete the fill. The first bottle was scanned and verified, but not the second, hence the error and the patient walking out with two different medications in the same vial. Now the question to each of you is does your scan technology allow the scanning of two (or more) stock bottles to fill one prescription? Some systems do not; some do. If not, why not, and does it not just make sense that it would? Technology still has its limits!

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