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News



Nevada State Board of Pharmacy

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Must I Get an ID on My Patient?

By ChaoFen (Stacy) Tan, PharmD Candidate, Idaho State University

Nevada Administrative Code (NAC) 639.748 requires a pharmacy to ask for identification (ID) of the person **picking up** a controlled substance (CS) prescription, except in specific circumstances. The ID prerequisite was put in place as an attempt to curb prescription drug abuse, which is well known as an epidemic in the United States. ID requirements hopefully make it more difficult to doctor shop and can be a great asset in helping police find the people involved in prescription drug diversion schemes.

Effective June 26, 2015, modifications were made to the ID law, designed to bolster the requirements yet still ensure access to drugs by legitimate patients. Following is a quick rundown of the law as it stands today:

1. The pharmacy must ID the person **picking up** a prescription for a CS **regardless** of the method of payment for the prescription.
2. The pharmacy must make a copy of the ID or record the person's full name, ID number (if applicable), and the agency that issued the ID.
3. Valid IDs must be current, have a photograph, and be issued by a federal, state, or local governmental agency.
4. Any ID with a photograph from a governmental agency (**foreign or domestic**) is acceptable, as long as it appears authentic.
5. The pharmacy should not dispense the medication if the ID provided appears to be altered or falsified.
6. An ID is **not** required in the following instances:
 - a. The patient has had prescriptions filled previously at your pharmacy (and is known by pharmacy staff).

b. The prescription is for an inpatient of a health care facility, long-term care facility, or a hospice care facility.

c. The prescription is for a mail-order patient.

The law only outlines the minimum ID requirements for a pharmacy. Individual pharmacies may have stricter policies if they feel it necessary. This is just another small part of the pharmacist's vigilance and his or her active role in helping deal with prescription drug abuse in our country.

Prescription Over-the-Counter Products

What is your procedure for the handling of a written prescription for an over-the-counter (OTC) product?

Consider:

- ◆ Should a pharmacy be required to put a prescription for an OTC product through the filling process? Is it mandated by law?
- ◆ If a choice is allowed, who makes it: the patient, the prescriber, the pharmacist, a pharmacy technician, or any pharmacy personnel?
- ◆ Does the pharmacy have an obligation to counsel the patient on an OTC prescription that is simply purchased and not put through the filling process?
- ◆ Does the pharmacy's responsibility "go away" if it chooses to sell the product OTC rather than fill the prescription?

Nevada State Board of Pharmacy staff received the following complaint from a veterinarian, which serves as a great example.

The veterinarian wrote a prescription for insulin for a canine that was newly diagnosed with diabetes. The pet owner was not experienced with or knowledgeable about insulin and injectables, so the veterinarian wrote the prescription with the expectation that the pharmacist would provide the necessary and critical counseling. The pet owner took the prescription to a pharmacy where it was tendered to a pharmacy technician. After looking at the prescription, the technician told the customer that a prescription was not necessary for insulin and to step to the next window, where it was sold to her along with a box of syringes and no mention of the instructions. When the pet owner asked how much to give on the syringe, the response was simply,

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

More Selected Medication Safety Risks to Manage in 2016



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as $154 \text{ mEq}/0.9\% = x/3\%$ and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag ($77 \text{ mEq}/0.9\% = x/3\%$).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,¹⁻⁵ and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.⁶ The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



most of these errors happened within the first 14 days after discharge.⁵ The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).⁴

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

1. Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med*. 2005;165(16):1842-1847.
2. Mesteig M, Helbostad JL, Sletvold O, Røstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. *BMC Health Serv Res*. 2010;10:1.
3. Lalonde L, Lampron AM, Vanier MC, Levasseur P, Khaddag R, Chaar N. Effectiveness of a medication discharge plan for transitions of care from hospital to outpatient settings. *Am J Health Syst Pharm*. 2008;65(15):1451-1457.
4. Mixon AS, Myers AP, Leak CL, et al. Characteristics associated with postdischarge medication errors. *Mayo Clin Proc*. 2014;89(8):1042-1051.
5. Kanaan AO, Donovan JL, Duchin NP, et al. Adverse drug events after hospital discharge in older adults: types, severity, and involvement of Beers criteria medications. *J Am Geriatr Soc*. 2013;61(11):1894-1899.
6. American Hospital Association. Rethinking the hospital readmissions reduction program. *TrendWatch*. March 2015.

USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at www.usp.org in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe,"

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at www.fda.gov/Drugs/DrugSafety/ucm489676.htm.

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.

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“It’s on the syringe.” The pet owner returned home, filled the syringe, injected the dog, and then watched as the dog bottomed out to near coma. After the dog was rushed to the veterinarian’s office, it was discovered that the owner had overdosed the pet tenfold and had no clue as to how to dose the insulin.

In discussing the issue with the veterinarian, and through testimony at a recent Board meeting by a physician, it was made quite clear that if a practitioner makes the effort to write a prescription for an OTC, the Board expects and assumes that more will be done than simply selling the product.

Through this case and other anecdotal occurrences, it seems that this practice may occur quite commonly. The glaring fact is that the prescription was tendered to a technician, and that technician failed to present it to the pharmacist. This is a good reminder that only pharmacists and pharmacy interns can interpret prescriptions, make judgmental decisions, or counsel patients (NAC 639.700 and NAC 639.245). The pet owner missed the opportunity to be counseled by the pharmacist, and ultimately the pet was harmed as a result.

Understanding the complexity of prescription OTCs (insurance considerations, costs, the prescriber’s expectations, and the like) the Board offers the following guidance:

1. **All** prescriptions (OTC and otherwise) need to be presented to a pharmacist for interpretation and filling decisions.
2. If you get a prescription OTC, most likely the prescriber is expecting more than just selling it to the patient.
3. The law is silent on prescription OTCs; however, it is quite clear on who must interpret **any** prescription (and it is **not** a pharmacy technician).
4. **Always** counsel; you owe it to your patients!

E-Prescribing – Who Can Send Electronic Prescriptions?

By Melissa Hampton, PharmD Candidate, Roseman University

Several pharmacies have contacted Board staff to determine who is allowed to send **new** electronic prescriptions.

Specifically, **is a medical assistant (MA) or registered nurse (RN) allowed to send electronic prescriptions on behalf of a prescriber?** The short answer is **no**.

The regulation describing the use of computer systems for transmission of electronic prescriptions, NAC 639.7102, states:

1. A practitioner may:

- a. Issue a prescription using a computer system approved by the Board; and
- b. Transmit the prescription using that computer system to a pharmacy specified by the patient for whom the practitioner issues the prescription.

Additionally, NAC 639.7105(2) states: “A practitioner shall not transmit a prescription electronically to a pharmacy unless (a) The practitioner is the only person who will have access to the prescription until it is received by the pharmacy.”

Thus, under long-established law, MAs and RNs are not allowed access to electronic prescribing software, nor are they allowed to send new electronic prescriptions on behalf of a practitioner. MAs and RNs, however, **can authorize refills** on behalf of the practitioner. This must be done separately and must clearly be a refill, not a new electronic prescription acting as a refill.

You must be diligent in checking all new electronic prescriptions to verify each was submitted by a prescriber, not by an MA, RN, or other office staff member. An electronic prescription is not valid if it states the agent is anyone other than a practitioner. You should not accept or fill such a prescription.

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