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# Nevada State Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## Board Members



## NPI Number and Veterinarians

It has been reported to the Nevada State Board of Pharmacy that some pharmacies are refusing to fill prescriptions written by a veterinarian simply because the veterinarian has no National Provider Identifier (NPI) number. Please be aware that a veterinarian is **not** required to obtain an NPI number. The NPI number applies only to health care providers covered under Health Insurance Portability and Accountability Act who bill Medicare. Obviously, veterinarians are not billing Medicare!

## Call for Bowl of Hygeia Award Nominations

The Bowl of Hygeia has been associated directly with pharmacy since 1796 and was adopted in 1964 by American Pharmacists Association as their symbol to represent the profession of pharmacy. Additionally, in 1958, the A.H. Robbins Company established the Bowl of Hygeia Award to recognize and encourage pharmacists to take active roles in their respective communities. The award focuses on community service and is presented annually to one recipient from each state in the United States, the District of Columbia, Puerto Rico, and the 10 provinces of Canada.

Please take the time to nominate that special deserving pharmacist who you feel fits the criteria. The Bowl of Hygeia is a special award, deserving a special pharmacist, of which there are many in Nevada. Contact Larry Pinson, executive secretary of the Board of Pharmacy, at lpinson@pharmacy.nv.gov to make a nomination.

## Reminder

If a practitioner's Drug Enforcement Administration (DEA) number is missing on a controlled substance prescription, the pharmacist may add it to the prescription, provided he or she initials that entry. The pharmacist may not simply write "R/A" (readily available) and initial near the missing DEA number as he or she can initial near a missing address of either the patient or the practitioner. (See NAC 453.440(3).)

## Update on Buprenorphine Drug Products

Currently, there are four different buprenorphine drug delivery systems available in the US. However, unlike most other groups of drug products that contain the same drug substance, there are significant differences in the indications for these individual products and, based on federal statute and regulation, restrictions on who can lawfully prescribe some of them for certain indications. States may also have further restrictions on which health care professionals can prescribe these various products. This article will clarify the similarities and differences among these products.

The buprenorphine drug products that are currently approved for clinical use by Food and Drug Administration (FDA), along with their corresponding indications and initial approval dates, are listed below. They are all classified by DEA in Schedule III (CIII) under the federal Controlled Substances Act.

| Formulation Type | Brand (Proprietary) Name | FDA-Approved Indication | Approval Date |
|---|---|---|---|
| Parenteral | Buprenex®, and generics | Relief of moderate to severe pain | December 29, 1981 |
| Sublingual Tablets | Suboxone®, Subutex®, and generics | Treatment of opioid dependence | October 8, 2002 |
| Sublingual Film | Suboxone | Maintenance treatment of opioid dependence | August 30, 2010 |
| Transdermal Delivery System | Butrans® | Management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time | June 30, 2010 |

The Drug Addiction Treatment Act of 2000 (DATA), codified at 21 USC 823 (g), limits the use of certain buprenorphine-containing drug products for the **maintenance or detoxification** treatment of opioid dependence (ie, opioid addiction) to **physicians** who (a) meet certain qualifying requirements and (b) have notified the Secretary of the Department of Health and Human Services (HHS)

*Continued on page 4*

## DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

## Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

## Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

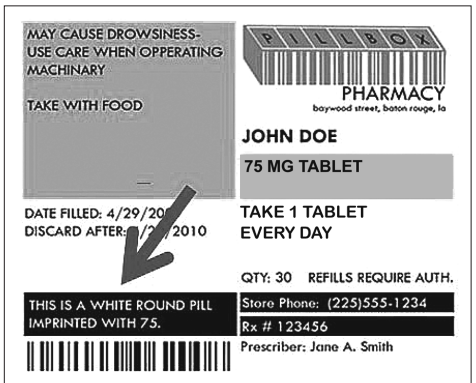
*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies 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.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.




*With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!*

## FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

## Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

## US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

*Continued from page 1*

of their intent to prescribe the products for the management of opioid dependence. HHS processes the notification and contacts DEA. Once the waiver is approved, HHS notifies the physician that he or she has a waiver under DATA and informs him or her of their modified DEA registration number (the so-called "X" number). At present, the only products that meet the criteria in DATA are the sublingual tablets and film (rows 2 and 3 in the table). It is important to note that, for the prescription of these sublingual products, the federal Substance Abuse and Mental Health Services Administration interprets the word **physicians** literally, precluding the prescription of these products by any other type of health care professional **for the management of opioid dependence.** The federal law and regulations do not address the off-label use of these products (eg, prescribing sublingual tablets for the management of pain).

The other buprenorphine products (injectable and transdermal formulations) are approved for analgesic use **only** and are **not** approved by FDA for maintenance or treatment of opioid dependence, so the provisions of DATA **do not affect their legal status or use.** Thus, a physician who does not have a DATA waiver, or a non-physician health care professional that has both federal and state authority to prescribe CIII products, can prescribe either of these analgesic formulations containing buprenorphine.

In promulgating policies and guidances, it is important for policy makers to be cognizant of the differences in indications, formulations, and legal framework related to these products to avoid confusion among licensees and to promote optimal care of the public. References are available upon request to the Board.

## *Collaborative Initiative to Reduce Adverse Drug Events*

Medications offer great benefits to patients, but they come with great risks when not administered or managed properly. Adverse drug events (ADEs) resulting from medications are the most common type of health care-associated adverse events, and as a result, a major source of potentially preventable patient harm. It is estimated that as many as 50% of injuries associated with medication use could be prevented.

*HealthInsight*, the Medicare Quality Improvement Organization for Nevada, is recruiting community teams to implement evidence-based practices for medication therapy management and medication reconciliation, with the goal of reducing or preventing patient harm caused by ADEs. Interventions will focus on patient-centered care models (as the patient is the one constant) and address the many variables along the care continuum, including multiple prescribers, changes in focus of care, and the care setting. The initiative's foundation is the **Patient Safety and Clinical Pharmacy Services Collaborative** (PSPC) and incorporates intervention strategies to improve clinical outcomes for an identified patient population of focus.

The **patient group** may be high-risk Medicare, Medicare Advantage, and/or dual-eligible patients age 65 or older. High risk patients are those that:

- Have two or more physicians
- Have five or more chronic conditions **or** eight or more medications
- Is prescribed one of the following:
  - Anticoagulant warfarin on a regular basis
    - At least weekly and for three months or more **and/or**
  - Short-acting or long-acting antipsychotics **and/or**
  - Hypoglycemic medication for diabetes

For more information or to join the collaborative effort, please contact:

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